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# Therapeutic 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.

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# OVERVIEW

The Therapeutic Products Directorate's (TPD) Annual Drug Submission Performance Report reflects pharmaceutical drug submission review activity over five consecutive fiscal years (April 1 to March 31) from 2013-2014 to 2017-2018.

Statistics are provided by submission type and show the number received, the number in workload, the number of decisions, the number of approvals and approval times. The report also includes detailed lists of Priority Submissions and New Active Substances approved during the 2017-2018 fiscal year (from April 1 2017 to March 31 2018).

## General Information

There are several steps involved in the drug submission review<sup>1</sup> 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**<sup>2</sup> 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 Patented Medicines (NOC) Regulations or due to changes from Prescription to Non-Prescription.

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

<sup>2</sup> Final results from confirmatory trials submitted in the form of an SNDS-C are now included in the SNDS Received, Workload and Performance figures. SNDS-C are not included in the SNDS Approval figures. For further Clarification refer to the [Guidance Document: Notice of Compliance with Conditions \(NOC/c\)](#).

A **review cycle completion**<sup>3</sup> 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](#)<sup>4</sup> 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"<sup>5</sup> 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](mailto:hc.osip-bppi.sc@canada.ca)

The section of the report pertaining to Electronic Common Technical Document (eCTD) regulatory activity data (Appendix C) has been removed. Inquiries concerning Regulatory Activities in eCTD format may be directed to [hc.ereview.sc@canada.ca](mailto:hc.ereview.sc@canada.ca).

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<sup>3</sup> 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.

<sup>4</sup> 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).

<sup>5</sup> 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
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
<b>New Active Substance (NAS)</b>	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.
<b>Clinical or Non-Clinical Data and Chemistry and Manufacturing data</b>	Submissions based on clinical or non-clinical data <b>and</b> chemistry and manufacturing data for a drug that does not include a NAS.
<b>Clinical or Non-Clinical Data Only</b>	Submissions based only on clinical or non-clinical data for a drug that does not include a NAS.
<b>Comparative Studies</b>	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.
<b>Chemistry and Manufacturing Data Only</b>	Submissions based only on chemistry and manufacturing data for a drug that does not include a NAS.
<b>Published Data Only</b>	Submissions based only on published clinical or non-clinical data for a drug that does not include a NAS.
<b>Switch from Prescription to Nonprescription Status</b>	Submissions based only on data that support the modification or removal of a medicinal ingredient on the <a href="#">Prescription Drug List</a> . This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug.
<b>Labelling Only<sup>6</sup></b>	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
<b>Administrative Submission<sup>7</sup></b>	Submissions in support of a manufacturer or product name change.
<b>Disinfectants<sup>8</sup></b>	Submissions and applications that include data in support of a disinfectant.
<b>Drug Identification Number (DIN) - Labelling Standards</b>	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](#)

<sup>6</sup> For more information, please consult the [Guidance Document: Question and Answers about Plain Language Labelling](#)

<sup>7</sup> For additional information, please consult the "[Changes in Manufacturer and/or Product Name Policy](#)" (2015)

<sup>8</sup> 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.

**New Drug Submission  
(NDS)**

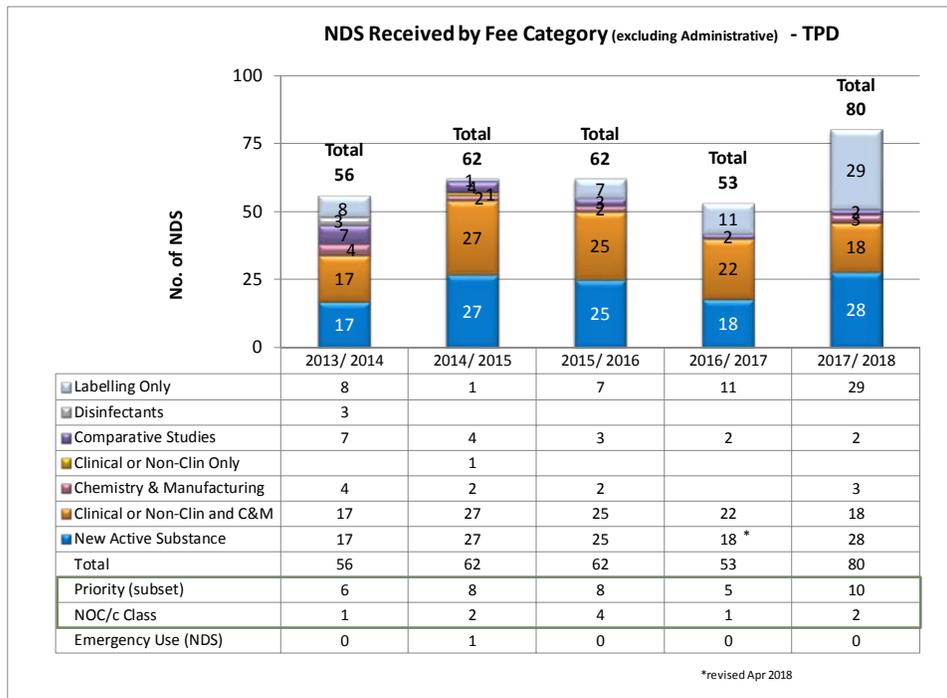
**&**

**Supplemental New Drug Submission  
(SNDS)**

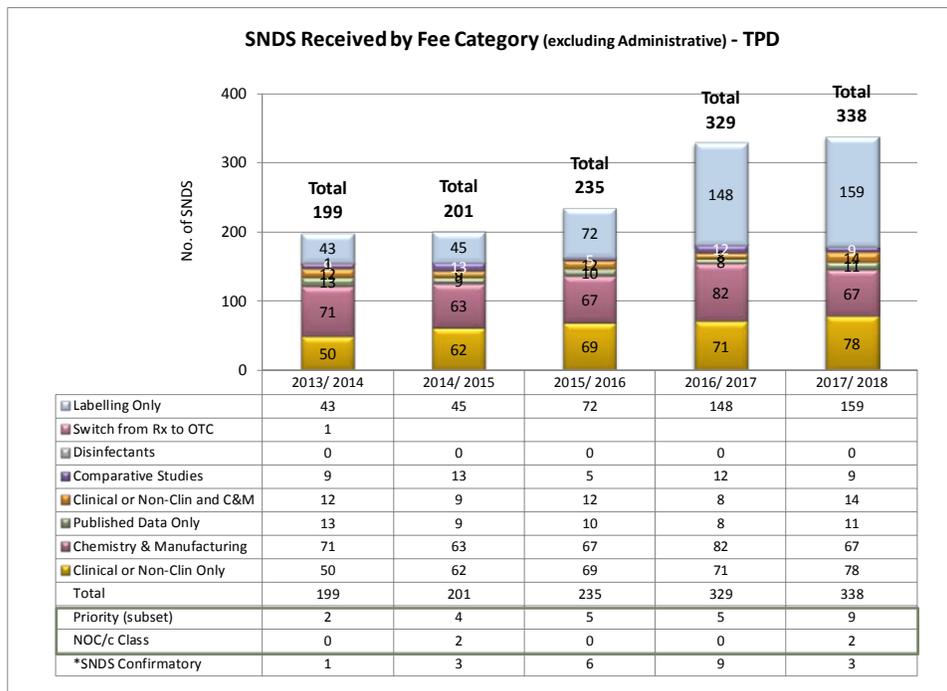
**SUBMISSIONS RECEIVED**

9 10

**New Drug Submissions (NDS) Received by Fee Category**



**Supplemental New Drug Submissions (SNDS) Received by Fee Category**

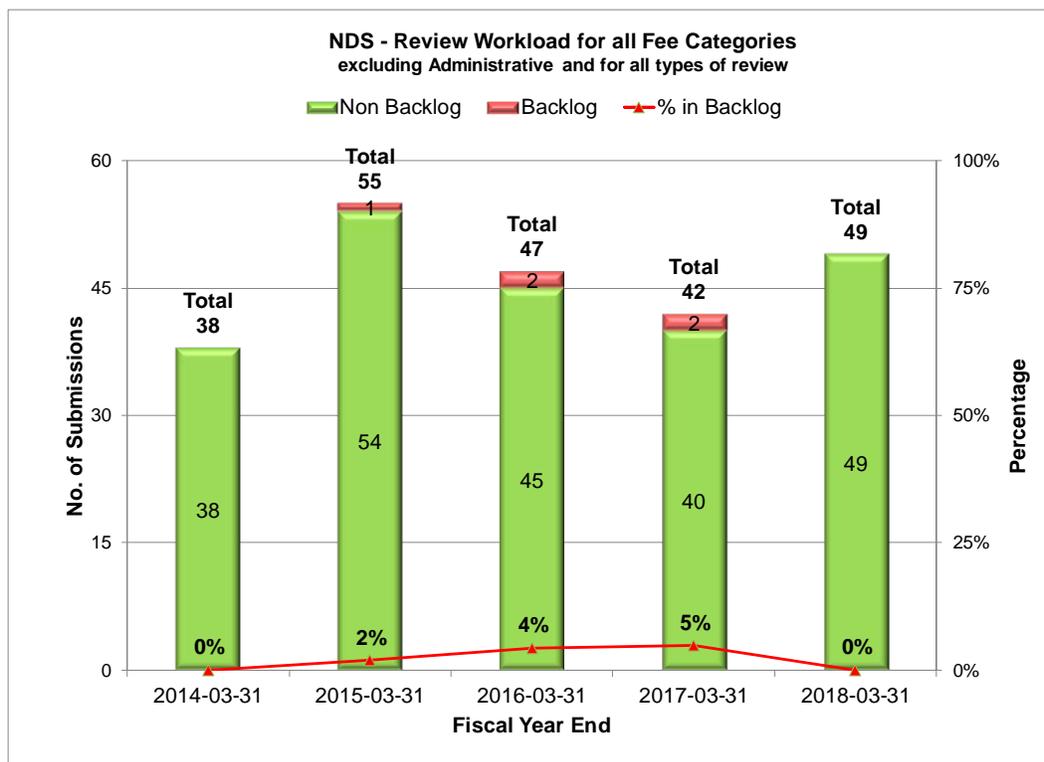


<sup>9</sup> TPD’s non-prescription and disinfectant drug review functions were moved to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013 and are reported separately in the NNHPD Annual Drug Submission Performance Annual Report.

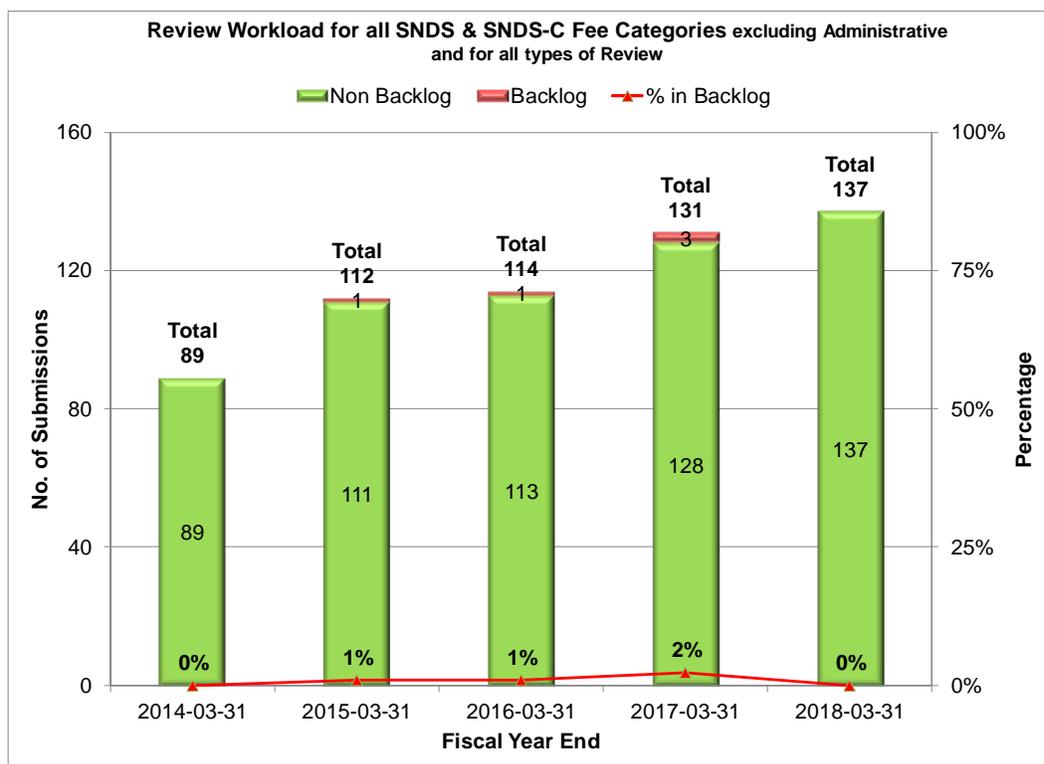
<sup>10</sup> Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the [Priority Review of Drug Submissions Policy](#), the [Notice of Compliance with conditions \(NOC/c\) Guidance](#) and the [Management of Drug Submissions Guidance](#).

### WORKLOAD

#### New Drug Submission (NDS) Review Workload / Backlog



#### Supplemental New Drug Submission (SNDS) Review Workload / Backlog



## WORKLOAD

## New Drug Submission (NDS) Review Workload by Fee Category

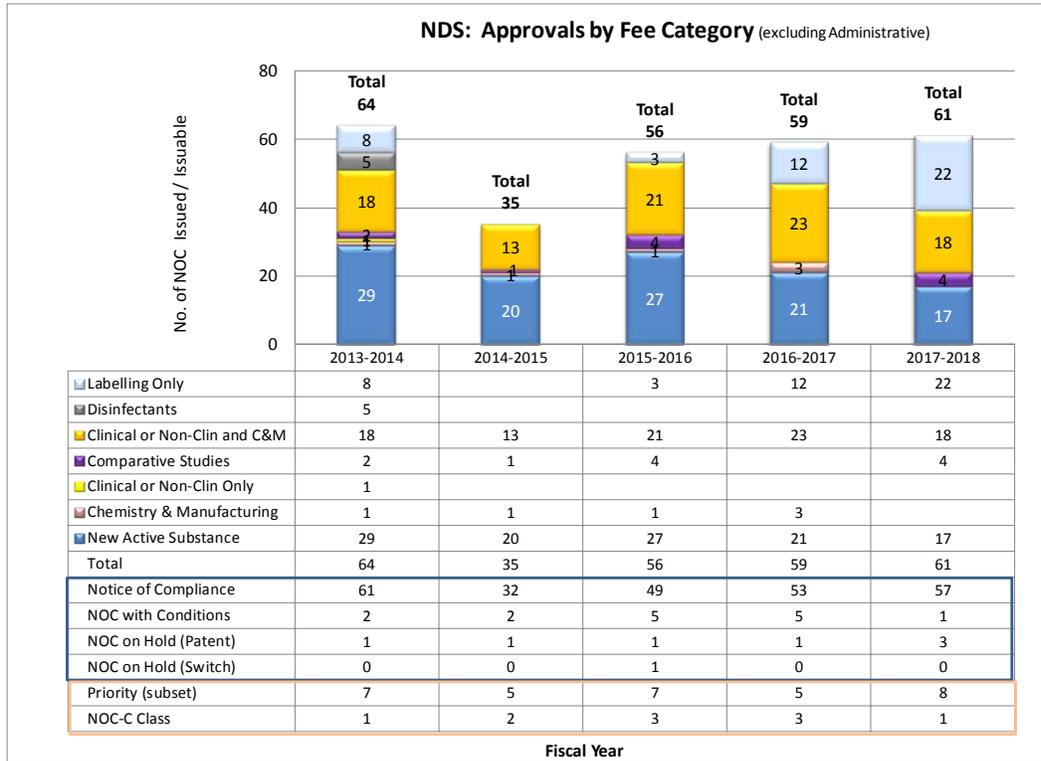
TPD NDS: All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
<b>Labelling Only</b>	0	1	3	1	4
<i>Backlog</i>	0	0	0	0	0
<b>Disinfectant</b>	3	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Comparative Studies</b>	3	2	0	3	1
<i>Backlog</i>	0	1	0	0	0
<b>Chemistry &amp; Manufacturing</b>	3	2	3	0	1
<i>Backlog</i>	0	0	2	0	0
<b>Clinical or Non-Clin Only</b>	0	1	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Clinical or Non-Clin and C&amp;M</b>	15	26	24	19	18
<i>Backlog</i>	0	0	0	1	0
<b>New Active Substance</b>	14	23	17	19	25
<i>Backlog</i>	0	0	0	1	0
<b>Total</b>	<b>38</b>	<b>55</b>	<b>47</b>	<b>42</b>	<b>49</b>
<b>Non Backlog</b>	38	54	45	40	49
<b>Backlog</b>	0	1	2	2	0
<b>% in Backlog</b>	0%	2%	4%	5%	0%
<b>Priority (subset)</b>	0	4	4	6	6
<i>Backlog</i>	0	0	0	0	0

## Supplemental New Drug Submission (SNDS) Review Workload by Fee Category

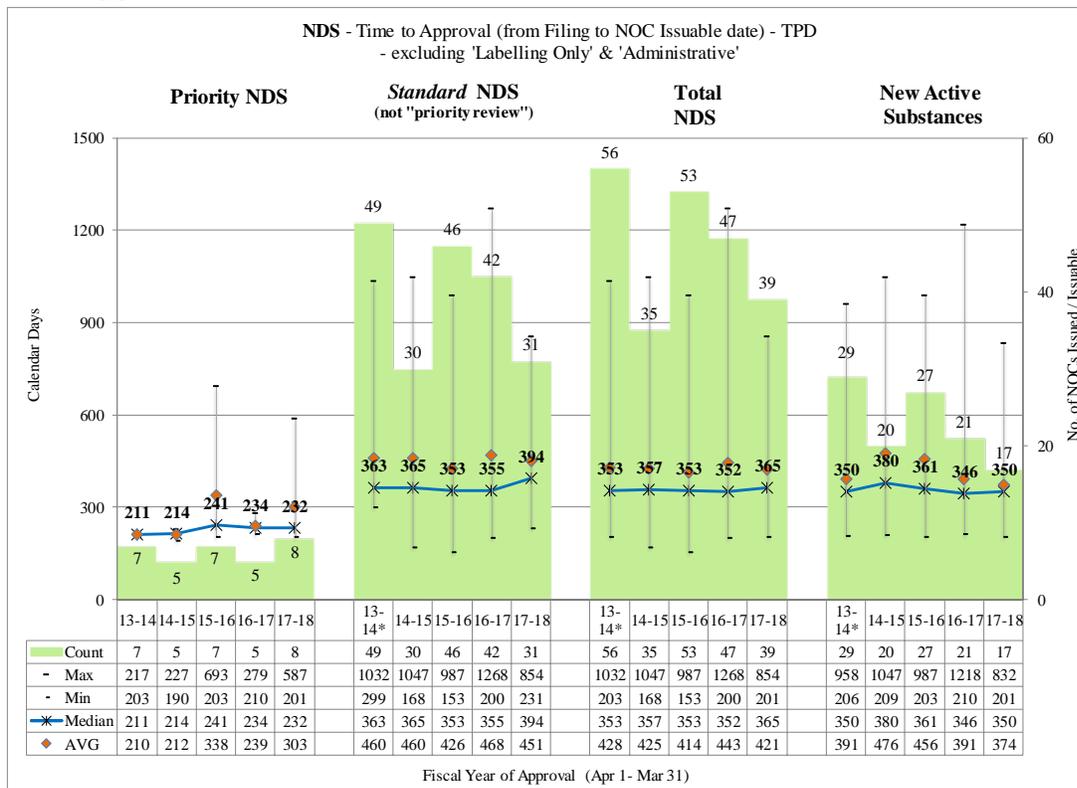
TPD SNDS and SNDS-C: All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
<b>Labelling Only</b>	7	9	13	22	19
<i>Backlog</i>	0	0	1	1	0
<b>Comparative Studies</b>	4	8	1	7	4
<i>Backlog</i>	0	0	0	0	0
<b>Chemistry &amp; Manufacturing</b>	22	29	31	34	30
<i>Backlog</i>	0	1	0	0	0
<b>Clinical or Non-Clin Only</b>	39	51	50	53	63
<i>Backlog</i>	0	0	0	2	0
<b>Clinical or Non-Clin and C&amp;M</b>	10	9	12	8	11
<i>Backlog</i>	0	0	0	0	0
<b>Published Data Only</b>	7	6	7	7	10
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>89</b>	<b>112</b>	<b>114</b>	<b>131</b>	<b>137</b>
<b>Non Backlog</b>	89	111	113	128	137
<b>Backlog</b>	0	1	1	3	0
<b>% in Backlog</b>	0%	1%	1%	2%	0%
<b>Priority (subset)</b>	1	2	5	4	7
<i>Backlog</i>	0	0	0	0	0
<b>*SNDS-C (Confirmatory)</b>	0	3	6	6	3
<i>Backlog</i>	0	0	0	0	0

## APPROVALS

### New Drug Submission (NDS) Approvals by Fee Category and by NOC Type



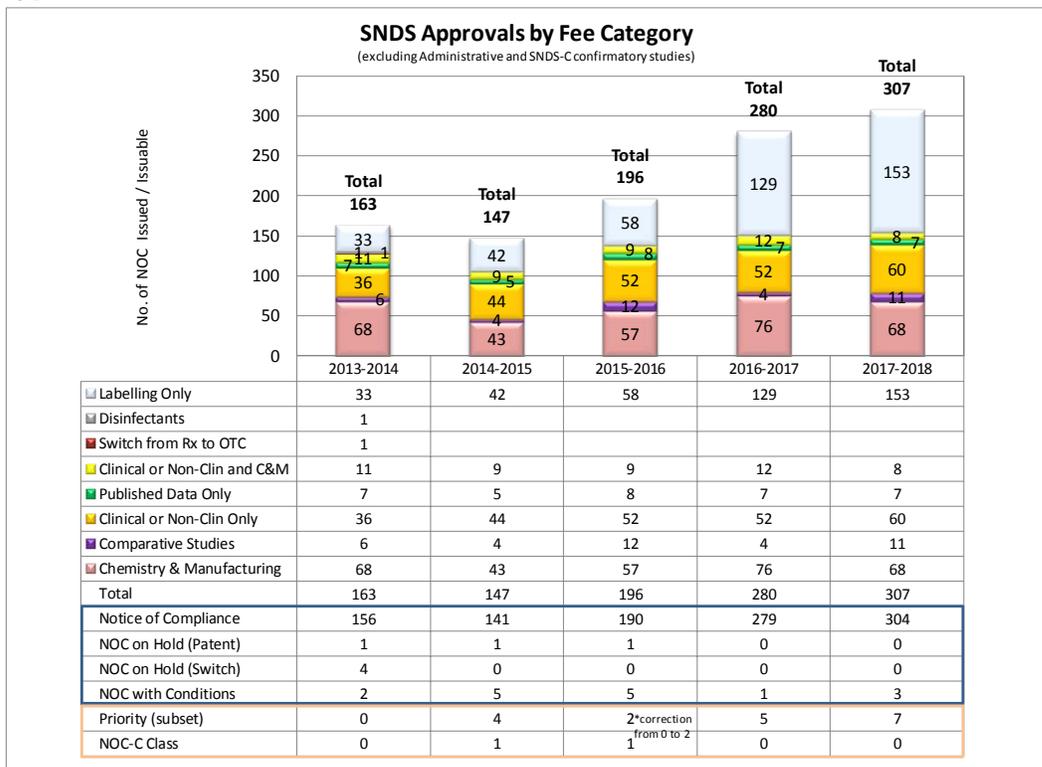
### NDS Approval Times



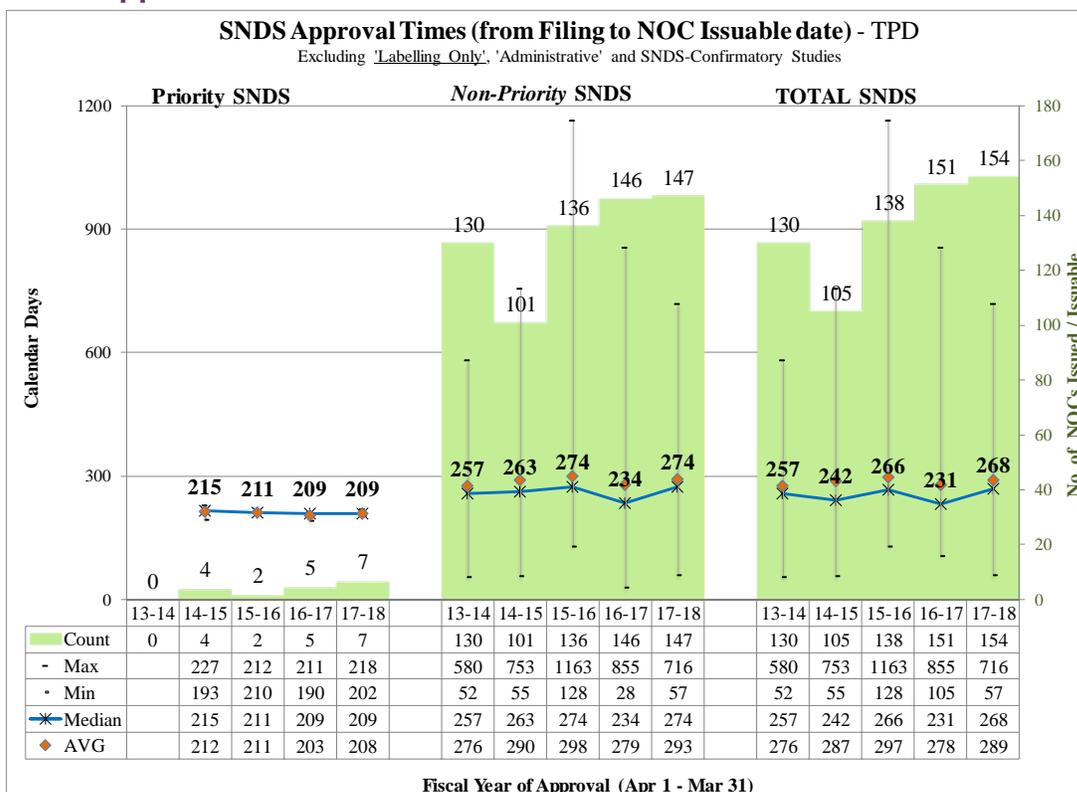
**Approval Time** is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

\*One outlier is included for fiscal year 2013-14. The NDS was in rejected status for over 4 years but following a judicial review decision, screening was resumed. For this "outlier NDS", the dates used to calculate the time to approval are the date the screening resumed and the date the submission was placed on intellectual property hold.

### Supplemental New Drug Submission (SNDS) Approvals by Fee Category and by NOC Type



### SNDS Approval Times



Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the [Priority Review of Drug Submissions Policy](#), the [Notice of Compliance with conditions \(NOC/c\) Guidance](#) and the [Management of Drug Submissions Guidance](#).

New Active Substance (NAS) Approvals  
And  
Priority Submission Approvals

## New Active Substance (NAS) Approvals - TPD - Fiscal Year 2017-2018

<b>New Active Substance Approvals – TPD</b> <b>Fiscal Year 2017-2018</b> (April 1 2017 – March 31 2018)				
Brand Name (Active Ingredient(s) - Indication(s))	Class	Company	Filing (CR <sup>11</sup> ) Date	Approval Date (dd-mon-yy)
<b>ADDYI (Flibanserin)</b> - is indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire for a minimum of 6 months, which occurs 75-100% of the time, that causes marked distress or interpersonal difficulty and is NOT due to: a co-existing medical or psychiatric condition, problems within the relationship, or the effects of a medication or other drug substance.	NAS	Sprout Pharmaceuticals Inc.	18-Nov-15	27-Feb-18
<b>ADLYXINE (Lixisenatide)</b> - is indicated for use as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus in combination with: metformin, a sulfonylurea (alone or with metformin), pioglitazone (alone or with metformin), a basal insulin (alone or with metformin), when the therapy listed above does not provide adequate glycemic control.	NAS	Sanofi-Aventis Canada Inc.	26-Apr-16	25-May-17
<b>AKYNZEO (Netupitant, Palonosetron (as Palonosetron Hydrochloride))</b> - in combination with dexamethasone, is indicated for once-per-cycle treatment in adult patients for: prevention of acute and delayed nausea and vomiting associated with highly emetogenic cancer chemotherapy and prevention of acute nausea and vomiting associated with moderately emetogenic cancer therapy that is uncontrolled by a 5-HT <sub>3</sub> receptor antagonist alone.	NAS	Purdue Pharma	13-Oct-16	28-Sep-17
<b>CERDELGA (Eliglustat as Eliglustat Tartrate)</b> - is indicated for the long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are CYP2D6 poor metabolizers (PMs), intermediate metabolizers (IMs) or extensive metabolizers (EMs), as determined by CYP2D6 genotype testing.	NAS	Sanofi Genzyme, a Division of Sanofi-Aventis Canada Inc.	19-Mar-15	21-Apr-17
<b>GALAFOLD (Migalastat as Migalastat Hydrochloride)</b> - is indicated for long-term treatment of adults with a confirmed diagnosis of Fabry disease [deficiency of $\alpha$ -galactosidase ( $\alpha$ -Gal A)] and who have an $\alpha$ -Gal A mutation determined to be amenable by an in vitro assay.	NAS	Amicus Therapeutics UK Ltd.	15-Jul-16	5-Sep-17

<sup>11</sup> The CR date is the date the submission is received and considered administratively complete by Health Canada.

**New Active Substance Approvals – TPD**  
**Fiscal Year 2017-2018**  
 (April 1 2017 – March 31 2018)

<b>Brand Name (Active Ingredient(s) - Indication(s))</b>	<b>Class</b>	<b>Company</b>	<b>Filing (CR<sup>11</sup>) Date</b>	<b>Approval Date (dd-mon-yy)</b>
<b>KISQALI (Ribociclib as Ribiciclib Succinate)</b> - is indicated: in combination with letrozole for the treatment of postmenopausal women with hormonereceptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negativeadvanced or metastatic breast cancer as an initial endocrine-based therapy.	NAS	Novartis Pharmaceuticals Canada Inc.	17-Mar-17	2-Mar-18
<b>LONSURF (Trifluridine, Tipiracil Hydrochloride)</b> - is indicated for the treatment of adult patients with metastatic colorectal cancer who have been previously treated with, or are not candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF biological agents, and, if RAS wild-type, anti-EGFR agents.	PRIORITY-NAS	Taiho Pharma Canada, Inc.	30-May-17	25-Jan-18
<b>MAVIRET (Pibrentasvir, Glecaprevir)</b> - is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection with or without compensated cirrhosis. This includes patients with HCV genotype 1 infection who were previously treated with either a regimen of NS5A inhibitor or with a NS3/4A protease inhibitor but not both classes of inhibitors.	PRIORITY-NAS	Abbvie Corporation	24-Jan-17	16-Aug-17
<b>OCALIVA (Obeticholic Acid)</b> - is indicated for the treatment of primary biliary cholangitis1 (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.	PRIORITY-NAS	Intercept Pharmaceuticals Inc.	16-Sep-16	24-May-17 NOC-C
<b>OZANEX (Ozenoxacin)</b> - is indicated for the topical treatment of impetigo in patients aged 2 months and older.	NAS	Ferrer Internacional SA	1-Apr-16	1-May-17
<b>PREVYMIS (Letermovir)</b> - is indicated for the prophylaxis of cytomegalovirus (CMV) infection in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).	PRIORITY-NAS	Merck Canada Inc.	10-Apr-17	1-Nov-17
<b>PROCYSBI (Cysteamine as Cysteamine Bitartrate)</b> - is indicated for the treatment of nephropathic cystinosis.	PRIORITY-NAS	Horizon Pharma Ireland Ltd.	21-Jan-16	13-Jun-17

<b>New Active Substance Approvals – TPD</b> <b>Fiscal Year 2017-2018</b> (April 1 2017 – March 31 2018)				
Brand Name (Active Ingredient(s) - Indication(s))	Class	Company	Filing (CR <sup>11</sup> ) Date	Approval Date (dd-mon-yy)
<b>RYDAPT (Midostaurin)</b> - is indicated in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy for the treatment of adult patients with newly diagnosed FLT3-mutated acute myeloid leukemia (AML).	PRIORITY-NAS	Novartis Pharmaceuticals Canada Inc.	9-Dec-16	21-Jul-17
<b>SPINRAZA (Nusinersen as Nusinersen Sodium)</b> - is indicated for the treatment of 5q Spinal Muscular Atrophy (SMA).	NOC-C-NAS	Biogen Canada Inc.	10-Nov-16	29-Jun-17 NOC (no conditions)
<b>VELPHORO (Sucroferric Oxyhydroxide)</b> - is indicated for the control of serum phosphorus levels in adult patients with end-stage renal disease (ESRD) on dialysis.	NAS	Vifor Fresenius Medical Care Renal Pharma Ltd.	22-Dec-16	5-Jan-18
<b>VOSEVI (Sofosbuvir, Velpatasvir, Voxilaprevir)</b> - is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adult patients, without cirrhosis or with compensated cirrhosis, who have: <ul style="list-style-type: none"> <li>• genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor;</li> <li>• genotype 1, 2, 3, or 4 infection and have been previously treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor.</li> </ul>	PRIORITY-NAS	Gilead Sciences Canada Inc.	27-Jan-17	16-Aug-17
<b>XIIDRA (Lifitegrast)</b> - is indicated for the treatment of the signs and symptoms of dry eye disease.	NAS	Shire Pharma Canada ULC	28-Oct-16	22-Dec-17

## Priority Submission Approvals - TPD - Fiscal Year 2017-2018

<b>Priority Submission Approvals – TPD</b> <b>Fiscal Year 2017-2018</b> (April 1 2017 – March 31 2018)				
Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR) Date	Approval Date
<b>HARVONI (Ledipasvir, Sofosbuvir)</b> - treatment indication to include adolescent patients (from 12 years of age) with chronic hepatitis C virus genotype 1 infection, without cirrhosis or with compensated cirrhosis.	PRIORITY-CLIN ONLY	Gilead Sciences Canada Inc.	27-Oct-16	24-May-17
<b>IMBRUVICA (Ibrutinib)</b> - new indication: for the treatment of patients with steroid dependent or refractory chronic graft versus host disease (cGVHD).	PRIORITY-CLIN ONLY	Janssen Inc.	4-Apr-17	25-Oct-17
<b>LONSURF (Trifluridine, Tipiracil Hydrochloride)</b> - is indicated for the treatment of adult patients with metastatic colorectal cancer who have been previously treated with, or are not candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF biological agents, and, if RAS wild-type, anti-EGFR agents.	PRIORITY-NAS	Taiho Pharma Canada, Inc.	30-May-17	25-Jan-18
<b>MAVIRET (Pibrentasvir, Glecaprevir)</b> - is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection with or without compensated cirrhosis. This includes patients with HCV genotype 1 infection who were previously treated with either a regimen of NS5A inhibitor or with a NS3/4A protease inhibitor but not both classes of inhibitors.	PRIORITY-NAS	Abbvie Corporation	24-Jan-17	16-Aug-17
<b>MEKINIST (Trametinib)</b> - new indication: in combination with Dabrafenib, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600 mutation whose disease has progressed following systemic therapy.	PRIORITY-CLIN ONLY	Novartis Pharmaceuticals Canada Inc.	18-Oct-16	16-May-17

<b>Priority Submission Approvals – TPD</b> <b>Fiscal Year 2017-2018</b> (April 1 2017 – March 31 2018)				
Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR) Date	Approval Date
<b>OCALIVA (Obeticholic Acid)</b> - is indicated for the treatment of primary biliary cholangitis1 (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.	PRIORITY-NAS	Intercept Pharmaceuticals Inc.	16-Sep-16	24-May-17 NOC-C
<b>ONIVYDE (Irinotecan Hydrochloride)</b> - is indicated for the treatment of metastatic adenocarcinoma of the pancreas, in combination with 5-fluorouracil (5-FU) and leucovorin (LV), in adult patients who have disease progression following gemcitabine-based therapy.	PRIORITY-CLIN/C&M	Baxalta Canada Corporation	31-Dec-15	9-Aug-17
<b>ORKAMBI (Lumacaftor, Ivacaftor)</b> - new indication: for the treatment of cystic fibrosis (CF) in patients 6 years of age and older who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. New strength: 100 mg Lumacaftor/125mg Ivacaftor for children 6-11 years old..	PRIORITY-CLIN/C&M	Vertex Pharmaceuticals (Canada) Incorporated	12-Sep-16	18-Apr-17
<b>PREVYMIS (Letermovir)</b> - is indicated for the prophylaxis of cytomegalovirus (CMV) infection in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).	PRIORITY-NAS	Merck Canada Inc.	10-Apr-17	1-Nov-17
<b>PROCYSBI (Cysteamine as Cysteamine Bitartrate)</b> - is indicated for the treatment of nephropathic cystinosis.	PRIORITY-NAS	Horizon Pharma Ireland Ltd.	21-Jan-16	13-Jun-17
<b>RYDAPT (Midostaurin)</b> - is indicated in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy for the treatment of adult patients with newly diagnosed FLT3-mutated acute myeloid leukemia (AML).	PRIORITY-NAS	Novartis Pharmaceuticals Canada Inc.	9-Dec-16	21-Jul-17
<b>STIVARGA (Regorafenib)</b> - new indication: for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.	PRIORITY-CLIN ONLY	Bayer Inc.	28-Feb-17	18-Sep-17

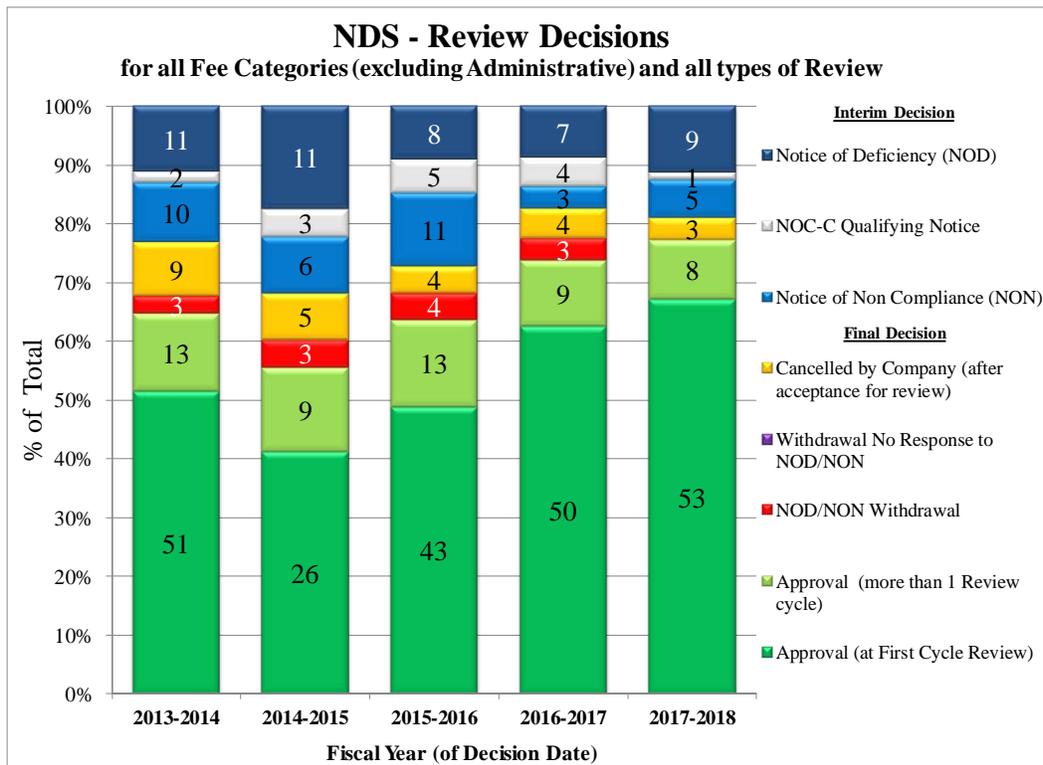
**Priority Submission Approvals – TPD**  
**Fiscal Year 2017-2018**  
 (April 1 2017 – March 31 2018)

Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR) Date	Approval Date
<b>TAFINLAR</b> <b>(Dabrafenib as Dabrafenib Mesylate)</b> - new indication: in combination with trametinib is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600 mutation whose disease has progressed following systemic therapy.	PRIORITY-CLIN ONLY	Novartis Pharmaceuticals Canada Inc.	18-Oct-16	16-May-17
<b>VOSEVI</b> <b>(Sofosbuvir, Velpatasvir, Voxilaprevir)</b> - is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adult patients, without cirrhosis or with compensated cirrhosis, who have: <ul style="list-style-type: none"> <li>• genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor;</li> <li>• genotype 1, 2, 3, or 4 infection and have been previously treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor.</li> </ul>	PRIORITY-NAS	Gilead Sciences Canada Inc.	27-Jan-17	16-Aug-17
<b>ZYTIGA (Abiraterone Acetate)</b> - new indication: in combination with prednisone and androgen deprivation therapy (ADT) for the treatment of patients with newly diagnosed hormone-sensitive high-risk metastatic prostate cancer who may have received up to 3 months of prior ADT.	PRIORITY-CLIN ONLY	Janssen Inc.	26-Jul-17	13-Feb-18

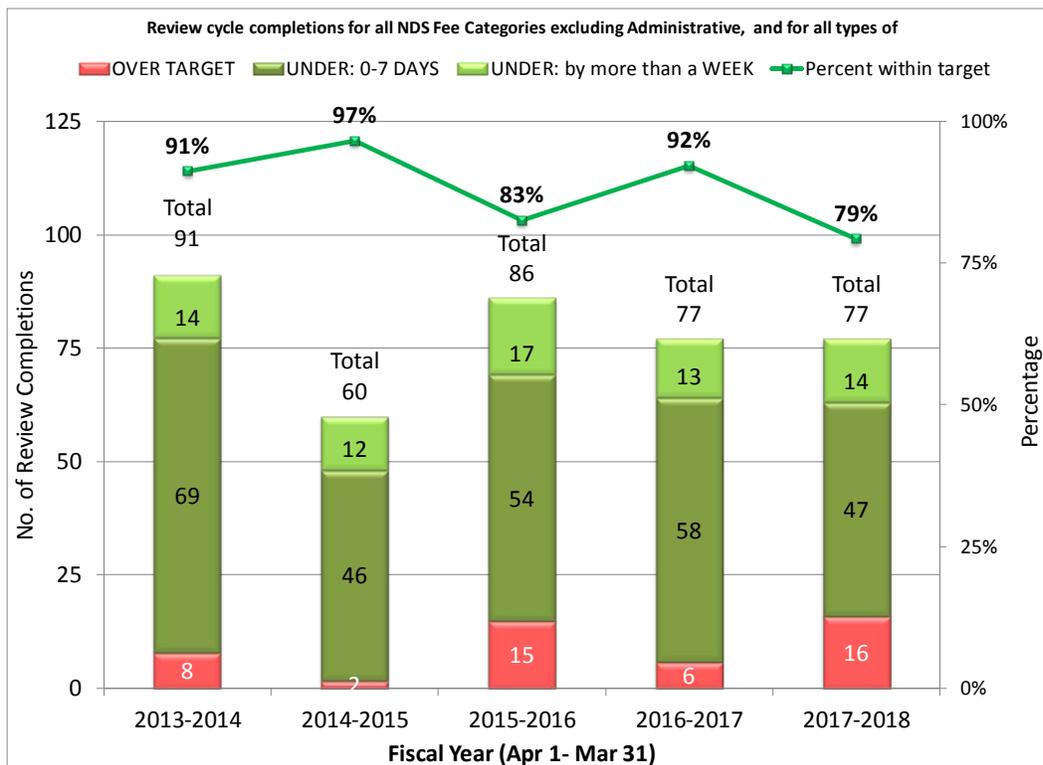
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### REVIEW CYCLE DECISIONS

#### New Drug Submission (NDS) Review Decisions

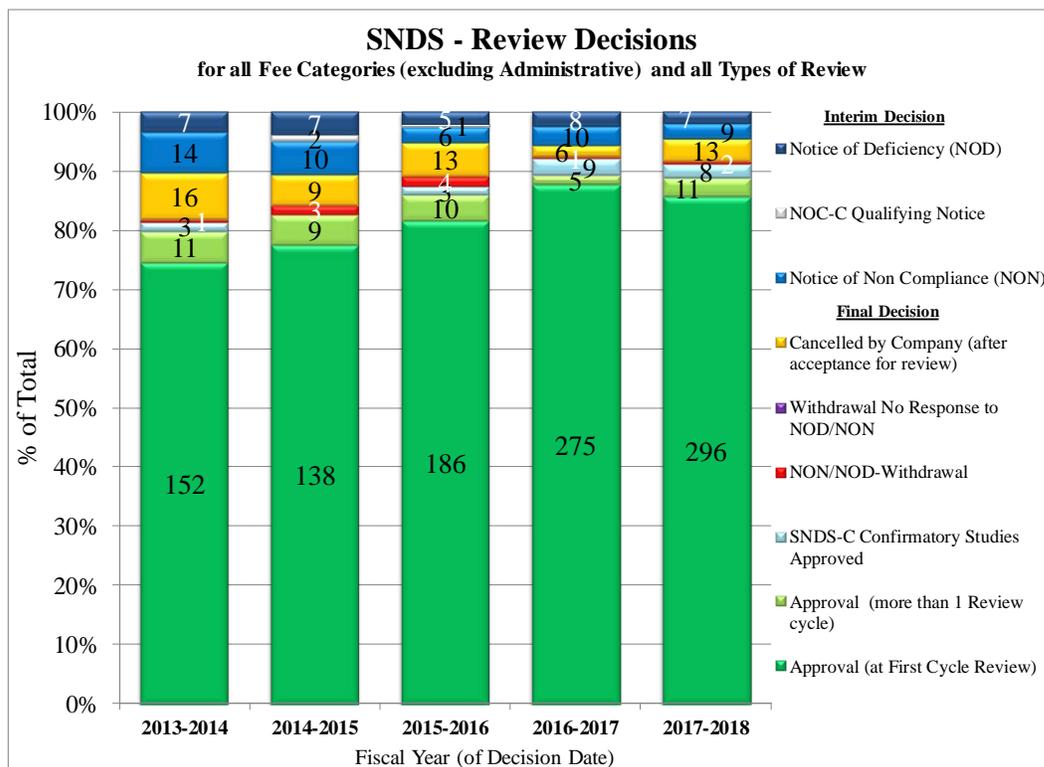


#### NDS - Review Cycle Completions Showing Percentage Within Target

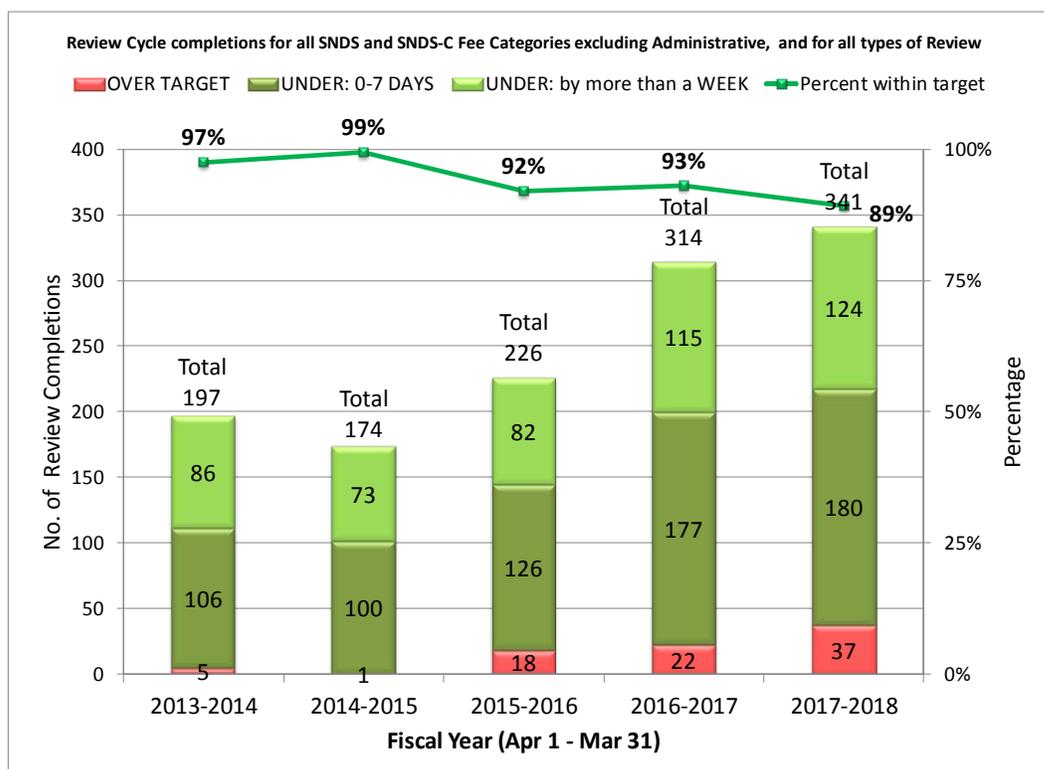


## REVIEW CYCLE DECISIONS

### Supplemental New Drug Submission (SNDS) Review Decisions

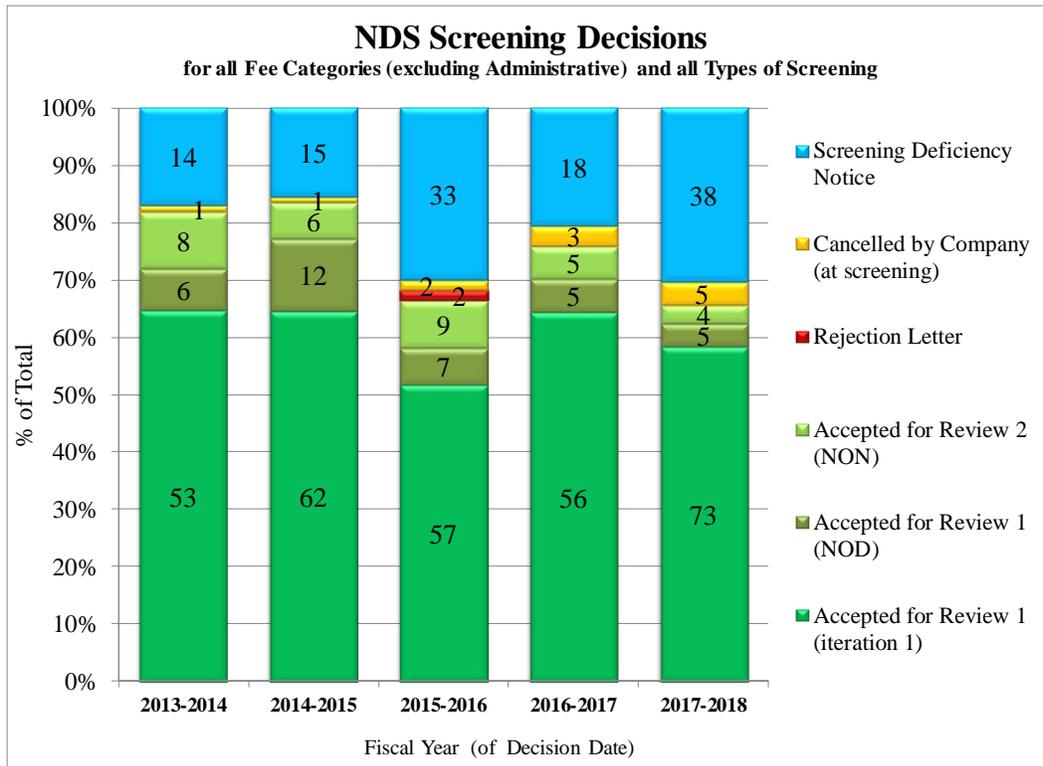


### SNDS - Review Cycle Completions Showing Percentage Within Target

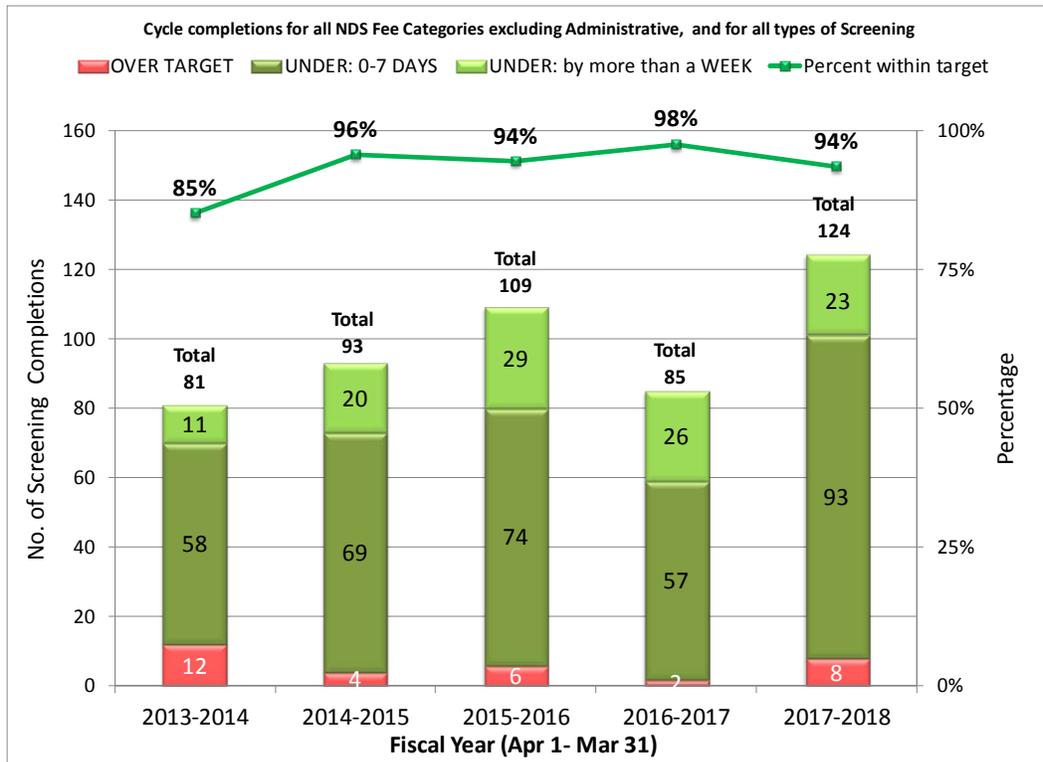


### SCREENING CYCLE DECISIONS

#### New Drug Submission (NDS) Screening Decisions

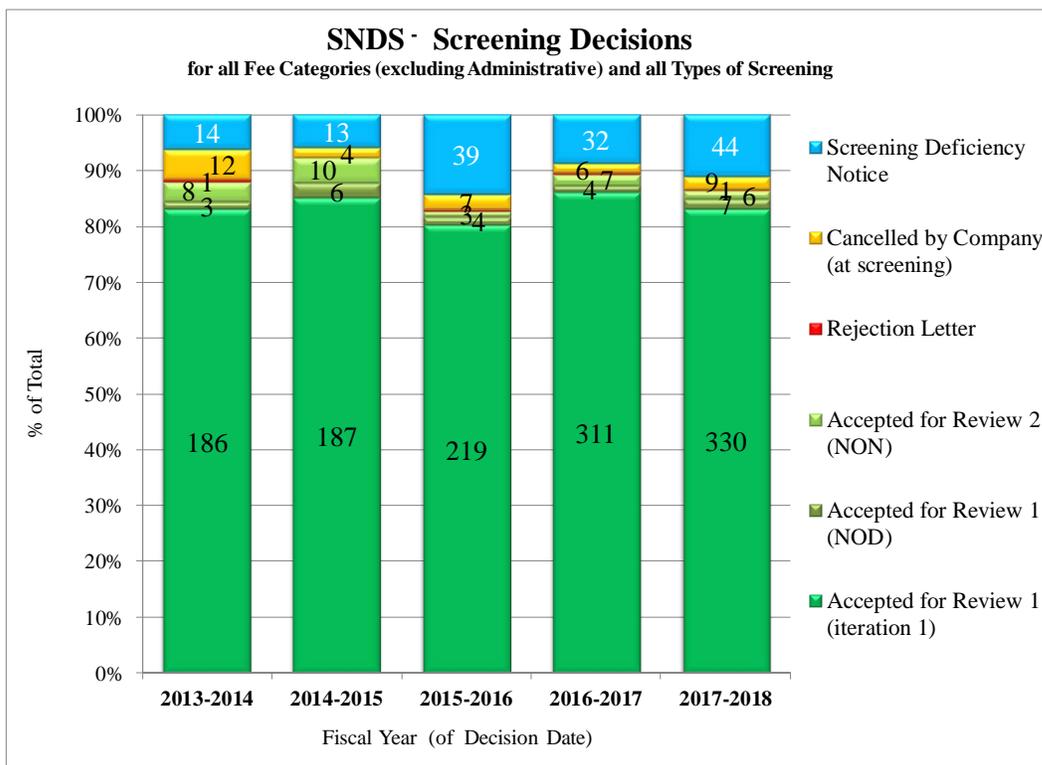


#### NDS - Screening Cycle Completions Showing Percentage Within Target

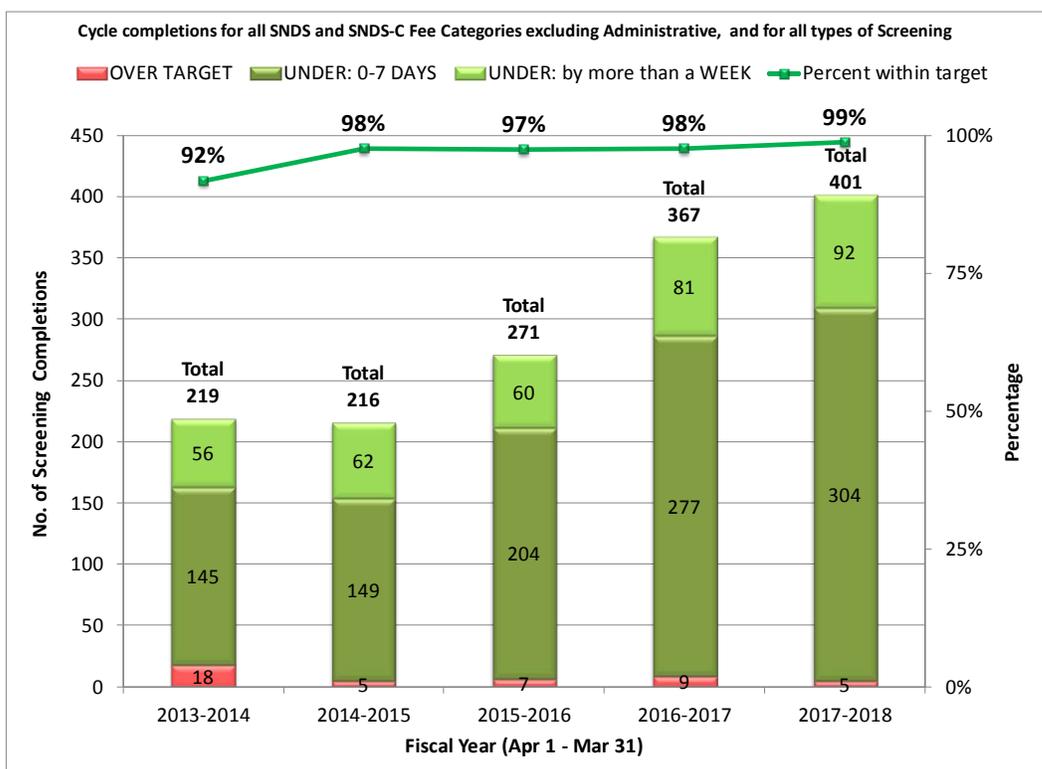


### SCREENING CYCLE DECISIONS

#### Supplemental New Drug Submission (SNDS) Screening Decisions



#### SNDS - Screening Cycle Completions Showing Percentage Within Target



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## REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

## Requests for Reconsideration of Final Decisions – New Drug Submissions (NDS)

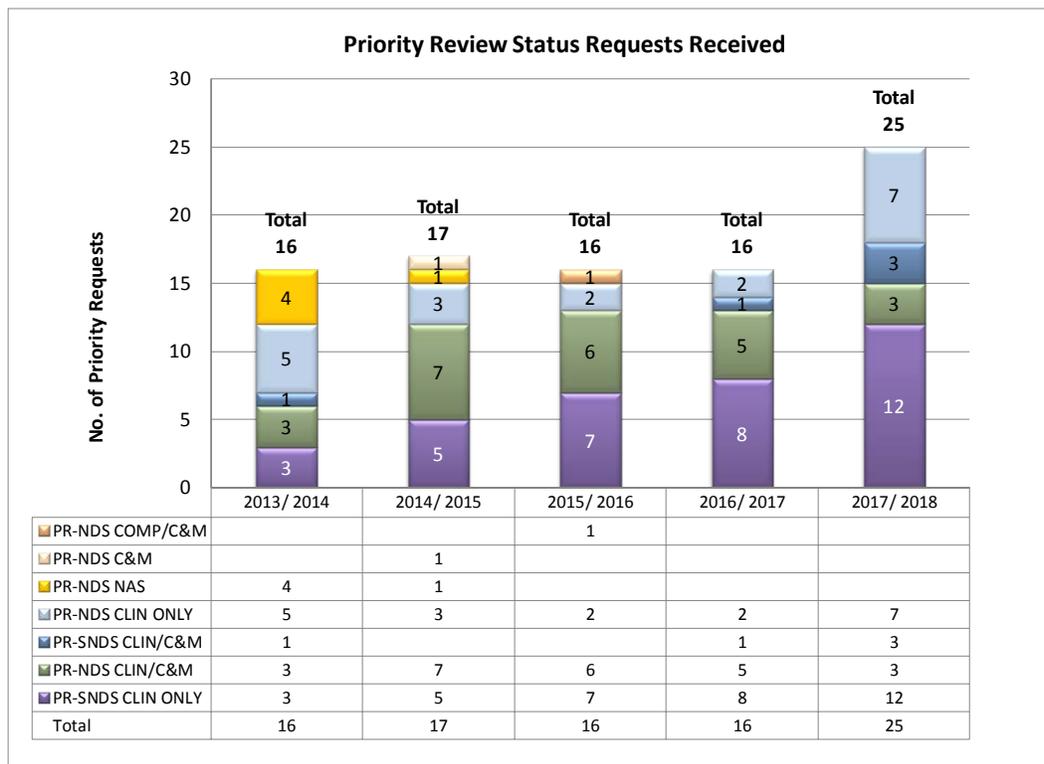
<b>NDS - Reconsideration of Final Decisions Requests Received</b>							
Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	13-14	14-15	15-16	16-17	17-18	Final Decision in Dispute	NDS Status (as of May 2018)
<b>Total Received</b>	1	0	2	1	0		
<b>Total Pending</b>	0	0	0	0	0		
<b>Total Granted</b>	1	0	1	0	0		
GRANTED	1					NON-Withdrawal	Cleared
GRANTED			1			NOD-Withdrawal	Cleared
<b>Total Denied</b>	0	0	1	1	0		
DENIED			1	1		NOD-Withdrawal	Withdrawn

## Requests for Reconsideration of Final Decisions – Supplemental New Drug Submissions (SNDS)

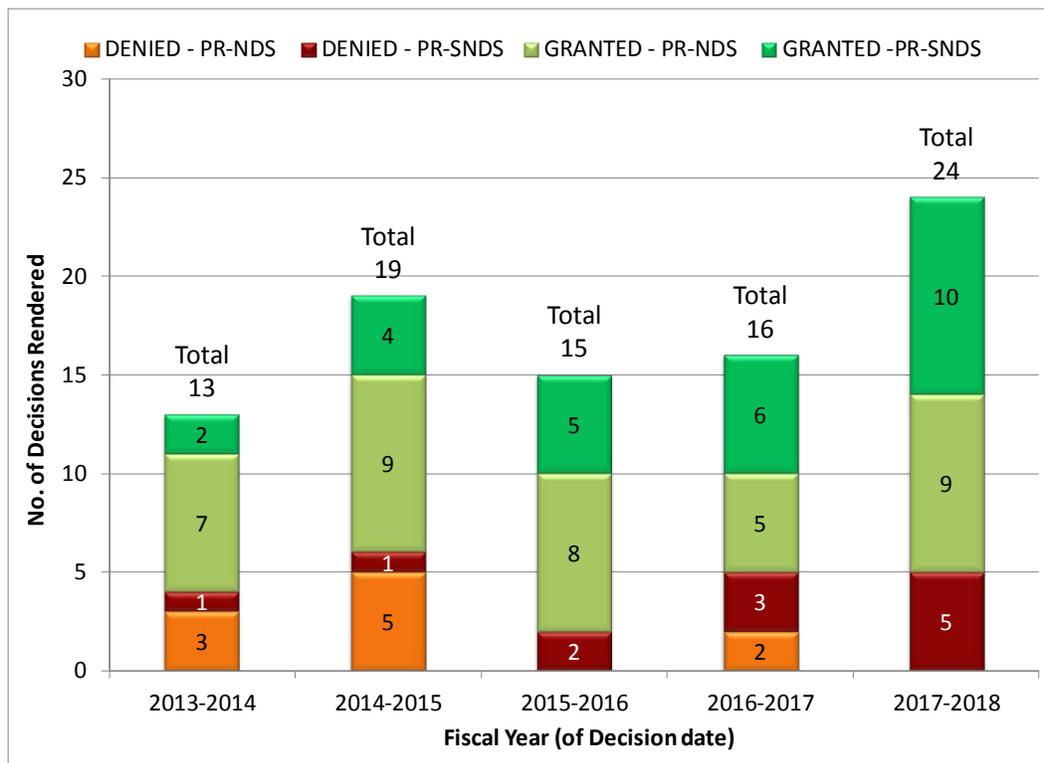
<b>SNDS - Reconsideration of Final Decisions Requests Received</b>							
Fiscal Year of Request (April 1 - March 31) * revised May 2018							
Breakdown by Reconsideration Decision	13-14	14-15	15-16*	16-17	17-18	Final Decision in Dispute	SNDS Status (as of May 2018)
<b>Total Received</b>	0	1	1	0	0		
<b>Total Pending</b>			1			NOD-Withdrawal	Under Reconsideration
<b>Total Granted</b>		1				NOD-Withdrawal	Withdrawn

## PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

### Priority Review Status Requests Received

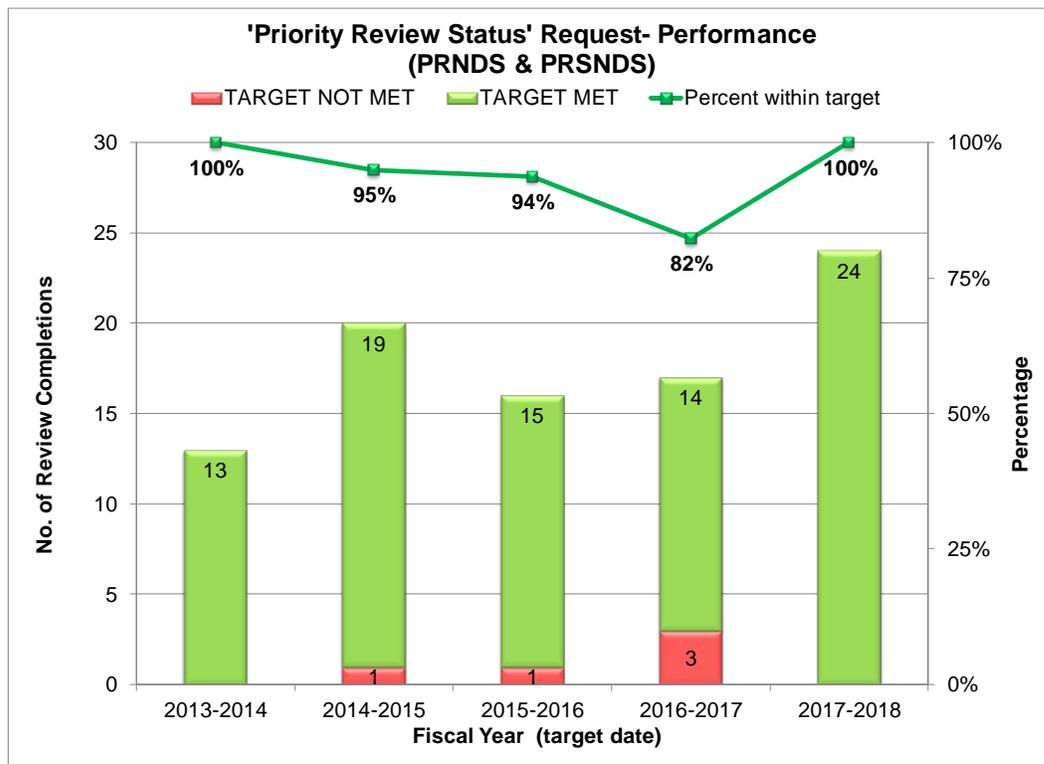


### Priority Review Status Requests: Decisions Rendered



## PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

### Priority Review Status Requests: Performance



## REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

### Requests for Reconsideration of Final Decisions – Priority Review Requests (for NDS and SNDS)

"Priority Review Request" - Requests for Reconsideration of Final Decisions							
Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	13-14	14-15	15-16	16-17	17-18	Final Decision in Dispute	Submission Status (as of May 2018)
<b>Total Received</b>	0	0	0	0	1		
<b>Total Granted</b>	0	0	0	0	1	Priority Review Request (for SNDS) Denied	Inactive-Reconsideration

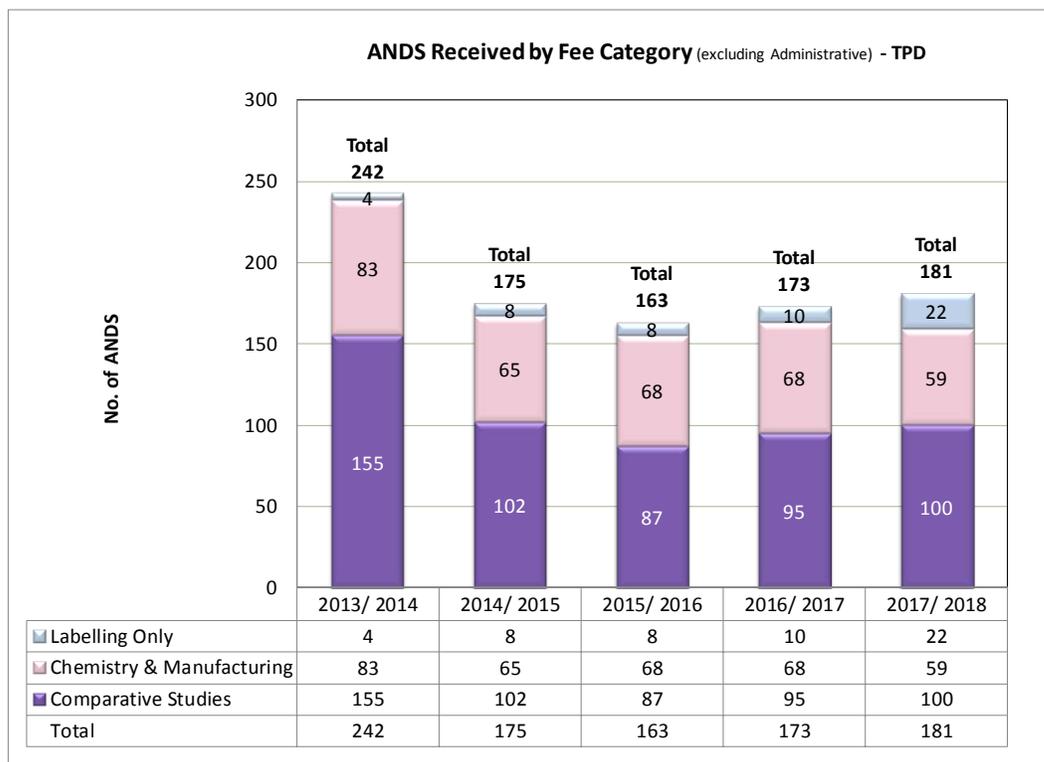
**Abbreviated New Drug Submissions  
(ANDS)**

**&**

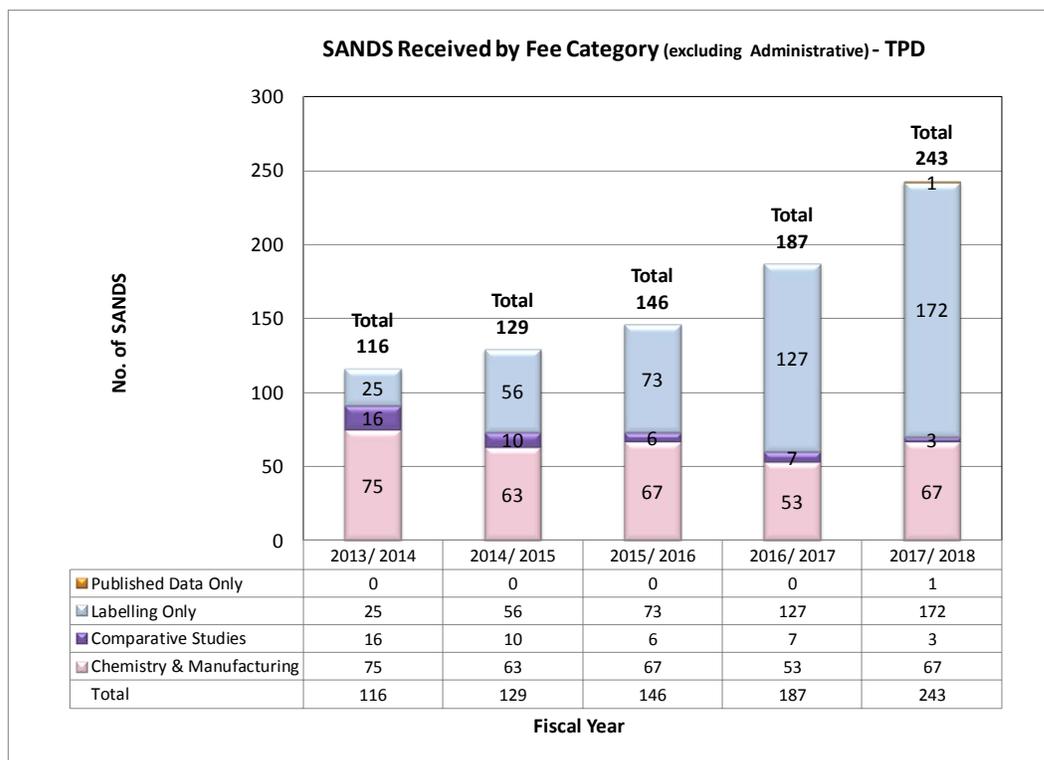
**Supplemental Abbreviated New Drug Submissions  
(SANDS)**

### SUBMISSIONS RECEIVED

#### Abbreviated New Drug Submissions (ANDS) Received by Fee Category

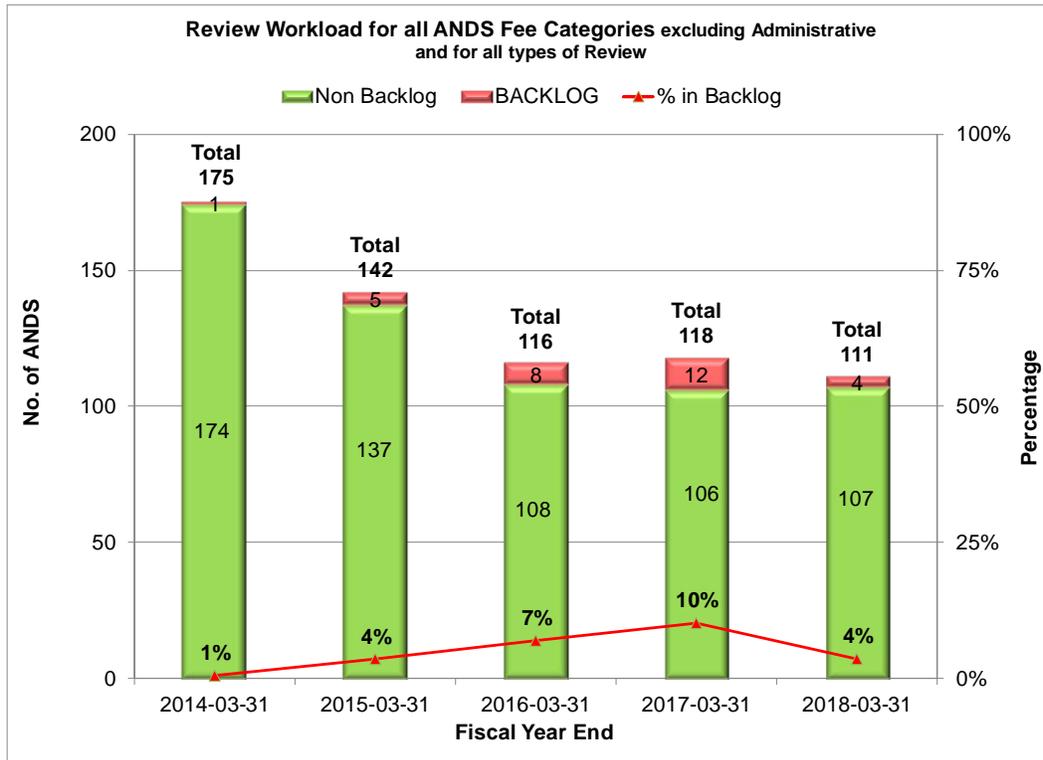


#### Supplemental Abbreviated New Drug Submission (SANDS) Received by Fee Category

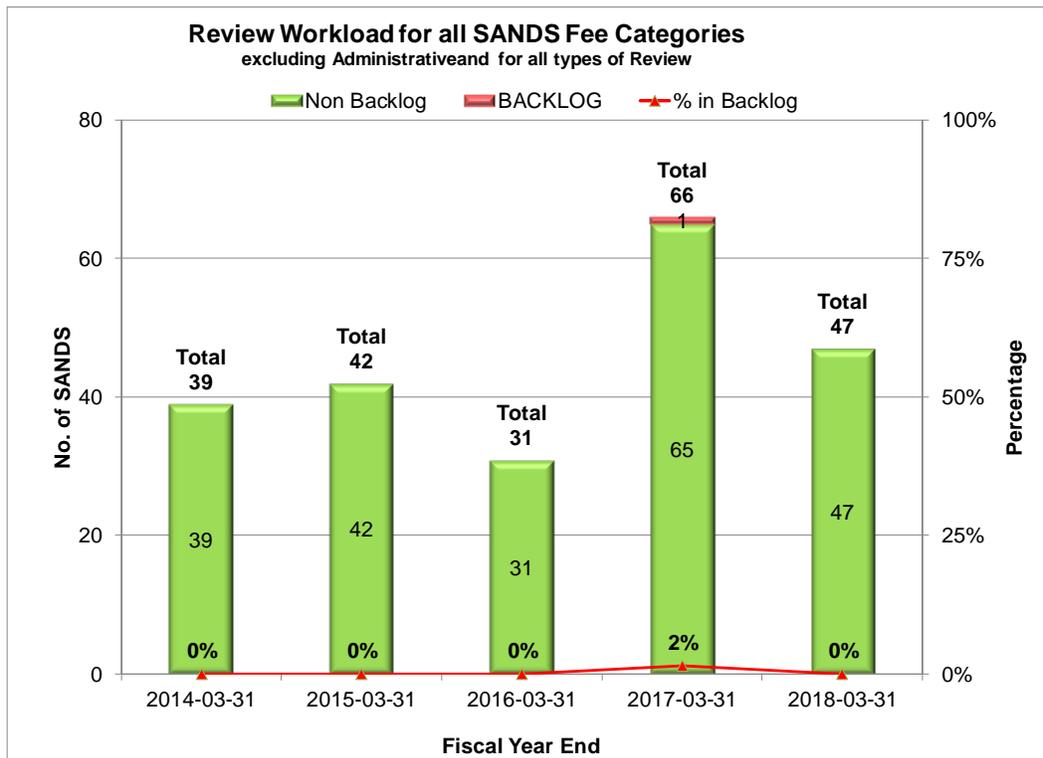


### WORKLOAD

#### Abbreviated New Drug Submission (ANDS) Review Workload / Backlog



#### Supplemental Abbreviated New Drug Submission (SANDS) Review Workload / Backlog



## WORKLOAD

## Abbreviated New Drug Submission (ANDS) Review Workload by Fee Category

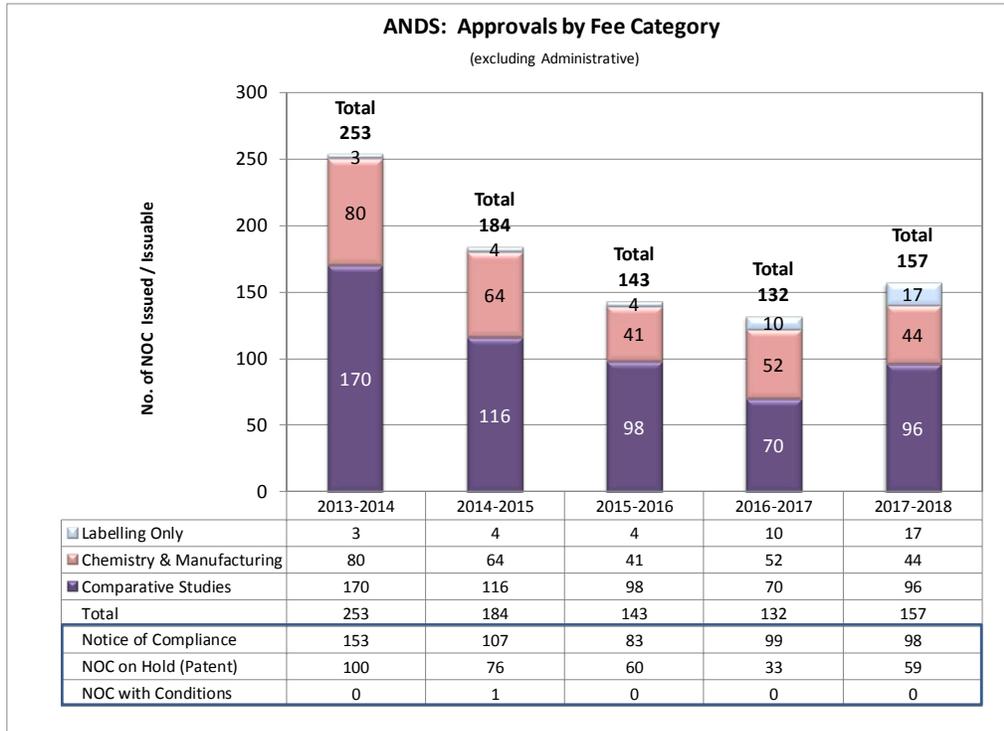
TPD ANDS All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
<b>Chemistry &amp; Manufacturing</b>	<b>58</b>	<b>59</b>	<b>49</b>	<b>46</b>	<b>43</b>
<i>Backlog</i>	<i>1</i>	<i>1</i>	<i>1</i>	<i>5</i>	<i>2</i>
<b>Comparative Studies</b>	<b>117</b>	<b>83</b>	<b>65</b>	<b>71</b>	<b>65</b>
<i>Backlog</i>	<i>0</i>	<i>4</i>	<i>7</i>	<i>7</i>	<i>2</i>
<b>Labelling Only</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>1</b>	<b>3</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Total</b>	<b>175</b>	<b>142</b>	<b>116</b>	<b>118</b>	<b>111</b>
<b>Non Backlog</b>	<b>174</b>	<b>137</b>	<b>108</b>	<b>106</b>	<b>107</b>
<b>BACKLOG</b>	<b>1</b>	<b>5</b>	<b>8</b>	<b>12</b>	<b>4</b>
<b>% in Backlog</b>	<b>1%</b>	<b>4%</b>	<b>7%</b>	<b>10%</b>	<b>4%</b>

## Supplemental Abbreviated New Drug Submission (SANDS) Review Workload by Fee Category

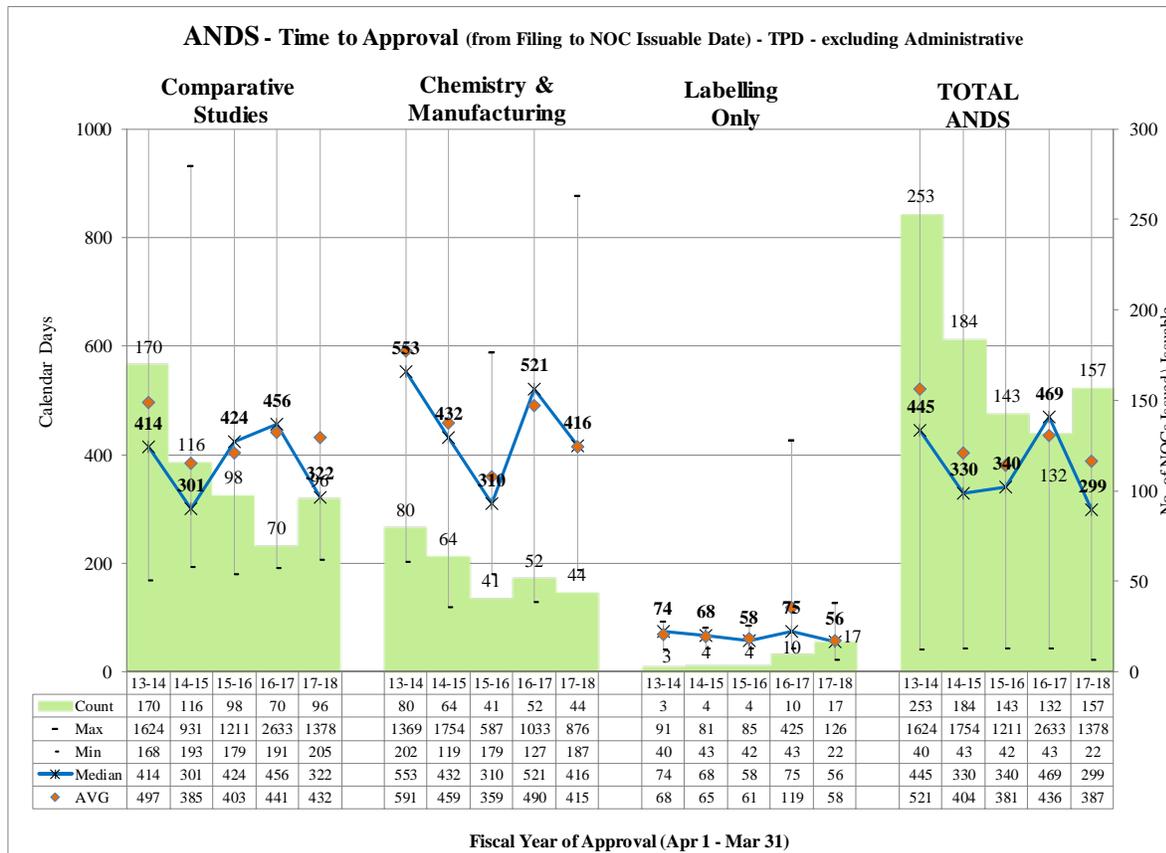
TPD SANDS All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
<b>Chemistry &amp; Manufacturing</b>	<b>27</b>	<b>27</b>	<b>24</b>	<b>32</b>	<b>26</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>1</i>	<i>0</i>
<b>Published Data Only</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Comparative Studies</b>	<b>10</b>	<b>7</b>	<b>2</b>	<b>4</b>	<b>2</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Labelling Only</b>	<b>2</b>	<b>8</b>	<b>5</b>	<b>30</b>	<b>19</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Total</b>	<b>39</b>	<b>42</b>	<b>31</b>	<b>66</b>	<b>47</b>
<b>Non Backlog</b>	<b>39</b>	<b>42</b>	<b>31</b>	<b>65</b>	<b>47</b>
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>2%</b>	<b>0%</b>

**APPROVALS**

**Abbreviated New Drug Submission (ANDS) Approvals by Fee Category & NOC Type**

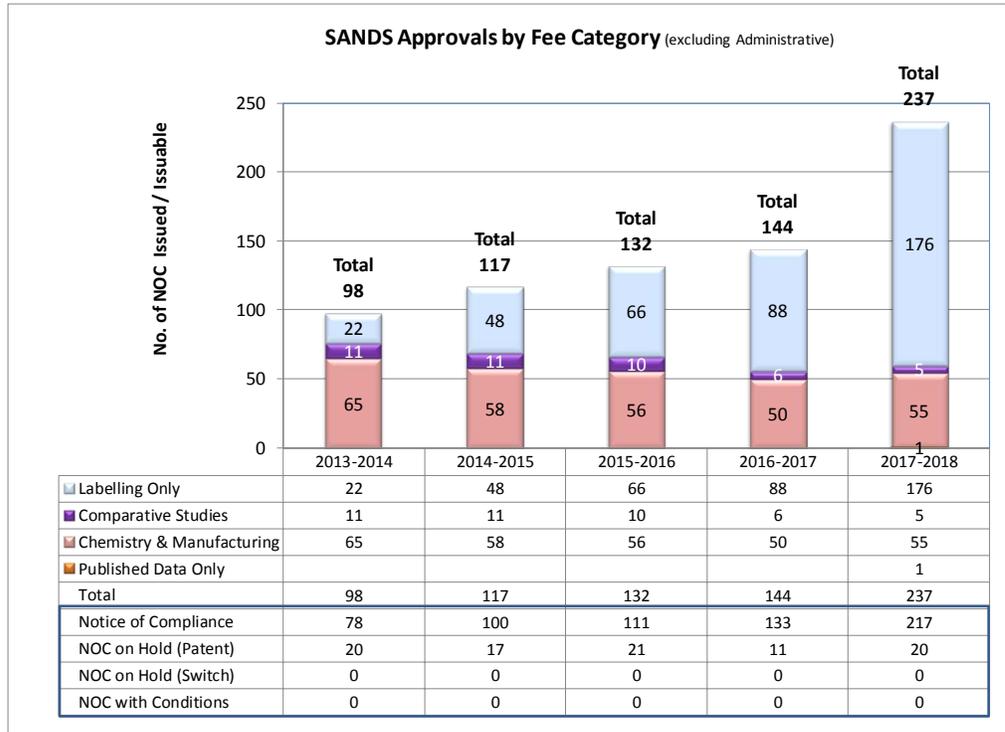


**ANDS Approval Times**

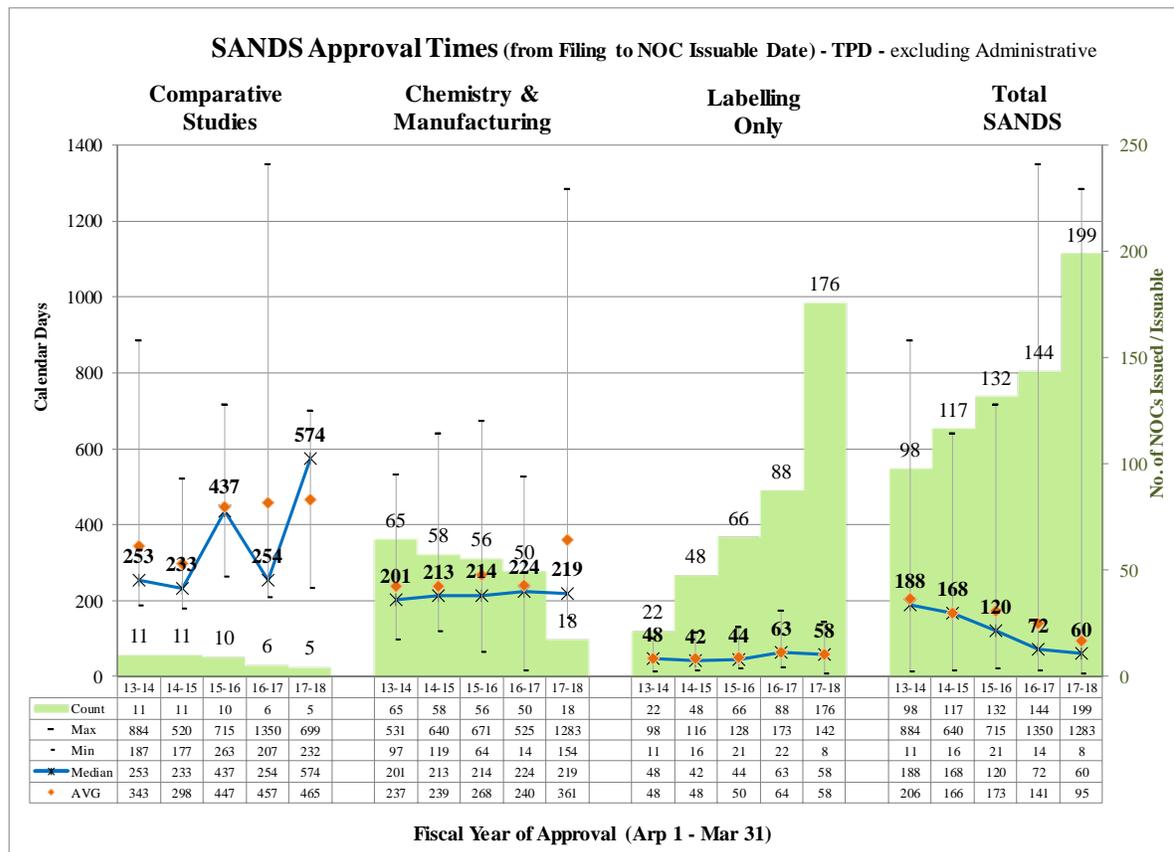


Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

Supplemental Abbreviated New Drug Submission (SANDS) Approvals by Fee Category and by NOC Type



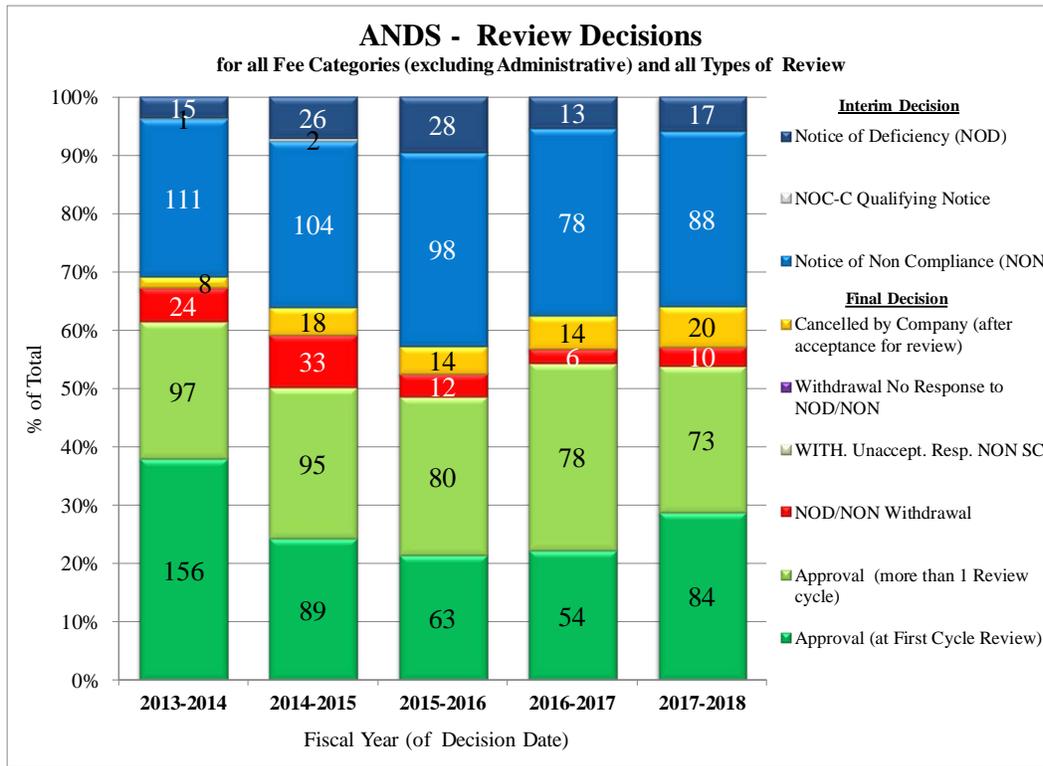
SANDS Approval Times



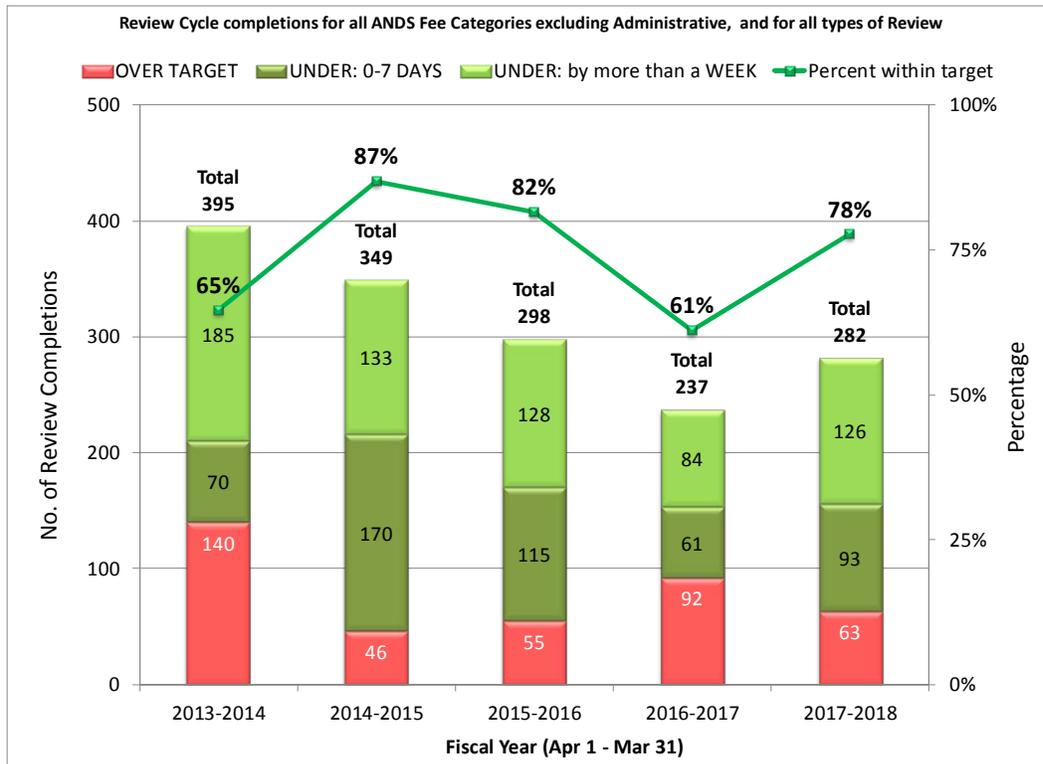
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

## REVIEW CYCLE DECISIONS

### Abbreviated New Drug Submission (ANDS) Review Decisions

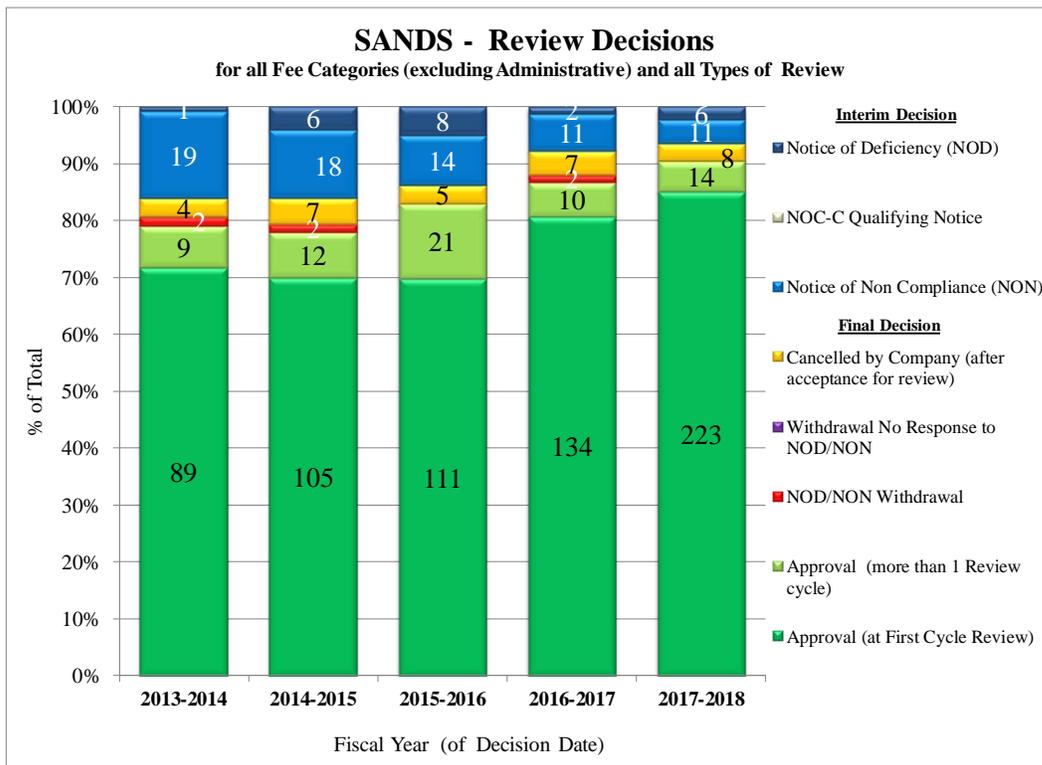


### ANDS - Review Cycle Completions Showing Percentage Within Target

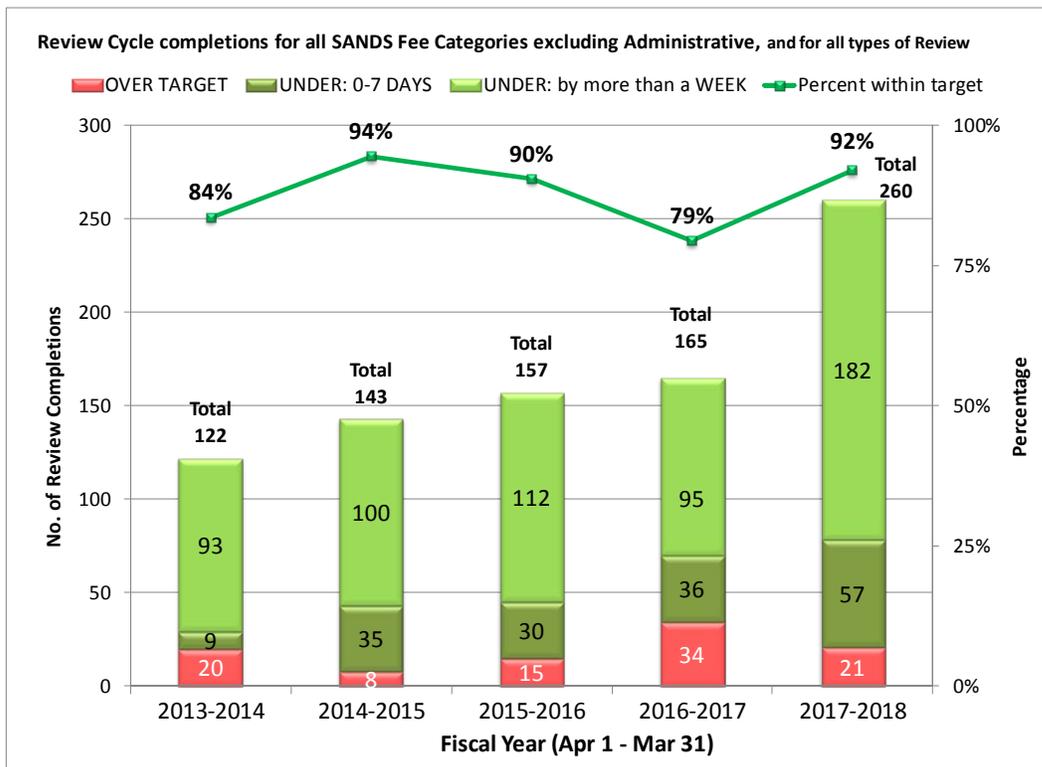


### REVIEW CYCLE DECISIONS

#### Supplemental Abbreviated New Drug Submission (SANDS) Review Decisions

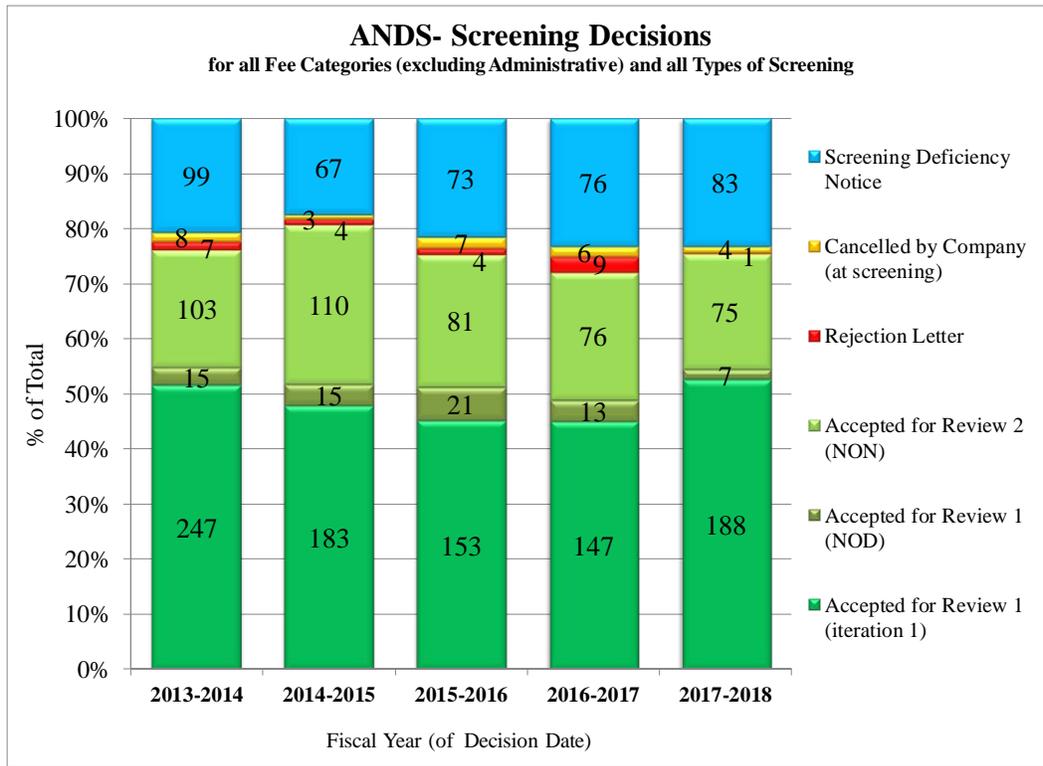


#### SANDS - Review Cycle Completions Showing Percentage Within Target

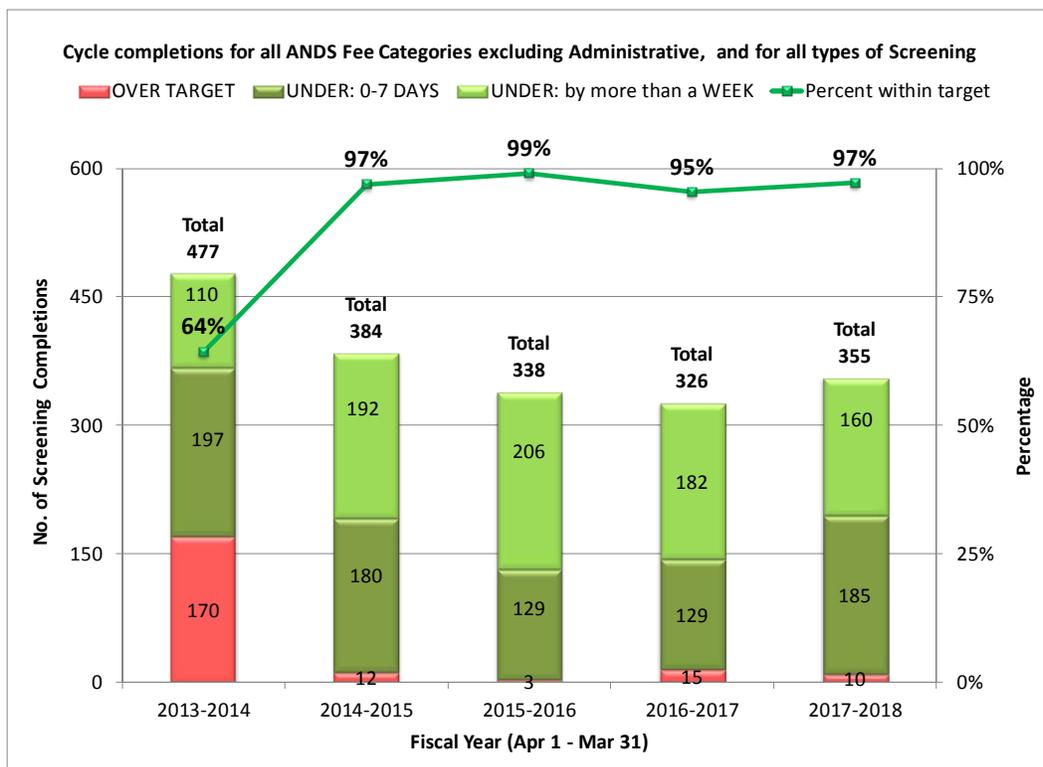


### SCREENING CYCLE DECISIONS

#### Abbreviated New Drug Submission (ANDS) Screening Decisions

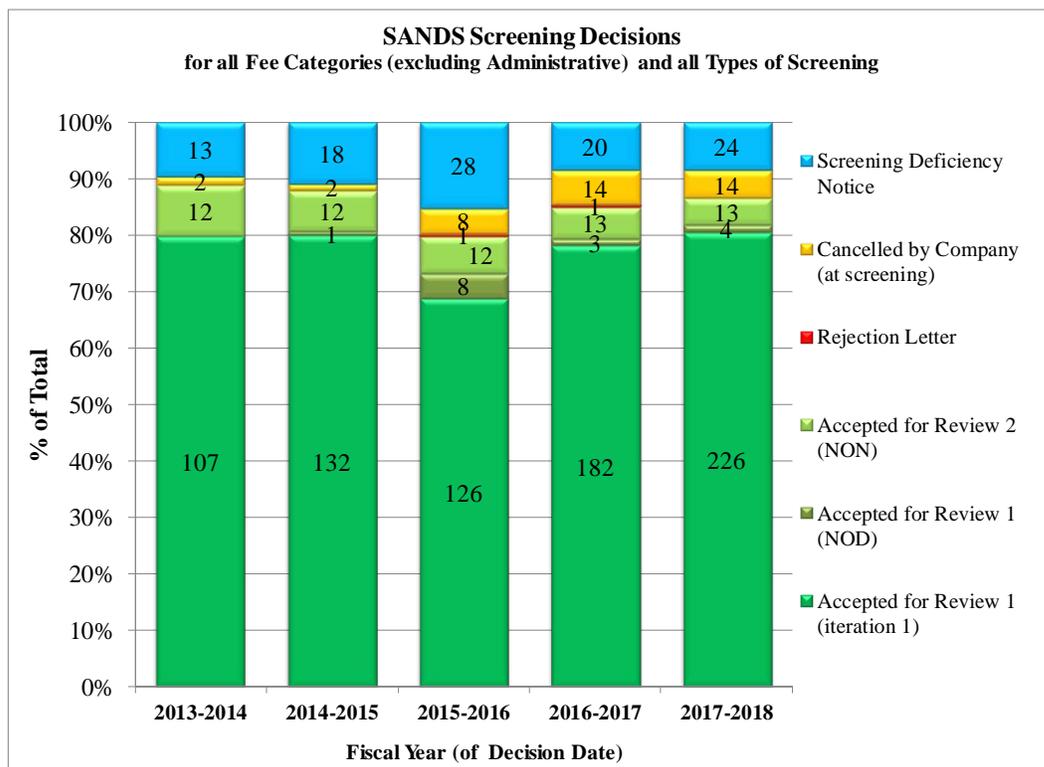


#### ANDS - Screening Cycle Completions Showing Percentage Within Target

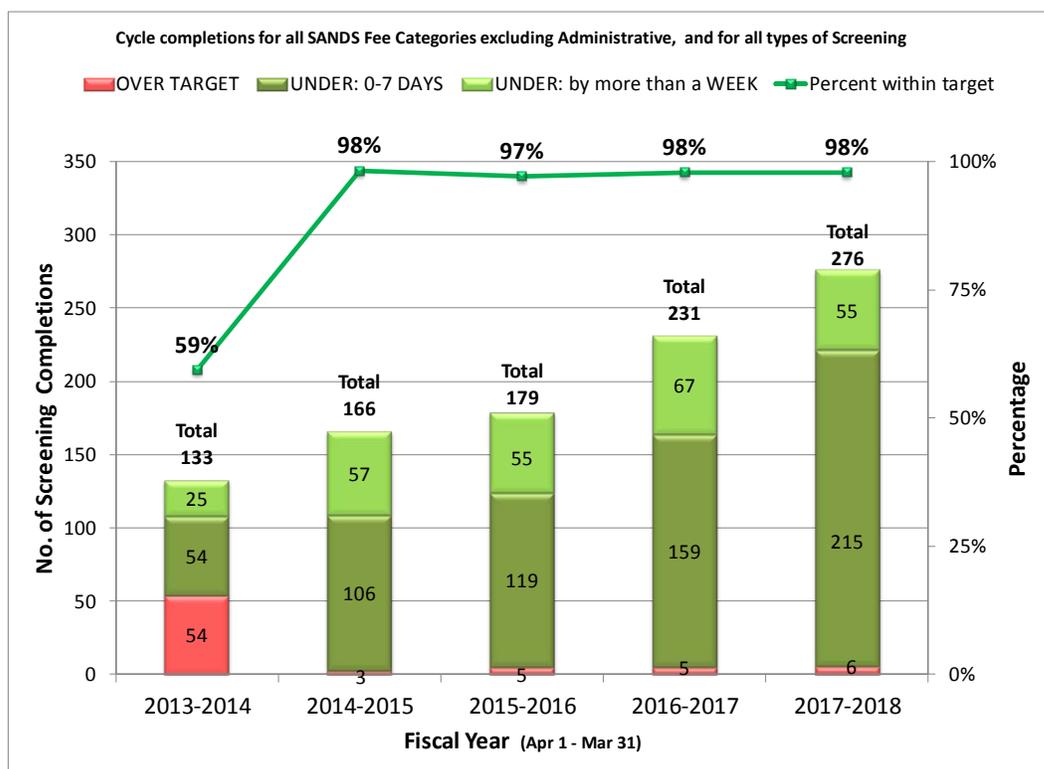


### SCREENING CYCLE DECISIONS

#### Supplemental Abbreviated New Drug Submission (SANDS) Screening Decisions



#### SANDS - Screening Cycle Completions Showing Percentage Within Target



## REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

## Requests for Reconsideration of Final Decisions – Abbreviated New Drug Submissions (ANDS)

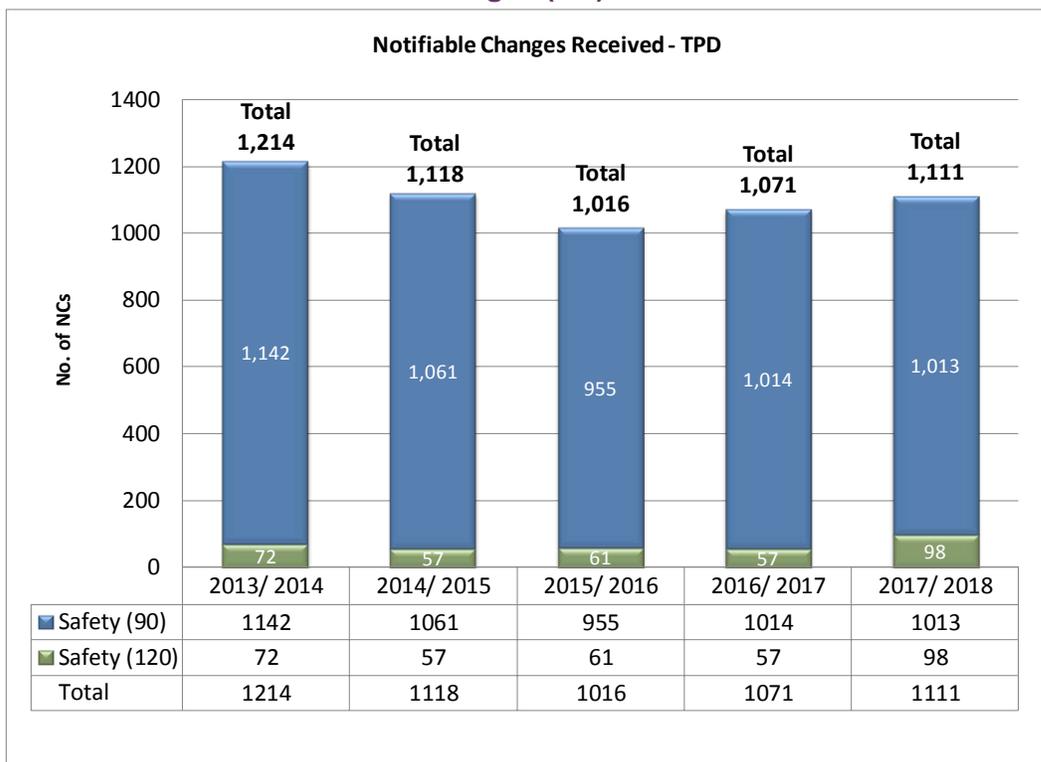
<b>ANDS - Reconsideration of Final Decisions Requests Received</b>							
Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	13-14	14-15	15-16	16-17	17-18	Final Decision in Dispute	ANDS Status (as of May 2018)
<b>TOTAL Received</b>	<b>8</b>	<b>8</b>	<b>3</b>	<b>2</b>	<b>0</b>		
<b>Total Pending</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>		
Pending			1			NON-Withdrawal	Under Reconsideration
<b>Total Granted</b>	<b>1</b>	<b>3</b>	<b>1</b>	<b>1</b>	<b>0</b>		
Granted	1	3				NON-Withdrawal	Cleared
Granted			1			NON-Withdrawal	Cleared
Granted				1		Rejection at Screening	Cleared
<b>Total Denied</b>	<b>3</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>0</b>		
Denied	2					NOD-Withdrawal	Withdrawn
Denied	1	1	1			NON-Withdrawal	Withdrawn
<b>Total Cancelled</b>	<b>4</b>	<b>4</b>	<b>0</b>	<b>1</b>	<b>0</b>		
Cancelled by Health Canada	1					NOD-Withdrawal	Cleared
Cancelled by Health Canada		1				NOD-Withdrawal	Withdrawn
Cancelled by Health Canada	2					NON-Withdrawal	Cleared
Cancelled by Health Canada		2				NON-Withdrawal	Withdrawn
Cancelled by Health Canada		1				Rejection at Screening	Cleared
Cancelled by Company				1		NOD-Withdrawal	Withdrawn
Cancelled by Company	1					NON-Withdrawal	Withdrawn

## Requests for Reconsideration of Final Decisions – Supplemental Abbreviated New Drug Submissions (SANDS)

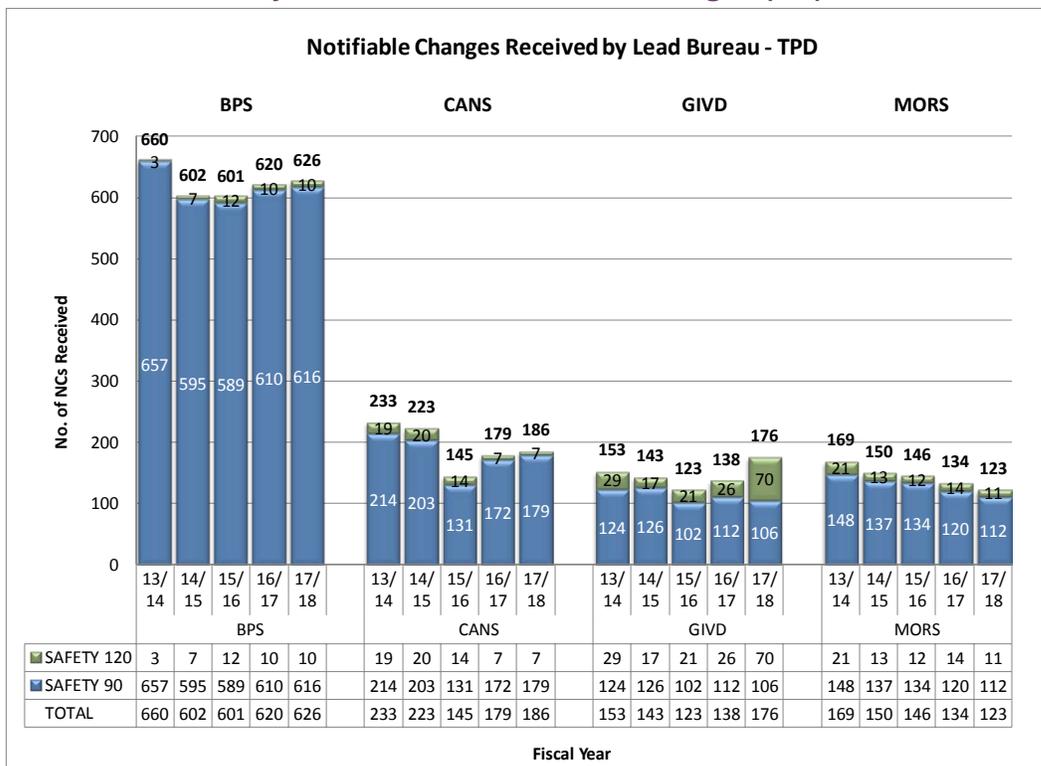
<b>SANDS - Reconsideration of Final Decisions Requests Received</b>							
Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	13-14	14-15	15-16	16-17	17-18	Final Decision in Dispute	SANDS Status (as of May 2018)
<b>Total Received</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>0</b>		
<b>Total Granted</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>		
Granted			1			NOD-Withdrawal	Cleared
<b>Total Cancelled</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>		
Cancelled by Health Canada				1		NOD-Withdrawal	Cleared

## NOTIFIABLE CHANGES (NC)

### Number Received - Notifiable Changes (NC)



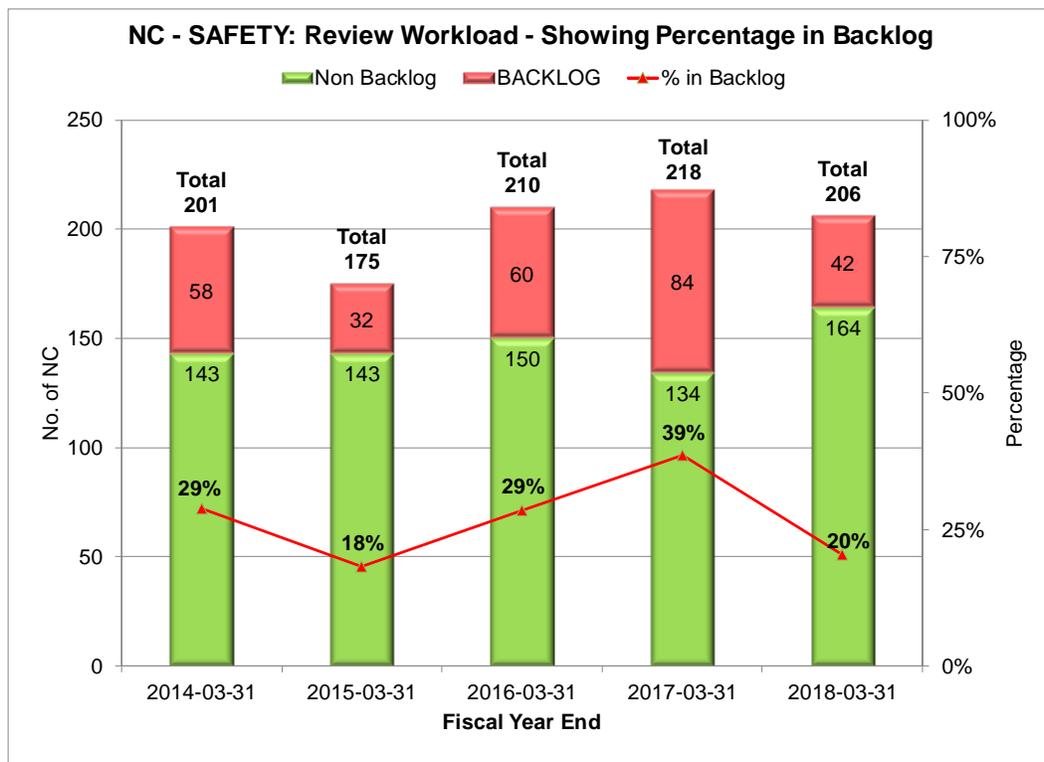
### Number Received by Lead Bureau- Notifiable Changes (NC)



In February 2013 the [Safety Labelling Changes to the Product Monographs of Brand Name Pharmaceutical Drug Products](#) process was introduced to inform generic drug manufacturers about new safety information for pharmaceutical drug products so that they can update their PMs for health care professionals and Canadians.

## WORKLOAD

### Notifiable Change (NC) SAFETY: Review Workload / Backlog



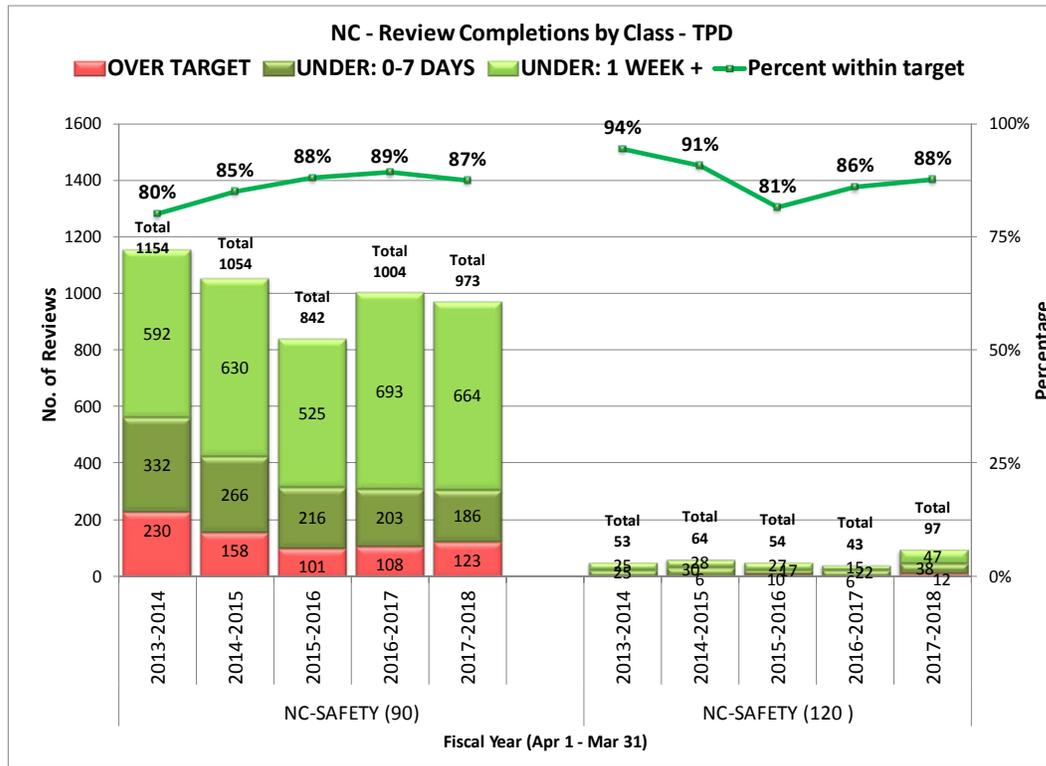
## WORKLOAD

### Notifiable Change (NC) SAFETY: Review Workload by Class

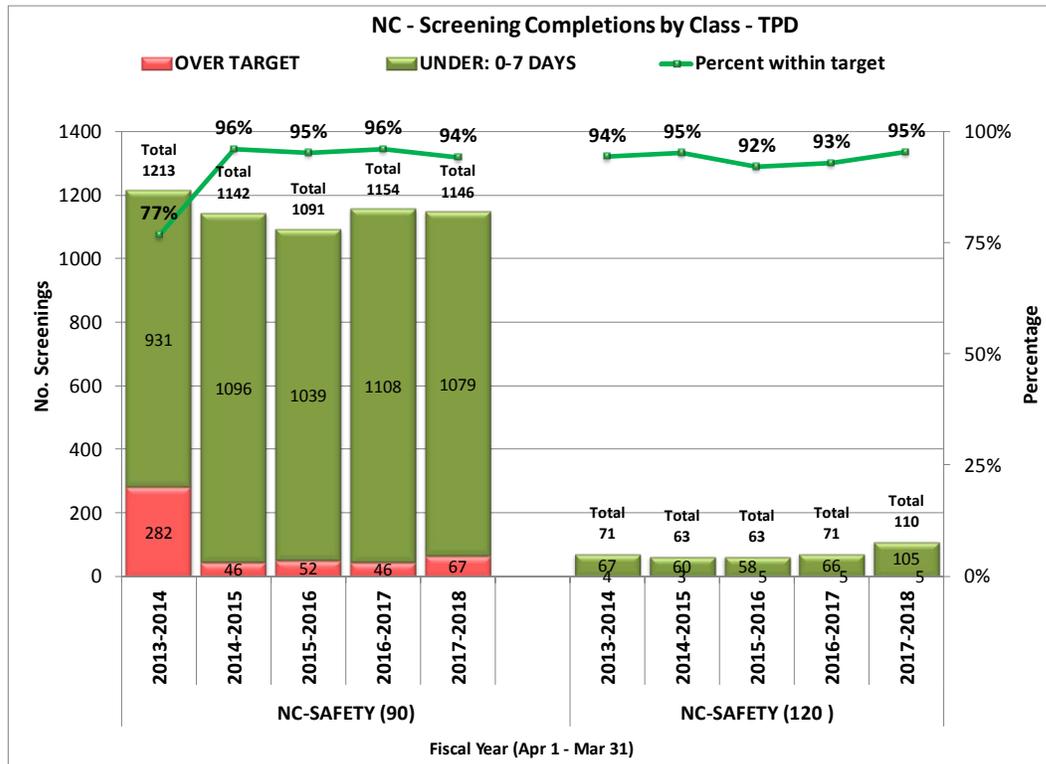
TPD NC- SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
<b>SAFETY - 90 day</b>	<b>177</b>	<b>156</b>	<b>194</b>	<b>188</b>	<b>184</b>
Backlog	57	32	60	78	39
<b>SAFETY - 120 day</b>	<b>24</b>	<b>19</b>	<b>16</b>	<b>30</b>	<b>22</b>
Backlog	1	0	0	6	3
<b>Total</b>	<b>201</b>	<b>175</b>	<b>210</b>	<b>218</b>	<b>206</b>
Non Backlog	143	143	150	134	164
<b>BACKLOG</b>	<b>58</b>	<b>32</b>	<b>60</b>	<b>84</b>	<b>42</b>
<b>% in Backlog</b>	<b>29%</b>	<b>18%</b>	<b>29%</b>	<b>39%</b>	<b>20%</b>

PERFORMANCE

REVIEW Completions by Class - Notifiable Changes (NC)



SCREENING Completions by Class - Notifiable Changes (NC)



**DECISIONS****Decision Documents by Class - Notifiable Change (NC) Safety**

<b>NC - SAFETY (90)</b>					
<b>DOCUMENT TYPE</b>	<b>2013-2014</b>	<b>2014-2015</b>	<b>2015-2016</b>	<b>2016-2017</b>	<b>2017-2018</b>
NO OBJECTION LETTER	1098	1065	834	954	990
CANCELLED BY COMPANY	42	49	62	65	66
NC - HOLD (PATENT)	72	34	45	69	46
SCREEN. DEFICIENCY NOTICE	91	85	197	136	161
REJECTION LETTER (SCR)	5	6	3	2	3
NOT SATISFACTORY NOTICE	2	5	1	2	
SPONSOR SUB CHANGE ACCEPT			1		

<b>NC - SAFETY (120)</b>					
<b>DOCUMENT TYPE</b>	<b>2013-2014</b>	<b>2014-2015</b>	<b>2015-2016</b>	<b>2016-2017</b>	<b>2017-2018</b>
NO OBJECTION LETTER	49	63	54	43	90
NOT SATISFACTORY NOTICE	1	1			
SCREENING DEFICIENCY NOTICE	1	3	6	11	20
CANCELLED BY COMPANY	7	1	6	4	8
REJECTION LETTER (SCR)	1		1		

**REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS****Requests for Reconsideration of Final Decisions – Notifiable Changes (NC)**

<b>Notifiable Changes - Requests for Reconsideration of Final Decisions</b>							
Fiscal Year of Request (April 1 - March 31)							
<b>Breakdown by Reconsideration Decision</b>	<b>13-14</b>	<b>14-15</b>	<b>15-16</b>	<b>16-17</b>	<b>17-18</b>	<b>Final Decision in Dispute</b>	<b>NC's Status (as of May 2018)</b>
<b>Total Received</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>		

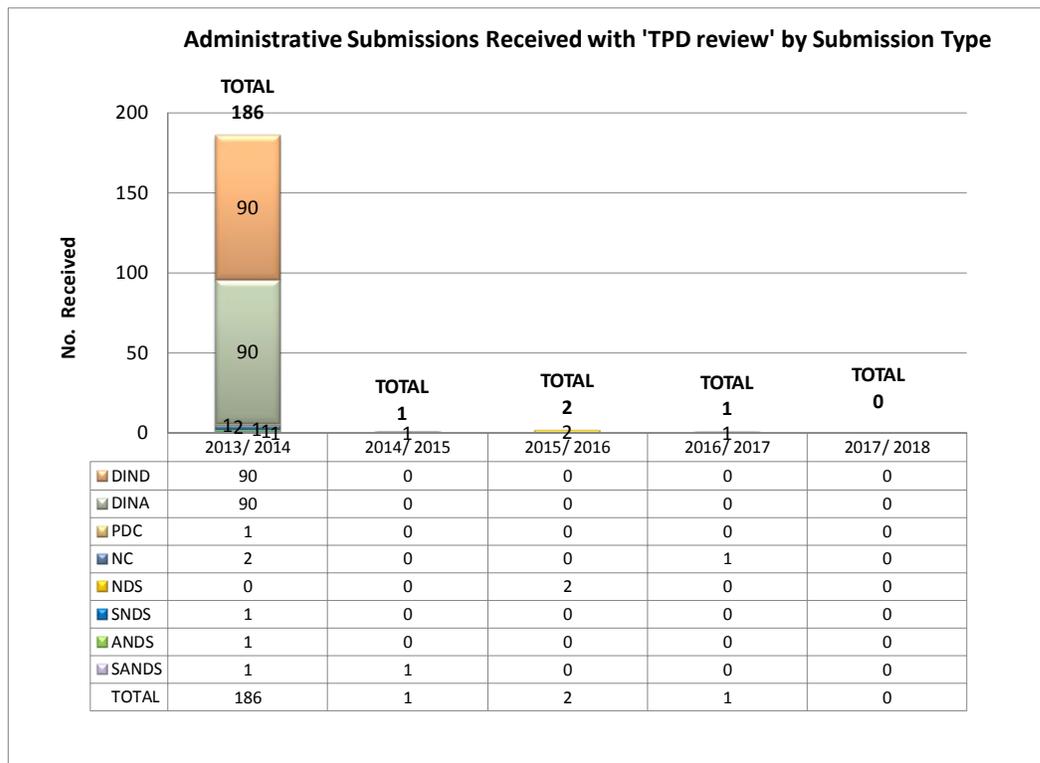
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## **Administrative Submissions**

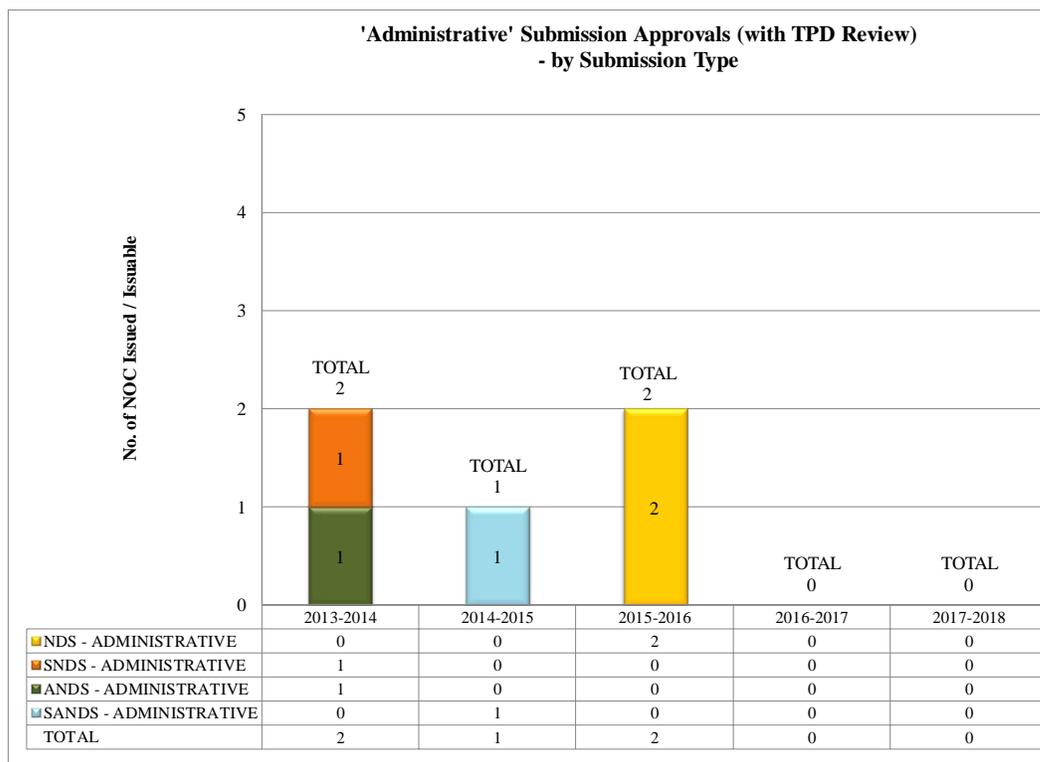
Submissions in support of a manufacturer or product name change.

**ADMINISTRATIVE SUBMISSIONS with TPD review**  
(such as product name change that requires a drug name review)

**Administrative Submissions Received (with TPD review)**

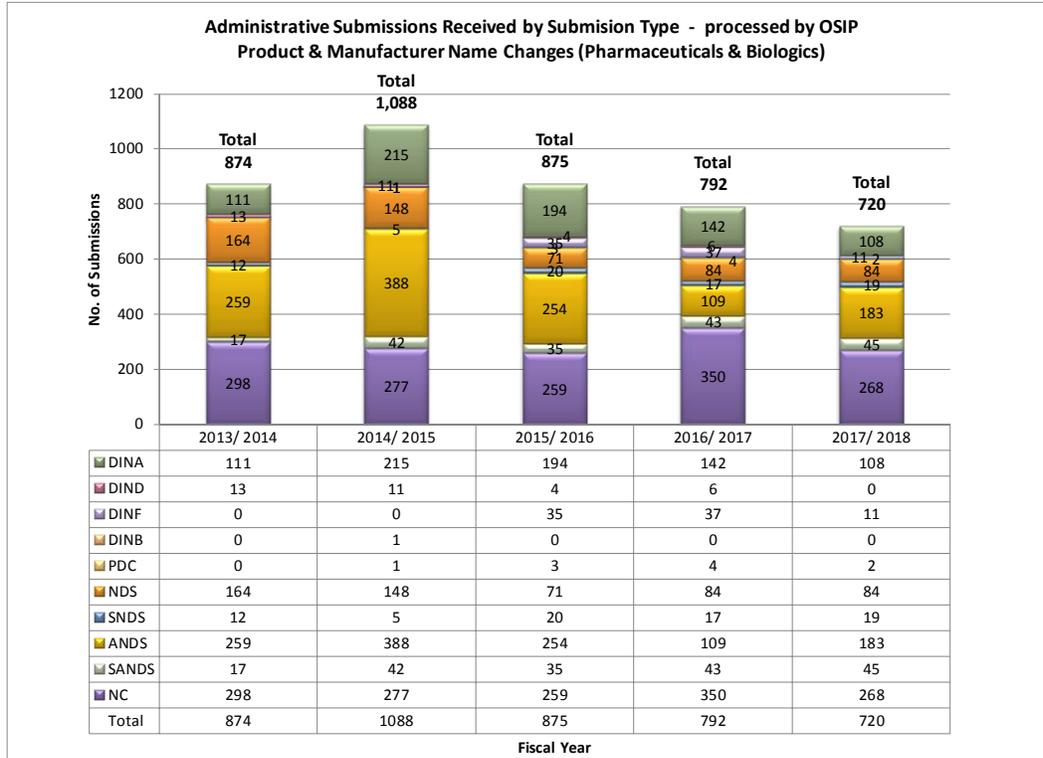


**Administrative Submission Approvals (with TPD Review)**

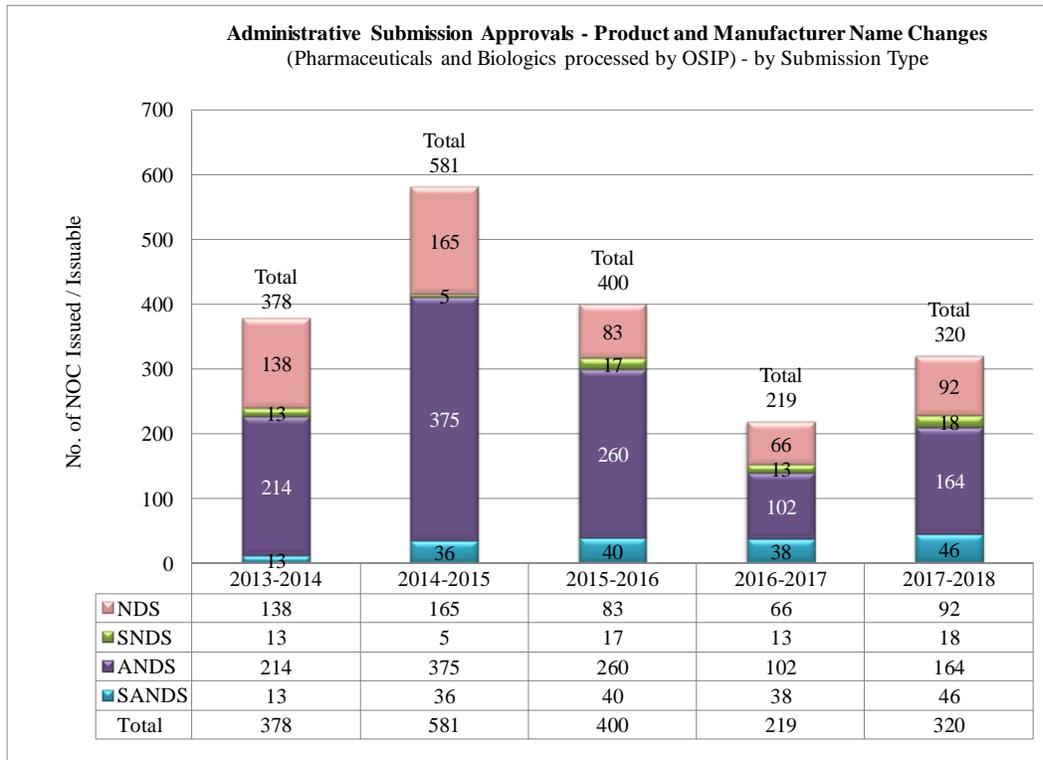


**ADMINISTRATIVE SUBMISSIONS (Processed by OSIP)**  
 (Product & Manufacturer Name Changes)  
 (Admin Ncs are for cross-referenced changes)

**Administrative Submissions Received by Submission Type (OSIP)**



**Administrative Submission Approvals (OSIP) for NDS, SNDS, ANDS and SANDS**

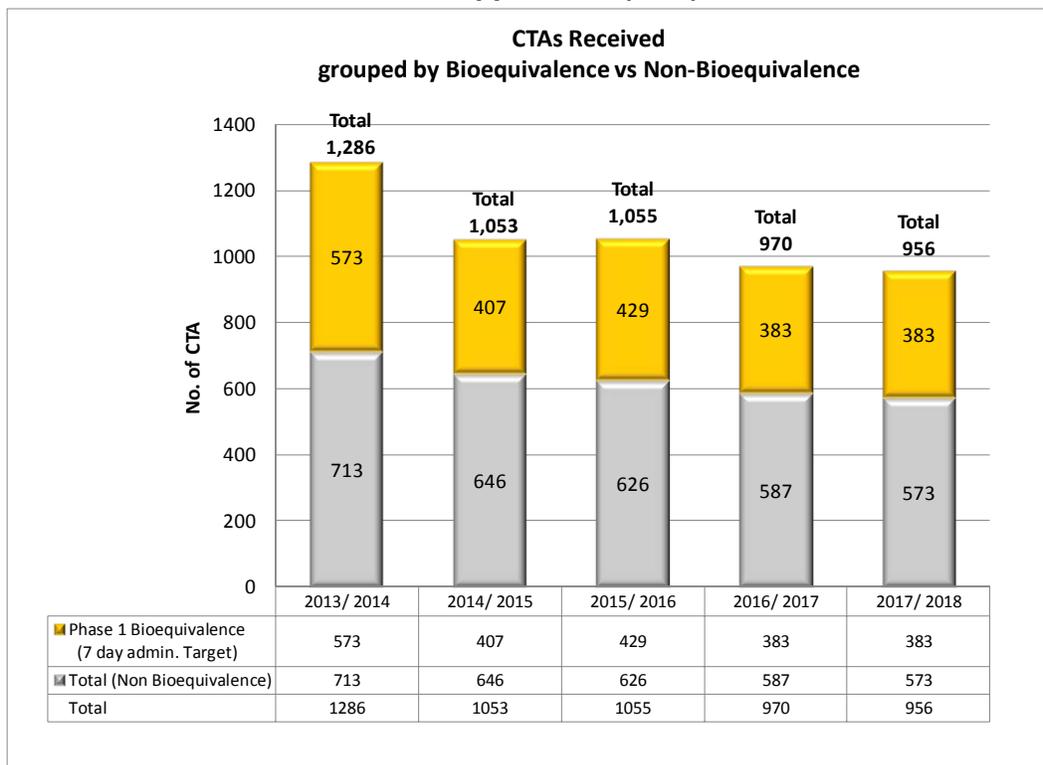


# **Clinical Trial Applications and Amendments**

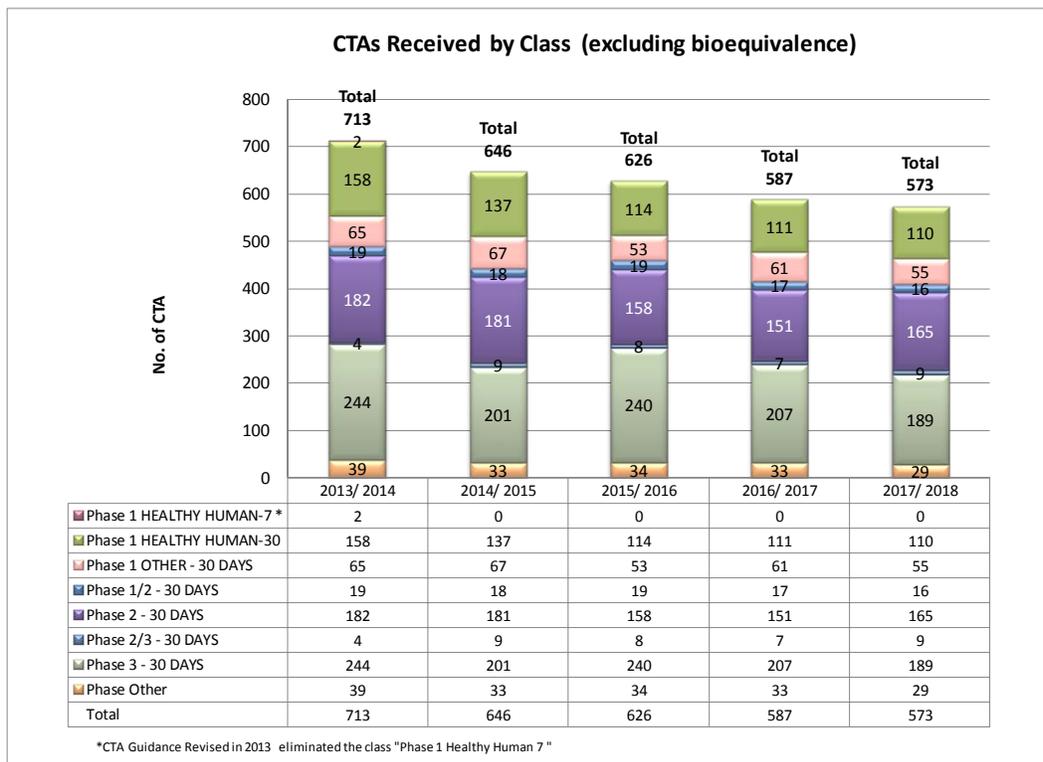
## **(CTA & CTA-A)**

## CLINICAL TRIAL APPLICATIONS

### Number Received - Clinical Trial Application (CTA)



### Number Received - Clinical Trial Application (CTA) - Excluding Bioequivalence (Generic)



## DECISION DOCUMENTS

## Decision Documents - Clinical Trial Application (CTA)

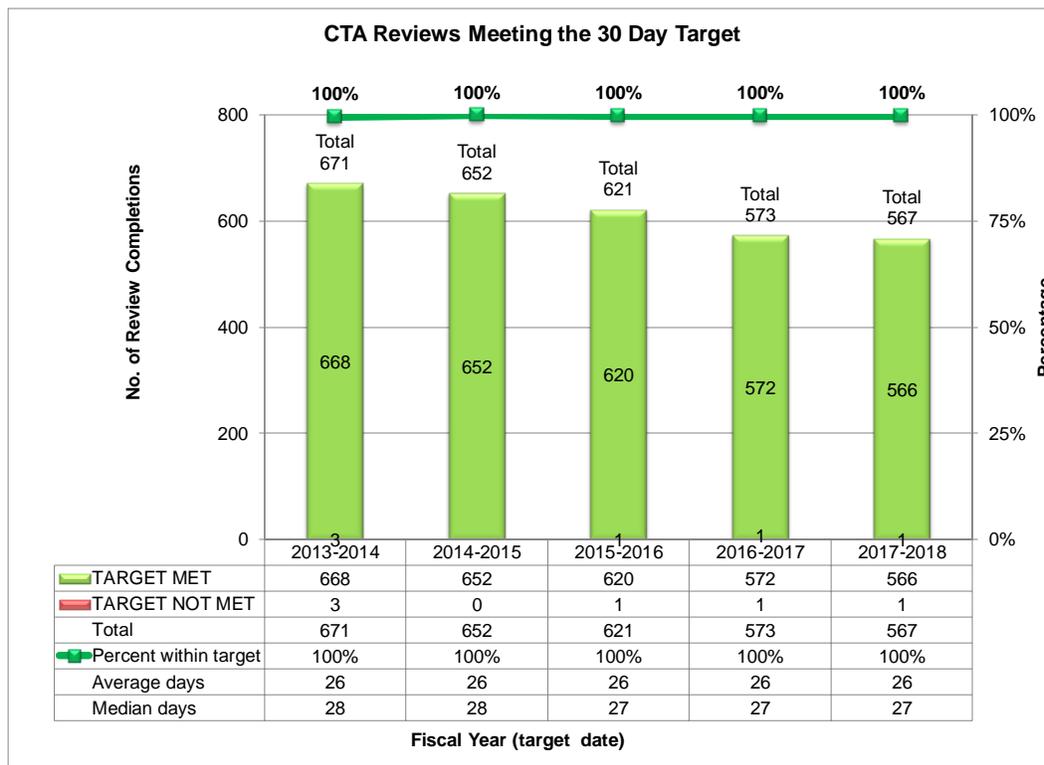
CTA (Total)					
DOCUMENT TYPE	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
NO OBJECTION LETTER	1186	1021	994	926	898
CANCELLED BY COMPANY DURING REVIEW	54	48	44	36	53
CANCELLED BY COMPANY AT PROCESSING	17	7	8	4	11

CTA (7 day administrative target*)					
*Phase 1 Bioequivalence (Class Phase 1 Healthy Human 7 eliminated in 2013)					
DOCUMENT TYPE	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
NO OBJECTION LETTER	553	410	405	386	379
CANCELLED BY COMPANY DURING REVIEW	16	6	12	3	3
CANCELLED BY COMPANY AT PROCESSING	2	0	0	0	1

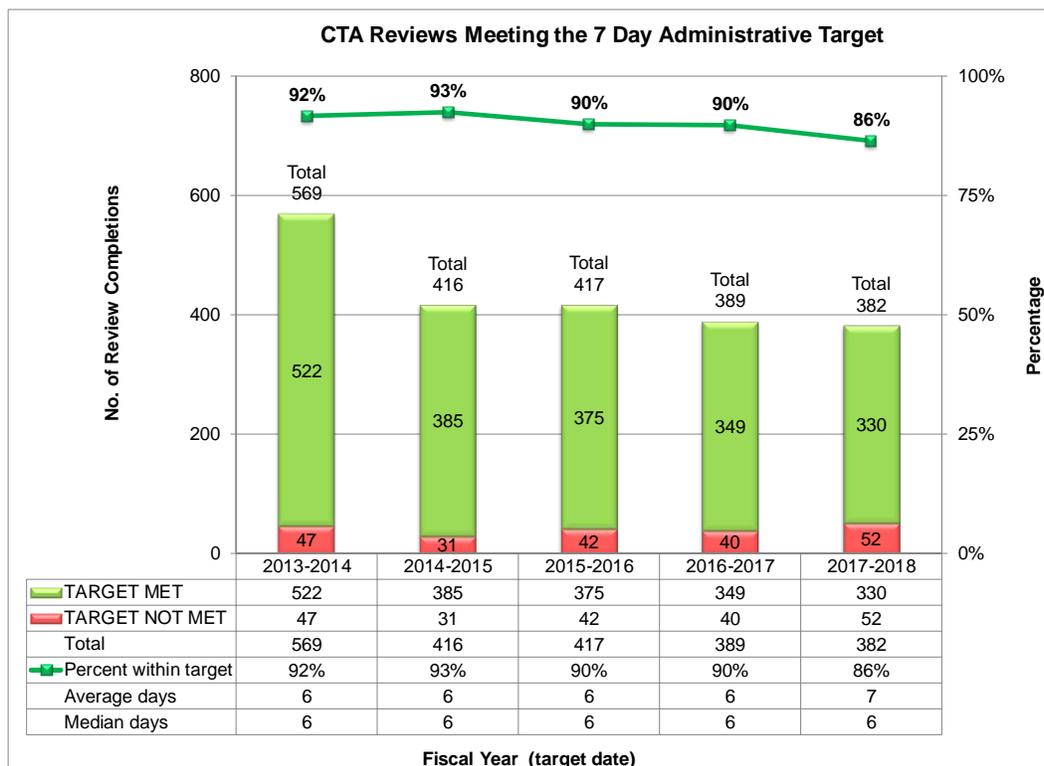
CTA (30 day target)					
DOCUMENT TYPE	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
NO OBJECTION LETTER	633	611	589	540	519
CANCELLED BY COMPANY DURING REVIEW	38	42	32	33	50
CANCELLED BY COMPANY AT PROCESSING	15	7	8	4	10

**PERFORMANCE**

**Performance - Clinical Trials Applications (CTA) Reviews Meeting the 30 Day Target**

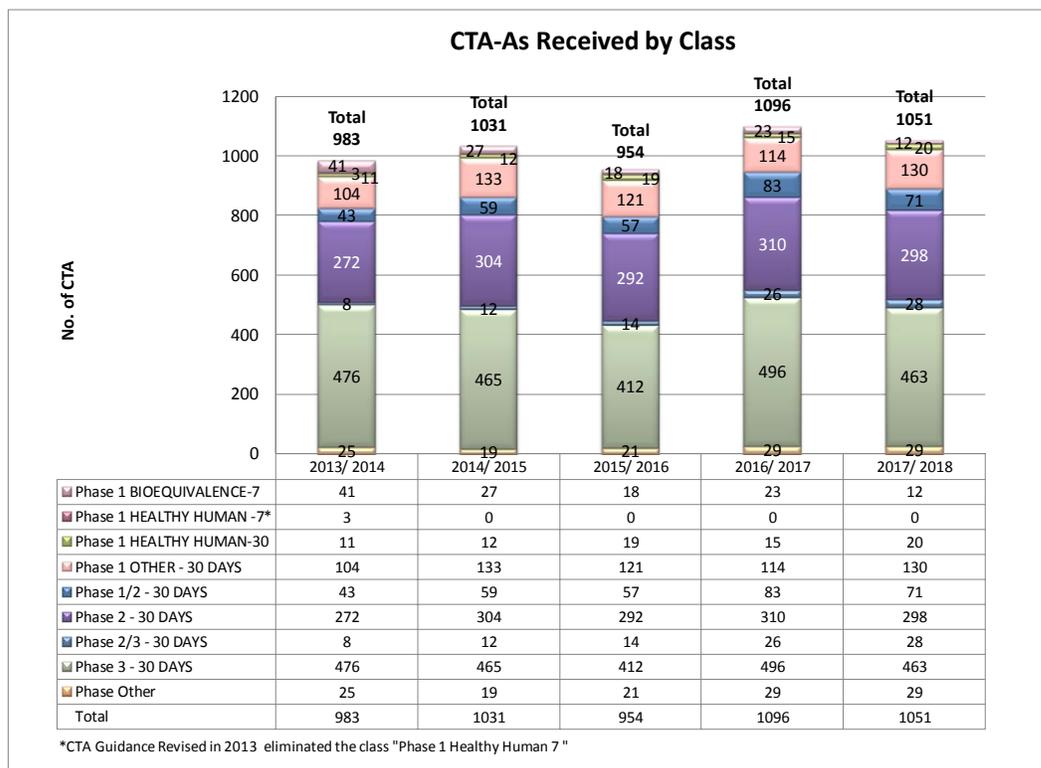


**Performance – CTA Reviews Meeting the 7 Day Administrative Target**



## CLINICAL TRIAL APPLICATION-AMENDMENTS

### Number Received - Clinical Trial Application-Amendments (CTA-A)



## DECISION DOCUMENTS

### Decision Documents - Clinical Trial Application-Amendments (CTA-A)

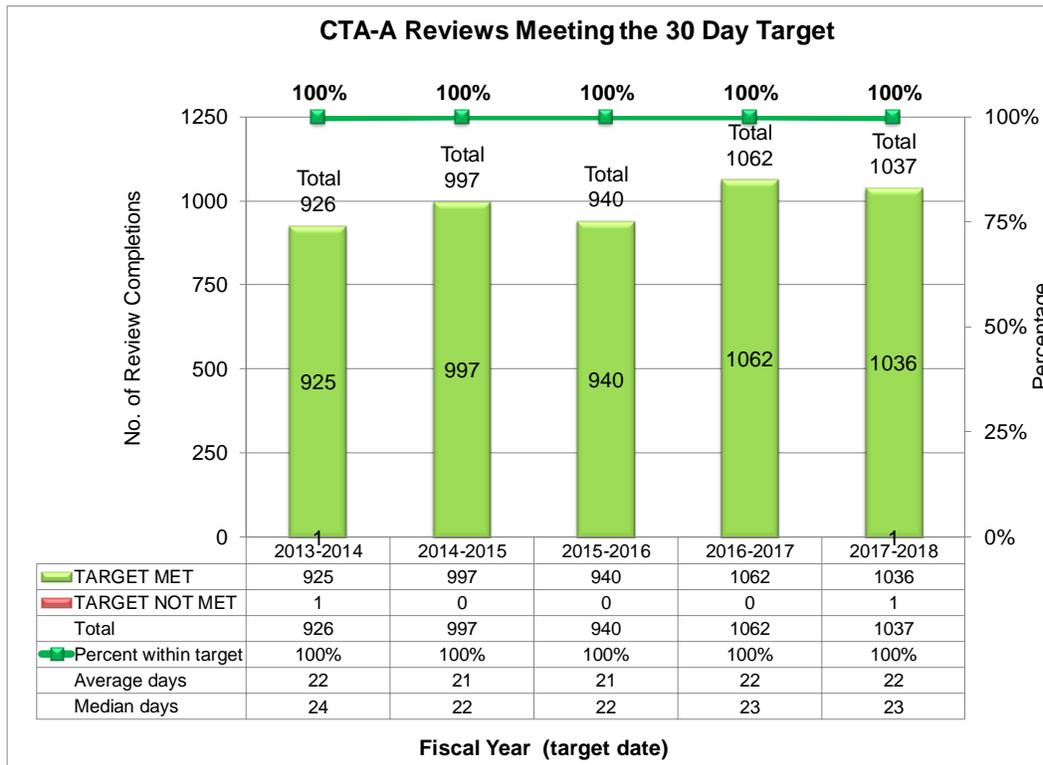
CTA-A (Total)					
DOCUMENT TYPE	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
NO OBJECTION LETTER	963	1013	949	1070	1037
CANCELLED BY COMPANY DURING REVIEW	8	11	9	15	11
CANCELLED BY COMPANY AT PROCESSING	0	4	0	0	1

CTA-A (7 day administrative target)					
DOCUMENT TYPE	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
NO OBJECTION LETTER	43	26	18	23	12
CANCELLED BY COMPANY DURING REVIEW	0	0	0	0	0
CANCELLED BY COMPANY AT PROCESSING	0	0	0	0	0

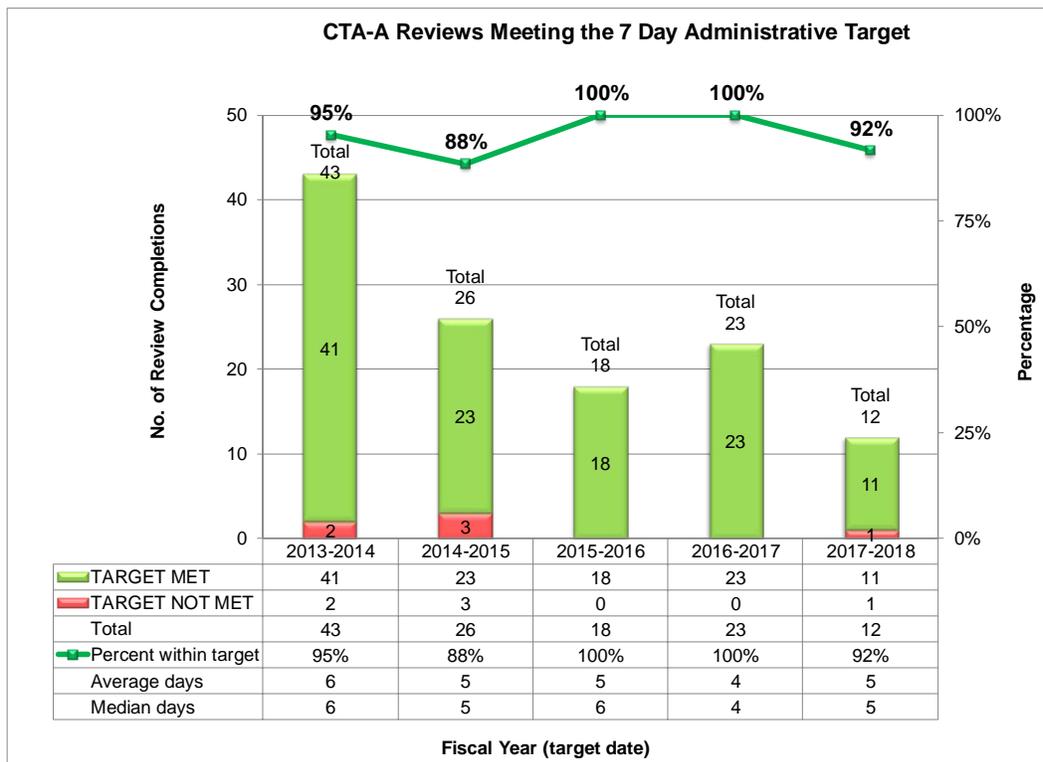
CTA-A (30 day target)					
DOCUMENT TYPE	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
NO OBJECTION LETTER	920	987	931	1047	1025
CANCELLED BY COMPANY DURING REVIEW	8	11	9	15	11
CANCELLED BY COMPANY AT PROCESSING	0	4	0	0	1

**PERFORMANCE**

**Performance - Clinical Trial Application Amendments (CTA-A) Reviews Meeting the 30 Day Target**



**Performance - CTA-A: Reviews Meeting the 7 Day Administrative Target**



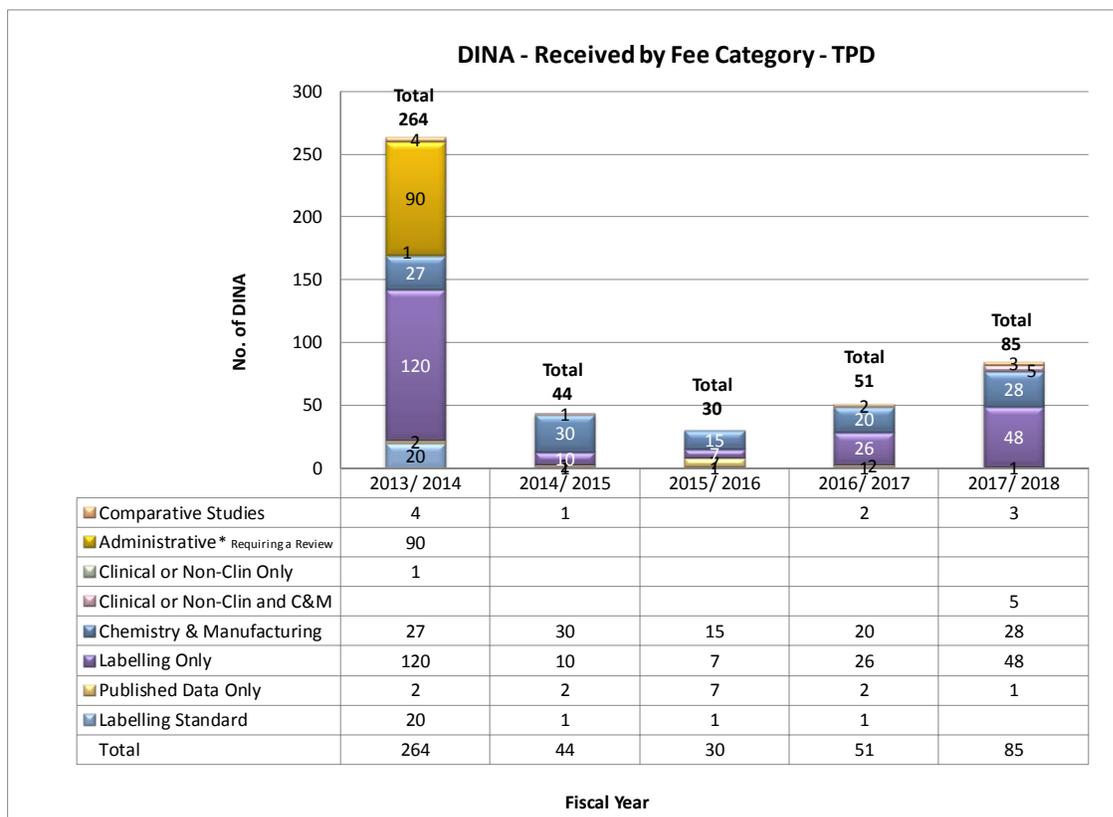
## **DINA**

### **Application for a Drug Identification Number**

Please note that TPD's non-prescription (or over-the-counter) and disinfectant drug review functions were moved to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013 and are now reported in the NNHPD Drug Submission Performance Annual Report

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

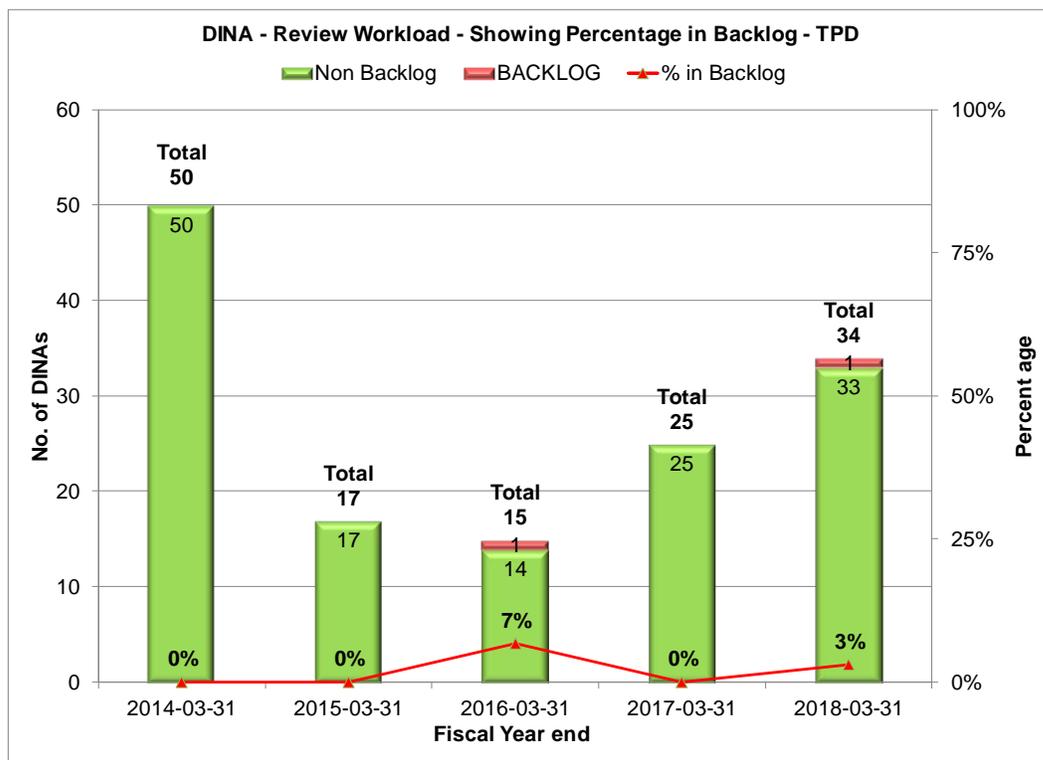
**DINA: Number Received**



TPD's non-prescription (or over-the-counter) and disinfectant drug review functions were moved to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013 and are now reported in the NNHPD Drug Submission Performance Annual Report.

## REVIEW WORKLOAD

### DINA: Review Workload / Backlog - Showing Percentage in Backlog

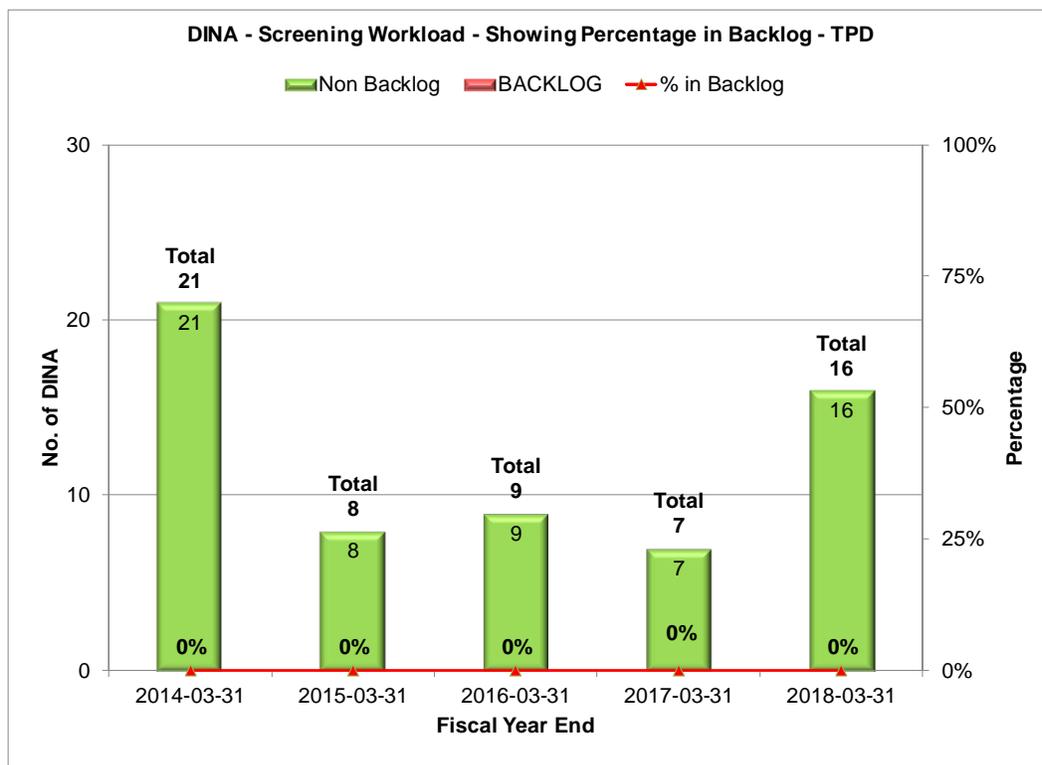


### DINA: Review Workload by Class

TPD DINA All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
<b>Labelling Only</b>	<b>32</b>	<b>2</b>	<b>4</b>	<b>13</b>	<b>13</b>
<i>Backlog</i>	0	0	0	0	1
<b>Clinical or Non-Clin Only</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<i>Backlog</i>	0	0	0	0	0
<b>Clinical or Non-Clin and C&amp;M</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<i>Backlog</i>	0	0	0	0	0
<b>Chemistry &amp; Manufacturing</b>	<b>15</b>	<b>14</b>	<b>9</b>	<b>12</b>	<b>19</b>
<i>Backlog</i>	0	0	1	0	0
<b>Published Data</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>
<i>Backlog</i>	0	0	0	0	0
<b>Comparative Studies</b>	<b>2</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>1</b>
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>50</b>	<b>17</b>	<b>15</b>	<b>25</b>	<b>34</b>
<b>Non Backlog</b>	<b>50</b>	<b>17</b>	<b>14</b>	<b>25</b>	<b>33</b>
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>7%</b>	<b>0%</b>	<b>3%</b>

### SCREENING WORKLOAD

#### DINA: Screening Workload Showing Percentage in Backlog



#### DINA: Screening Workload by Class

TPD DINA All SCREENING WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
<b>Labelling Only</b>	<b>13</b>	<b>3</b>	<b>1</b>	<b>4</b>	<b>8</b>
<i>Backlog</i>	0	0	0	0	0
<b>Labelling Standard</b>	<b>4</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<i>Backlog</i>	0	0	0	0	0
<b>Chemistry &amp; Manufacturing</b>	<b>3</b>	<b>3</b>	<b>5</b>	<b>2</b>	<b>4</b>
<i>Backlog</i>	0	0	0	0	0
<b>Clinical or Non-Clinical Only</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<i>Backlog</i>	0	0	0	0	0
<b>Clinical or Non-Clin and C&amp;M</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>
<i>Backlog</i>	0	0	0	0	0
<b>Published Data Only</b>	<b>0</b>	<b>1</b>	<b>3</b>	<b>0</b>	<b>0</b>
<i>Backlog</i>	0	0	0	0	0
<b>Comparative Studies</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>2</b>
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>21</b>	<b>8</b>	<b>9</b>	<b>7</b>	<b>16</b>
<b>Non Backlog</b>	<b>21</b>	<b>8</b>	<b>9</b>	<b>7</b>	<b>16</b>
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

## DECISION DOCUMENTS

## DINA: Decision Documents by Fee Category

CLASS	DOCUMENT TYPE	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
DINA - LABELLING ONLY	NOTIFICATION FORM/DIN ISSUED	92	4	1	3	12
	NO OBJECTION LETTER	21	6	5	4	25
	CANCELLED BY COMPANY	10		1	6	3
	DIN INCORR SUBTYPE-CLASS	17				
	NEW DRUG LETTER SCREEN	3				
	NON WITHDRAWAL LETTER					
	NOTICE OF DEFICIENCY		2		1	
	NOTICE OF NON-COMPLIANCE	8			1	
	REJECTION LETTER (SCREENING)					1
	SCREENING DEFICIENCY NOTICE	17	4	2	9	8
SPONSOR SUB CHANGE ACCEPT	10					
DINA - ADMINISTRATIVE	NOTIFICATION FORM/DIN ISSUED	87	-	-	-	-
	NO OBJECTION LETTER	1	-	-	-	-
	REJECTION LETTER (SCREENING)	10	-	-	-	-
	SCREENING DEFICIENCY NOTICE	6	-	-	-	-
	CANCELLED BY COMPANY	2	-	-	-	-
DINA - LABELLING STANDARD	NOTIFICATION FORM/DIN ISSUED	16				-
	NO OBJECTION LETTER					-
	NEW DRUG LETTER SCREEN	1				-
	REJECTION LETTER (SCREENING)				1	-
	SCREENING DEFICIENCY NOTICE	1	1			-
	SPONSOR SUB CHANGE ACCEPT					-
	DIN INCORR SUBTYPE-CLASS					-
CANCELLED BY COMPANY	1	1			-	
DINA - PUBLISHED DATA ONLY	NO OBJECTION LETTER			3	2	
	NOTICE OF DEFICIENCY					
	NON WITHDRAWAL LETTER					
	REJECTION LETTER (SCREENING)		1			
	SCREENING DEFICIENCY NOTICE					1
	CANCELLED BY COMPANY	2		1	1	
	NOTICE OF NON-COMPLIANCE			1	1	
NOT SATISFACTORY NOTICE				1		
DINA - CHEMISTRY & MANUFACTURING	NOTIFICATION FORM/DIN ISSUED	8	17	12	6	13
	NOD WITHDRAWAL LETTER					
	NOTICE OF DEFICIENCY		3	2	1	2
	REJECTION LETTER (SCREENING)	3			3	
	SCREENING DEFICIENCY NOTICE	15	11	12	17	9
	CANCELLED BY COMPANY	5		3	4	3
	NO OBJECTION LETTER	3	8	6	5	3
	NEW DRUG LETTER SCREEN	1				
	NEW DRUG LETTER REVIEW					1
	NOTICE OF NON-COMPLIANCE	6	3	4	8	6
NON WITHDRAWAL LETTER				1	2	
DINA - CLINICAL OR NON-CLINICAL DATA	NOTIFICATION FORM/DIN ISSUED	1				
	NOTICE OF DEFICIENCY					
	NO OBJECTION LETTER	3				
DINA - CLINICAL OR NON CLINICAL DATA AND C&M	CANCELLED BY COMPANY					1
	SCREENING DEFICIENCY NOTICE					2
DINA - COMPARATIVE STUDIES	NOTIFICATION FORM/DIN ISSUED	1	2	1	2	1
	NO OBJECTION LETTER	1				
	NOTICE OF DEFICIENCY	1	1	1		
	NOTICE OF NON-COMPLIANCE					1
	SCREENING DEFICIENCY NOTICE	1			1	3

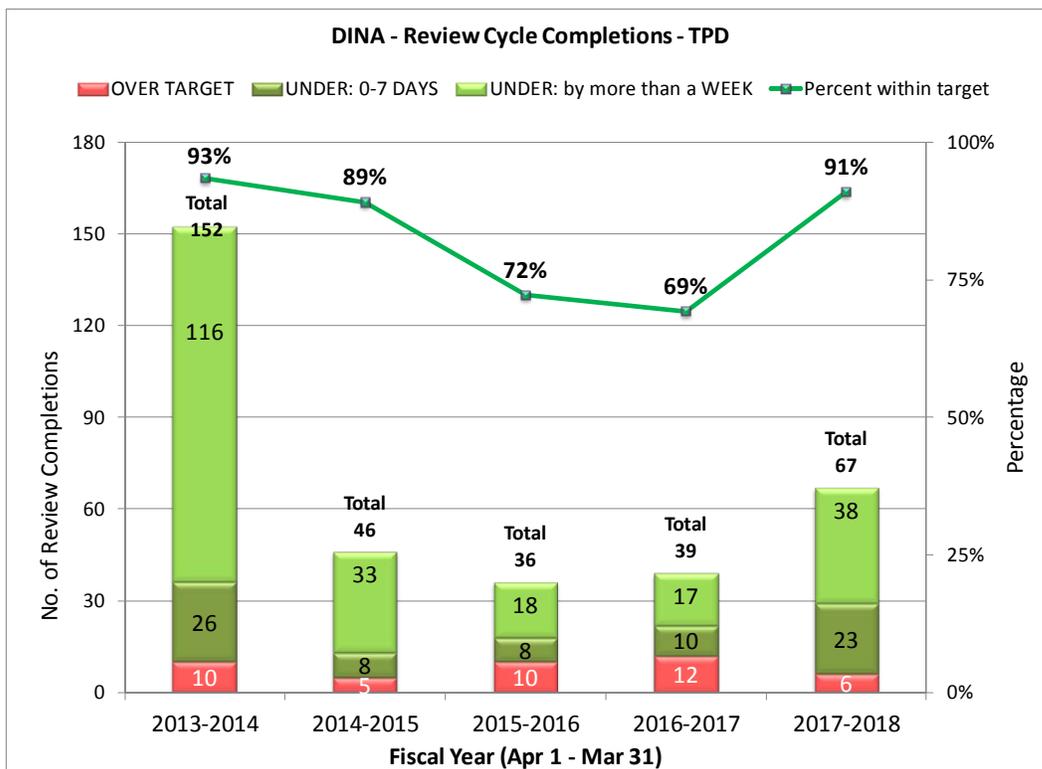
## REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

## DINA: Requests for Reconsideration of Final Decisions

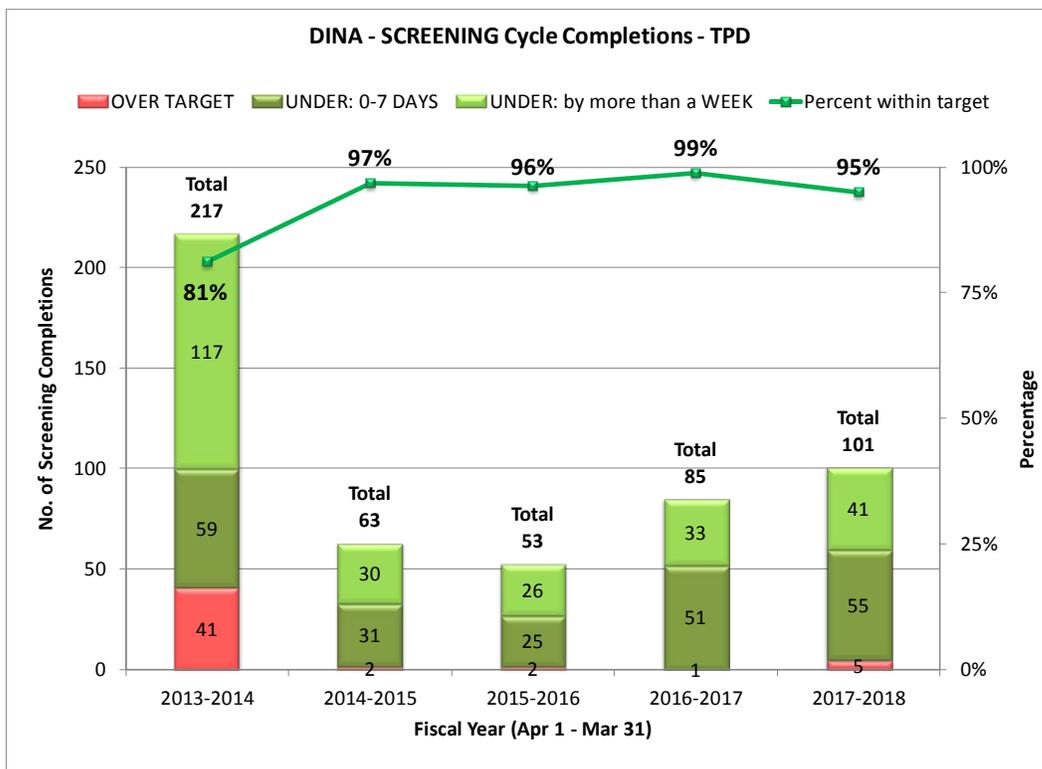
<b>DINA - Reconsideration of Final Decisions by Year Requested</b>							
Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	13-14	14-15	15-16	16-17	17-18	Final Decision in Dispute	Submission Status (as of May 2018)
<b>Total Received</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>		
<b>Total Granted</b>	0	0	0	1	0	NON-Withdrawal	Cleared
<b>Total Cancelled</b>	0	1	0	0	0		
Cancelled by Health Canada		1				New Drug Letter	Withdrawn

**PERFORMANCE**

**DINA: Review Cycle Completions**

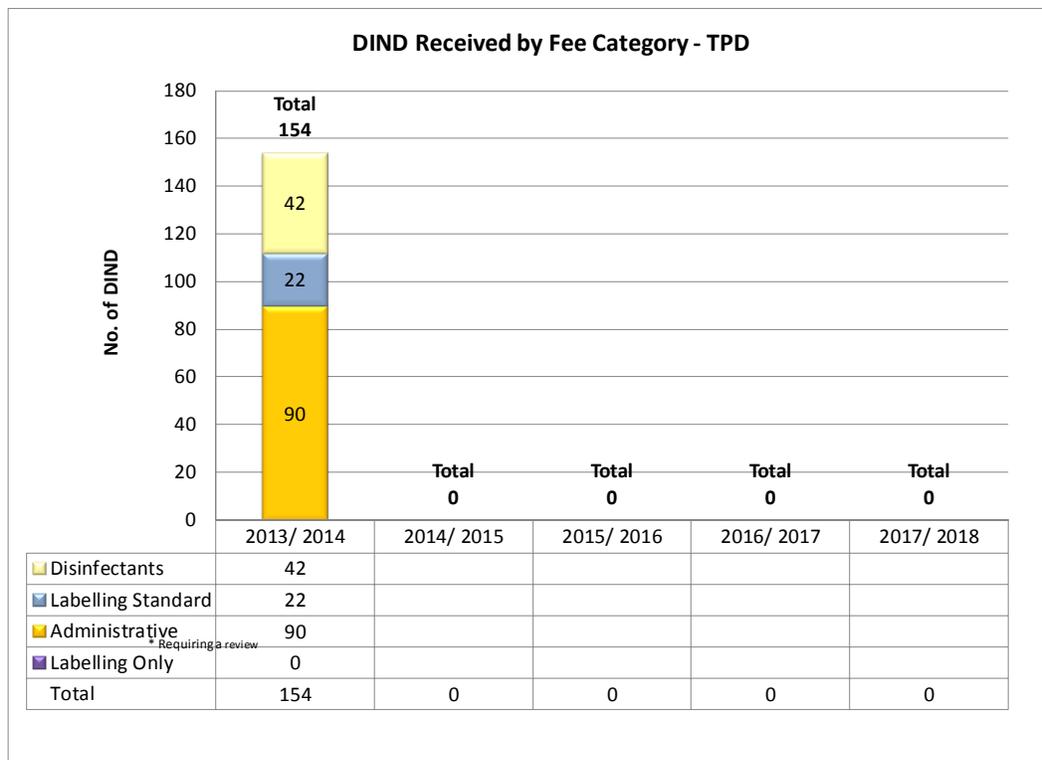


**DINA: Screening Cycle Completions**



## DIND: Application for a Drug Identification Number - DISINFECTANT PRODUCT

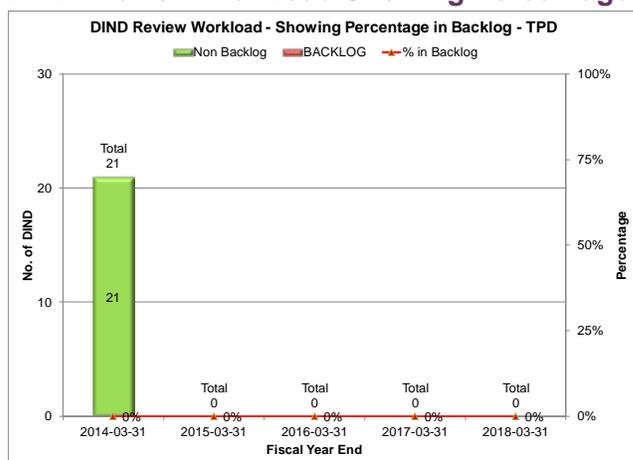
### DIND: Number Received



TPD's non-prescription (or over-the-counter) and disinfectant drug review functions were moved to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013 and are now reported in the NNHPD Drug Submission Performance Annual Report

## REVIEW WORKLOAD

### DIND: Review Workload Showing Percentage in Backlog

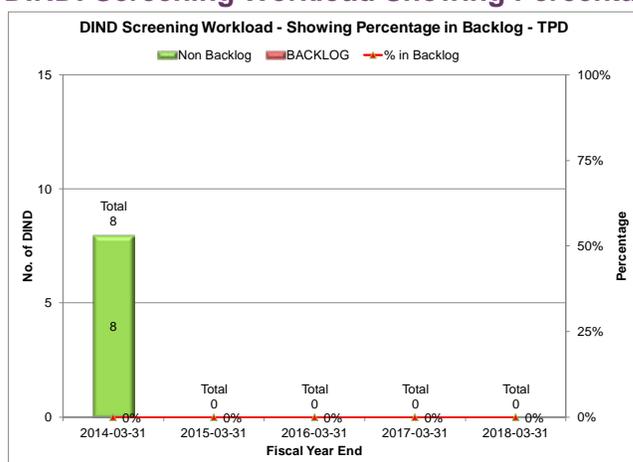


### DIND: Review Workload by User Fee Category

	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
<b>Disinfectant</b>	21	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	21	0	0	0	0
Non Backlog	21	0	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

## SCREENING WORKLOAD

### DIND: Screening Workload Showing Percentage in Backlog



### DIND: Screening Workload by Class

CLASS	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
<b>Labelling Only</b>	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Disinfectant</b>	7	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Labelling Standard</b>	1	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	8	0	0	0	0
Non Backlog	8	0	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

## DECISION DOCUMENTS

## DIND: Decision Documents by Class

DIND - ADMINISTRATIVE					
DOCUMENT TYPE	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
NOTIFICATION FORM/DIN ISSUED	75	-	-	-	-
NO OBJECTION LETTER	1	-	-	-	-
CANCELLED BY COMPANY		-	-	-	-
REJECTION LETTER (SCREENING)		-	-	-	-
SCREENING DEFICIENCY NOTICE	18	-	-	-	-

DIND - LABELLING STANDARD					
DOCUMENT TYPE	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
NOTIFICATION FORM/DIN ISSUED	25	-	-	-	-
REJECTION LETTER (SCREENING)		-	-	-	-
SCREENING DEFICIENCY NOTICE	17	-	-	-	-
CANCELLED BY COMPANY		-	-	-	-
REJECTION LETTER (SCREENING)		-	-	-	-
NEW DRUG LETTER SCREEN	1	-	-	-	-

DIND - DIS NONCLIN/CLINICAL					
DOCUMENT TYPE	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
NOTIFICATION FORM/DIN ISSUED	24	-	-	-	-
DIN INCORR SUBTYPE-CLASS		-	-	-	-
NO OBJECTION LETTER	7	-	-	-	-
NOTICE OF NON-COMPLIANCE	4	-	-	-	-
REJECTION LETTER (SCREENING)		-	-	-	-
SCREENING DEFICIENCY NOTICE		-	-	-	-
SPONSOR SUB CHANGE ACCEPT		-	-	-	-
CANCELLED BY COMPANY	1	-	-	-	-
NON WITHDRAWAL LETTER	1	-	-	-	-

DIND - DISINFECT LABEL ONLY					
DOCUMENT TYPE	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
SCREENING DEFICIENCY NOTICE	2	-	-	-	-
CANCELLED BY COMPANY		-	-	-	-

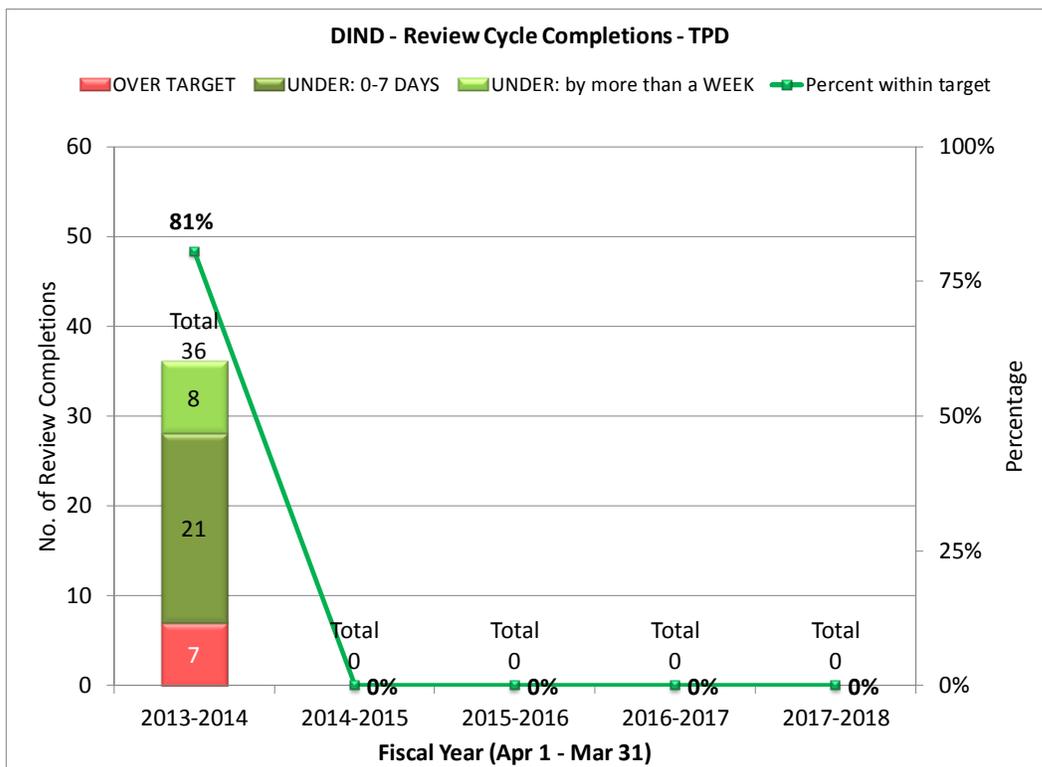
## REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

## DIND: Requests for Reconsideration of Final Decisions

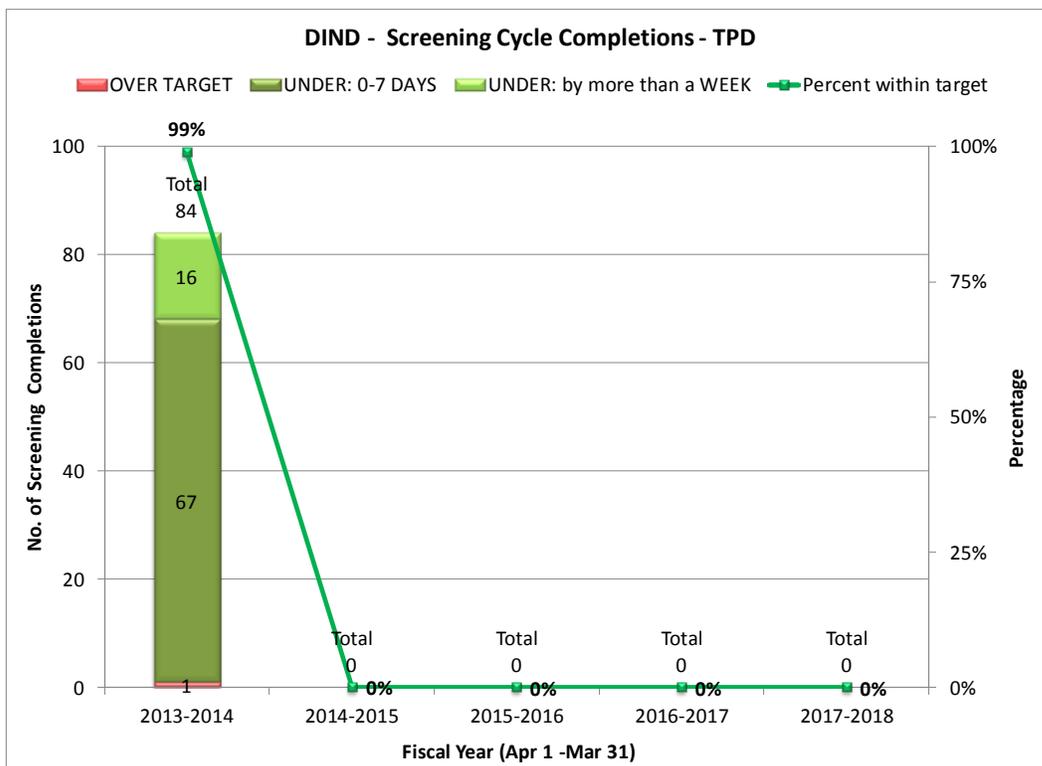
DIND - Reconsideration of Final Decisions by Year Requested							
Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	13-14	14-15	15-16	16-17	17-18	Final Decision in Dispute	Submission Status (as of May 2018)
Total Received	0	0	0	0	0		

**PERFORMANCE**

**DIND: Review Cycle Completions**

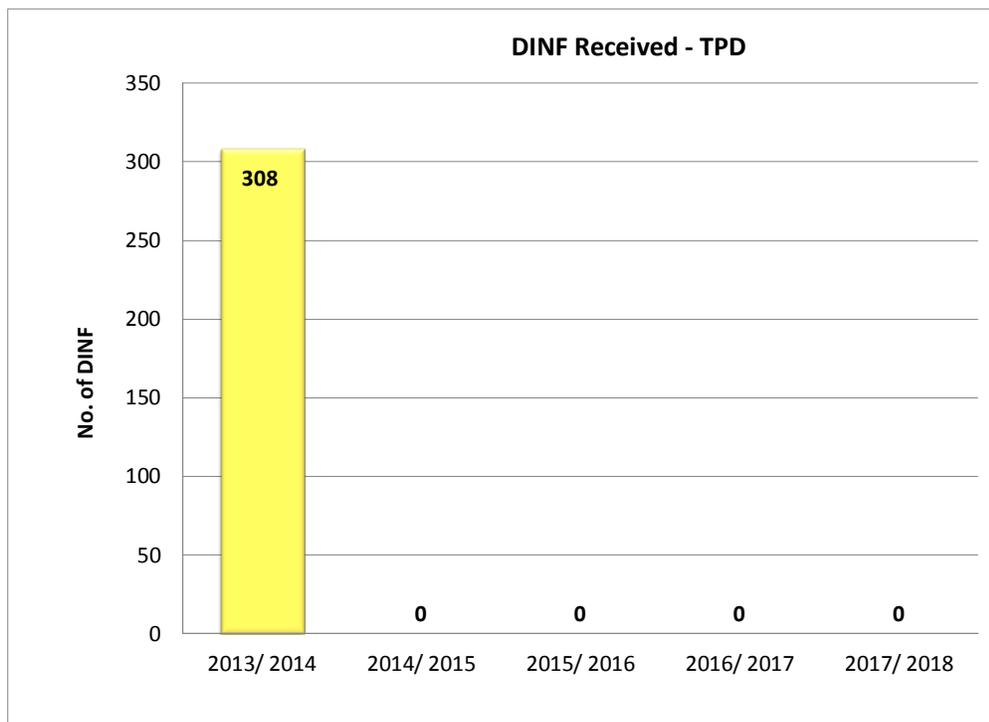


**DIND: Screening Cycle Completions**

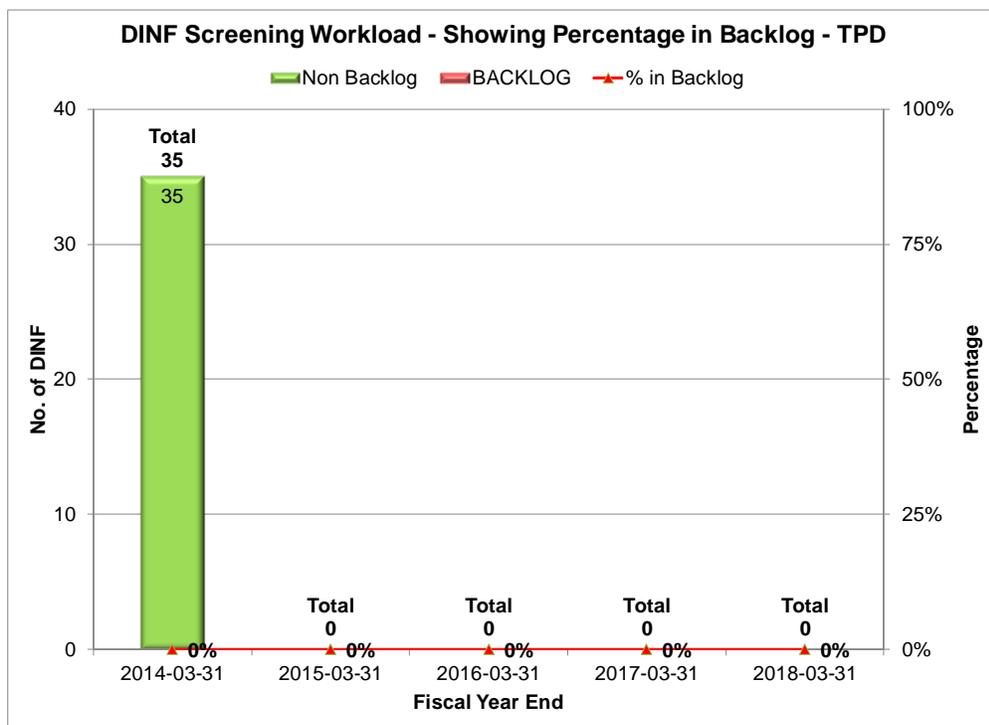


## DINF: CATEGORY IV PRODUCT - (LABELLING STANDARD)

### DINF: Number Received



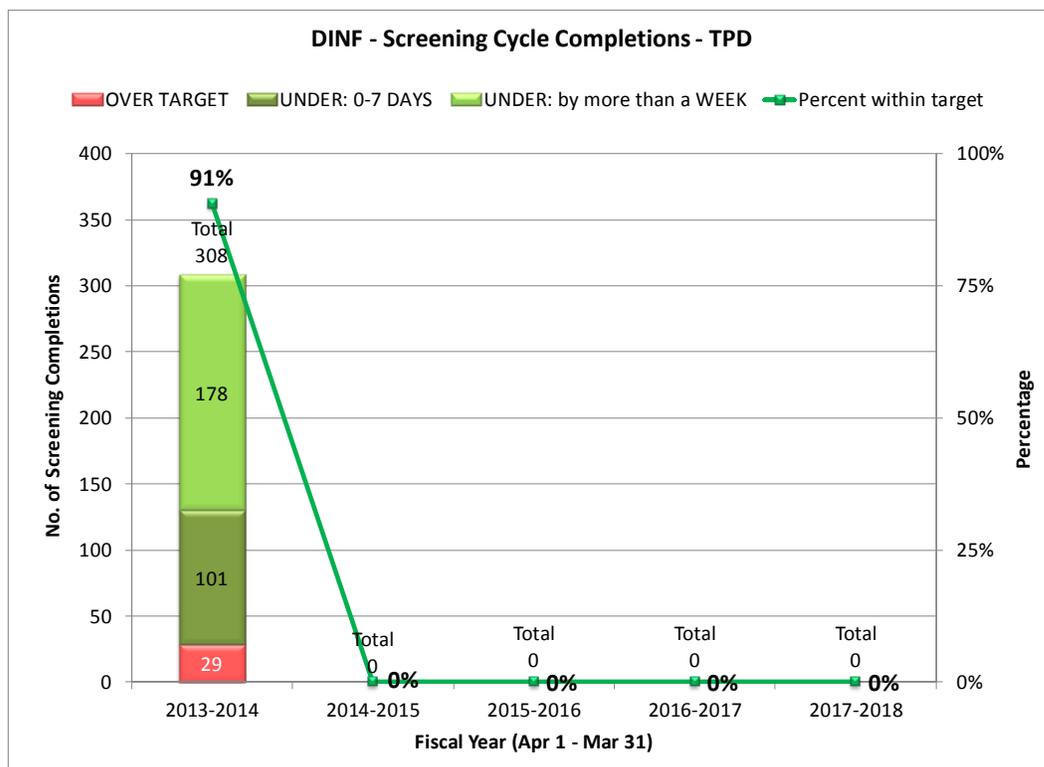
### DINF: Screening Workload Showing Percentage in Backlog



TPD's non-prescription (or over-the-counter) and disinfectant drug review functions were moved to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013 and are now reported in the NNHPD Drug Submission Performance Annual Report

**PERFORMANCE**

**DINF: Screening Cycle Completions**



**DECISION DOCUMENTS**

**DINF: Decision Documents**

DINF - LABELLING STANDARD	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
DOCUMENT TYPE					
NOTIFICATION FORM/DIN ISSUED	286	-	-	-	-
NO OBJECTION LETTER	1	-	-	-	-
CANCELLED BY COMPANY	11	-	-	-	-
DIN INCORR SUBTYPE-CLASS	1	-	-	-	-
NEW DRUG LETTER SCREEN		-	-	-	-
NOT SATISFACTORY NOTICE		-	-	-	-
REJECTION LETTER (SCREENING)	8	-	-	-	-
SCREENING DEFICIENCY NOTICE	12	-	-	-	-
SPONSOR SUB CHANGE ACCEPT	1	-	-	-	-

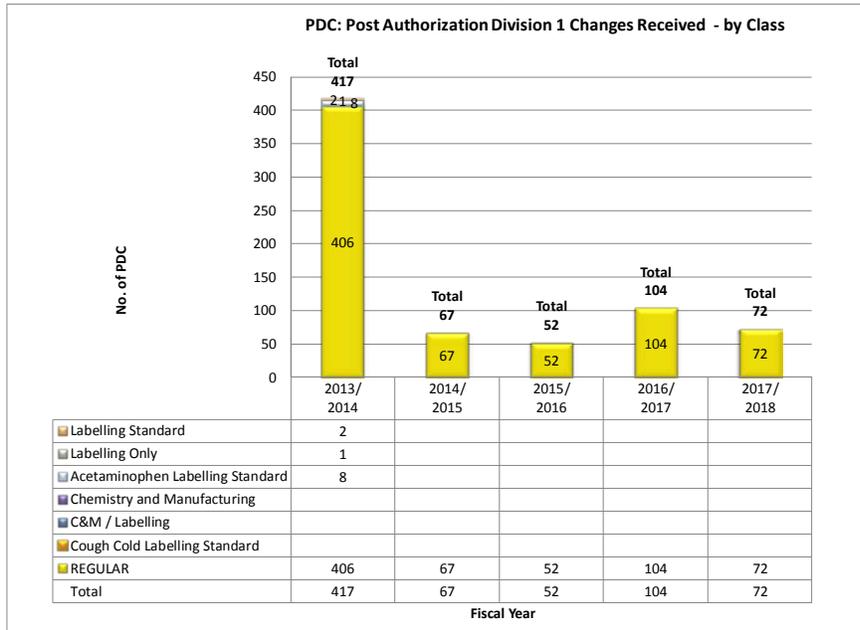
**REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS**

**Requests for Reconsideration of Final Decisions – DINF**

DINF - Reconsideration of Final Decisions by Year Requested							
Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	13-14	14-15	15-16	16-17	17-18	Final Decision in Dispute	Submission Status (as of May 2018)
<b>Total Received</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>		

## PDC: POST-AUTHORIZATION DIVISION 1 CHANGES

### Post-Authorization Division 1 Changes (PDC) Received



### Post-Authorization Division 1 Changes (PDC) - Decision Documents by Class

<b>PDC</b>					
DOCUMENT TYPE	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
<b>COUGH COLD LABELLING STANDARD</b>					
NO OBJECTION LETTER					
NOT SATISFACTORY NOTICE					
<b>ACETAMINOPHEN LS</b>					
CANCELLED BY COMPANY					
NO OBJECTION LETTER	10				
NOT SATISFACTORY NOTICE					
<b>REGULAR</b>					
CANCELLED BY COMPANY	16	7	11	18	15
NO OBJECTION LETTER	362	67	43	80	35
NOT SATISFACTORY NOTICE	15			1	
NOTIFICATION FORM/DIN ISSUED					
REJECTION LETTER (SCREENING)					
<b>C&amp;M ONLY</b>					
NO OBJECTION LETTER					
CANCELLED BY COMPANY					
<b>C&amp;M LABELLING</b>					
NO OBJECTION LETTER					
CANCELLED BY COMPANY					
NOT SATISFACTORY NOTICE					
<b>LABELLING ONLY</b>					
NO OBJECTION LETTER	1				
<b>LABELLING STANDARD</b>					
NO OBJECTION LETTER	2				

## REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

### Requests for Reconsideration of Final Decisions – Post-Authorization Division 1 Changes (PDC)

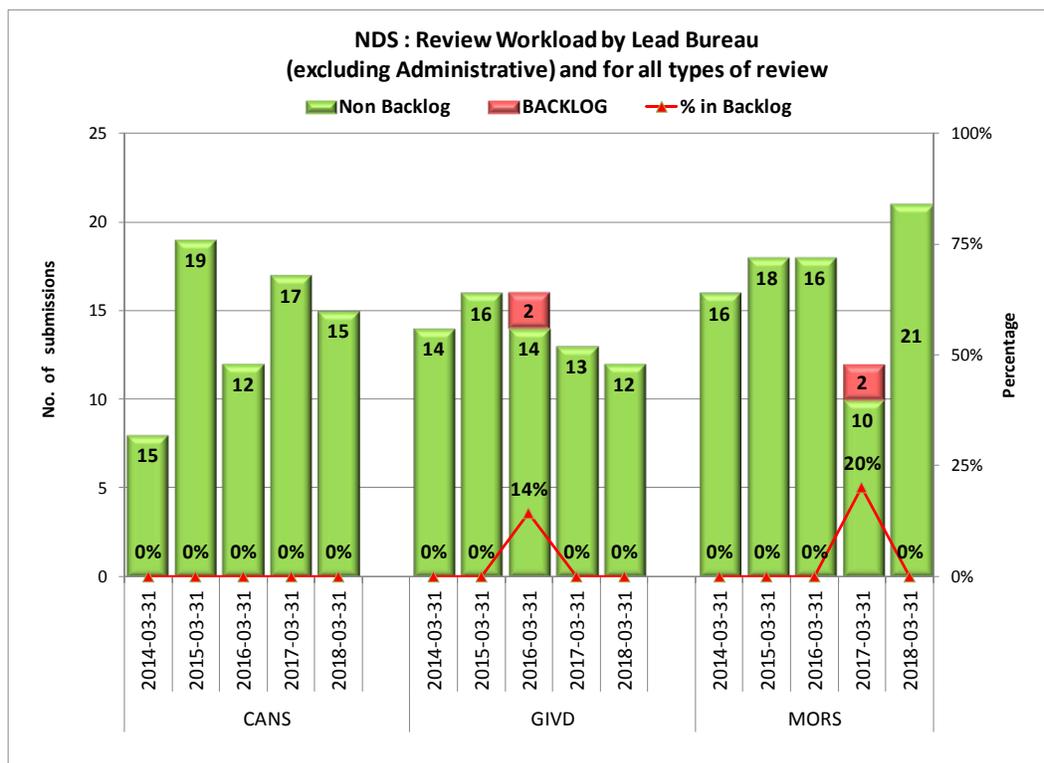
<b>PDC - Reconsideration of Final Decisions by Year Requested</b>							
Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	13-14	14-15	15-16	16-17	17-18	Final Decision in Dispute	Submission Status (as of May 2018)
<b>Total Received</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>		
<b>Total Cancelled by Company</b>	<b>2</b>					Not Satisfactory Notice	Rejected

# **APPENDIX A - Lead Bureau Summaries**

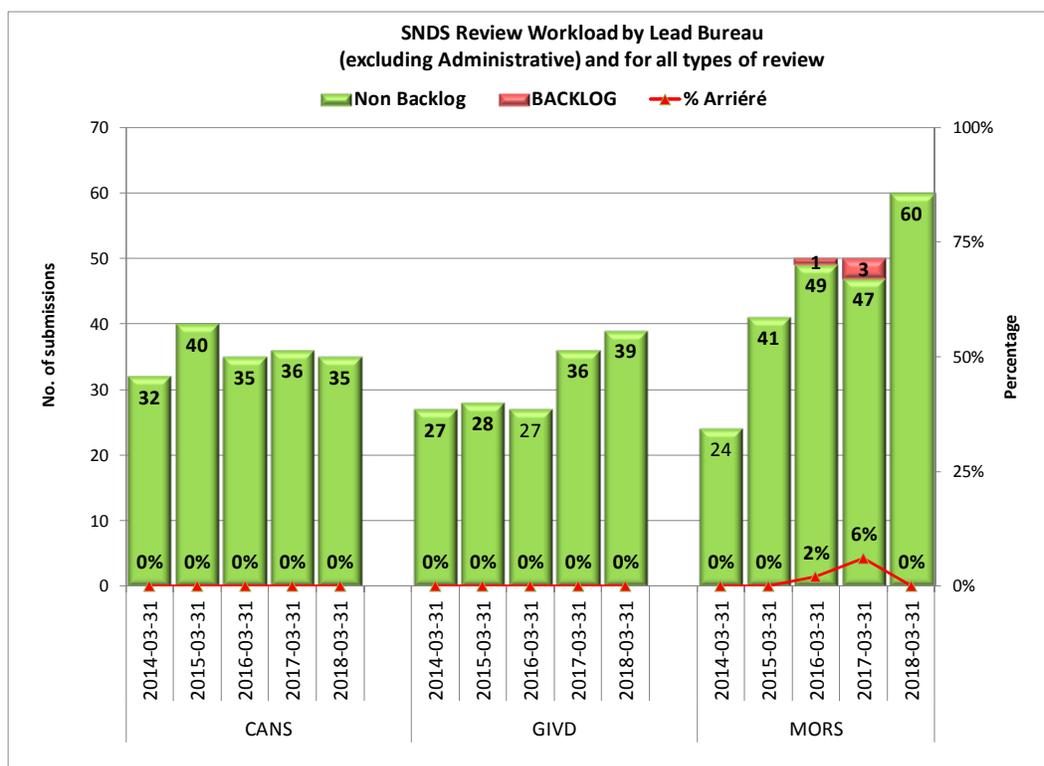
## **NDS & SNDS**

### WORKLOAD by Lead Bureau

#### NDS Review Workload by Lead Bureau

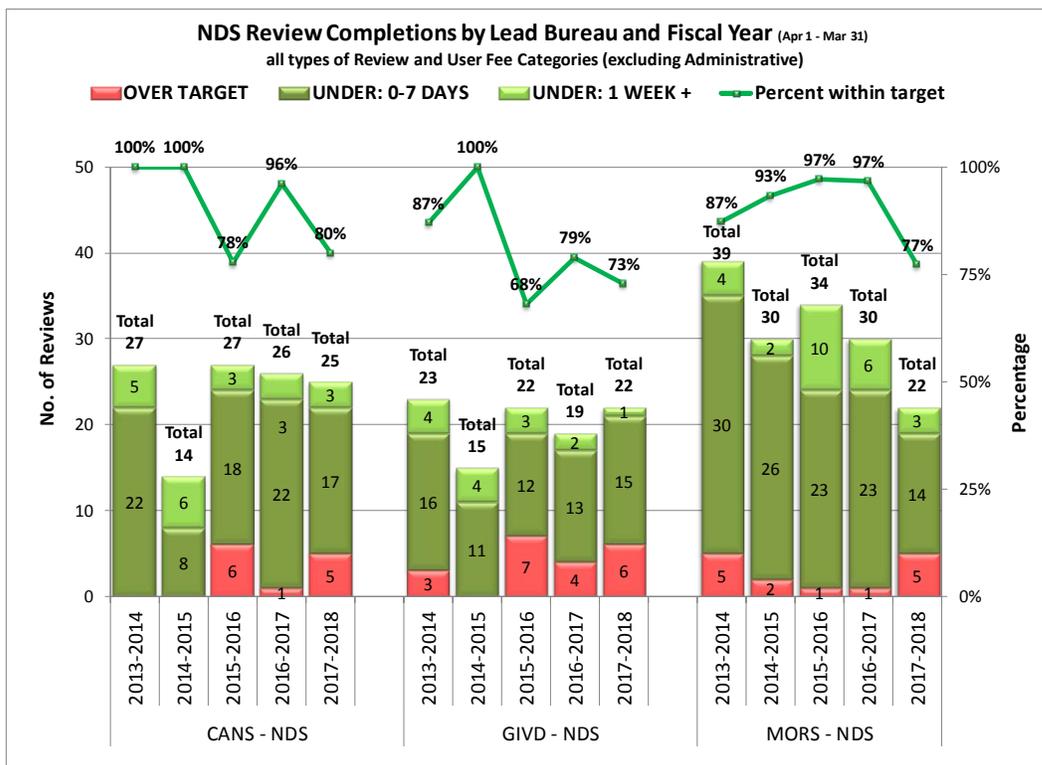


#### SNDS Review Workload by Lead Bureau

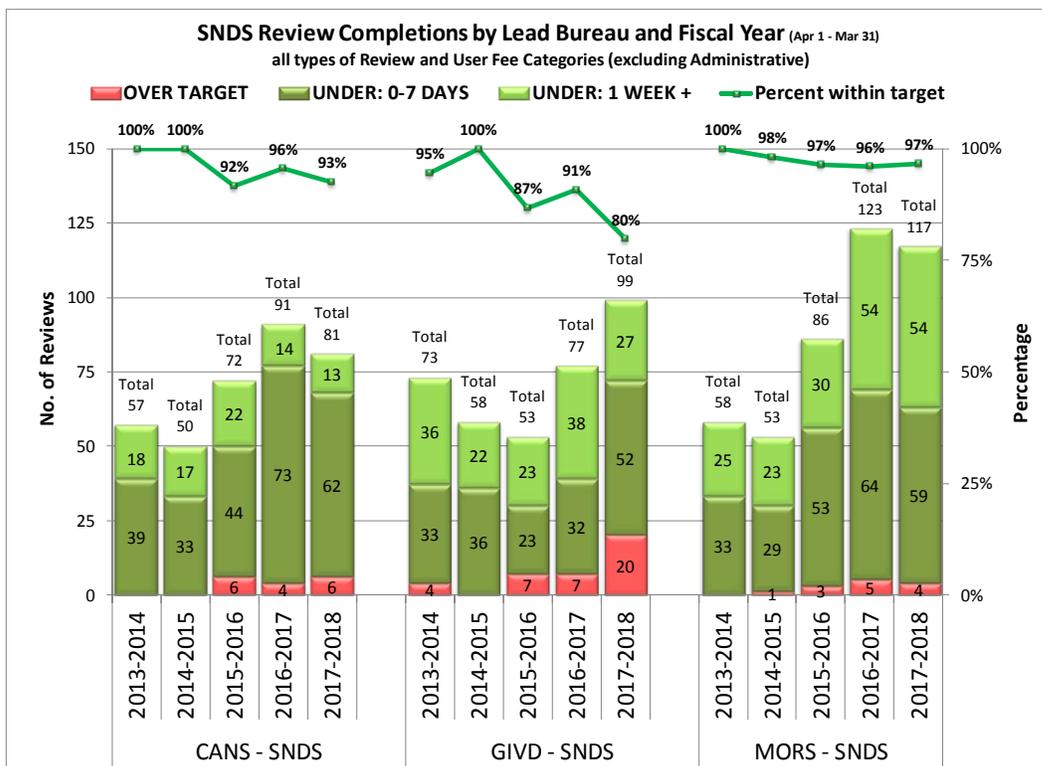


**PERFORMANCE by Lead Bureau**

**NDS Review Performance by Lead Bureau**

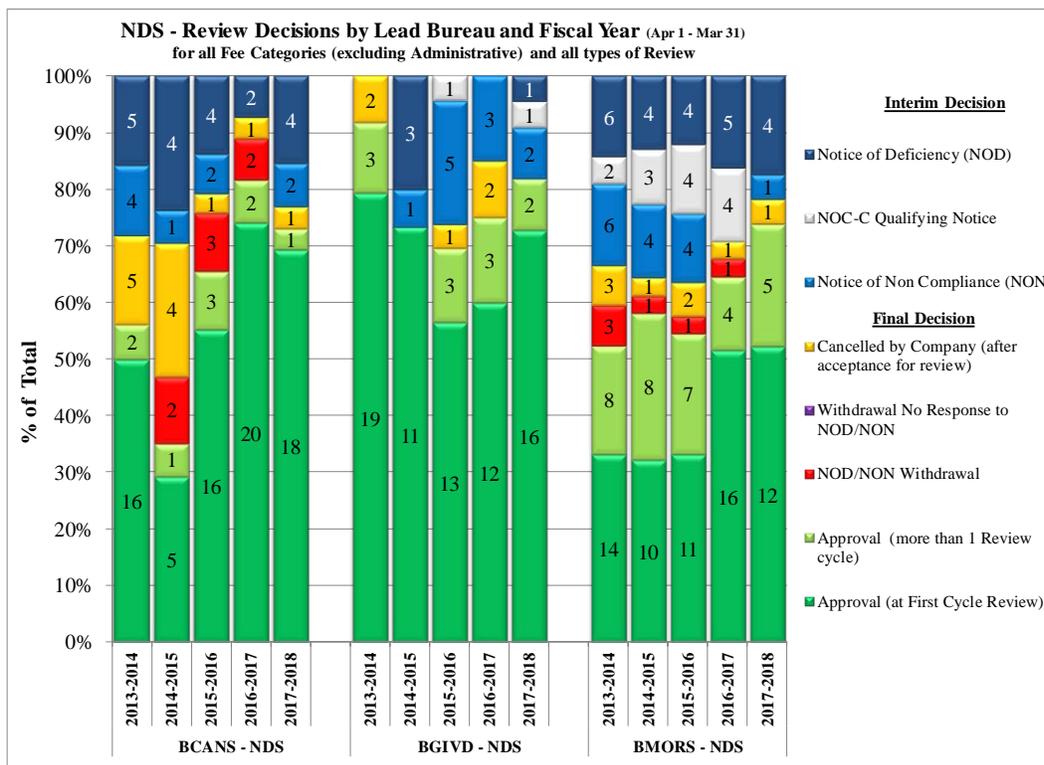


**SNDS Review Performance by Lead Bureau**

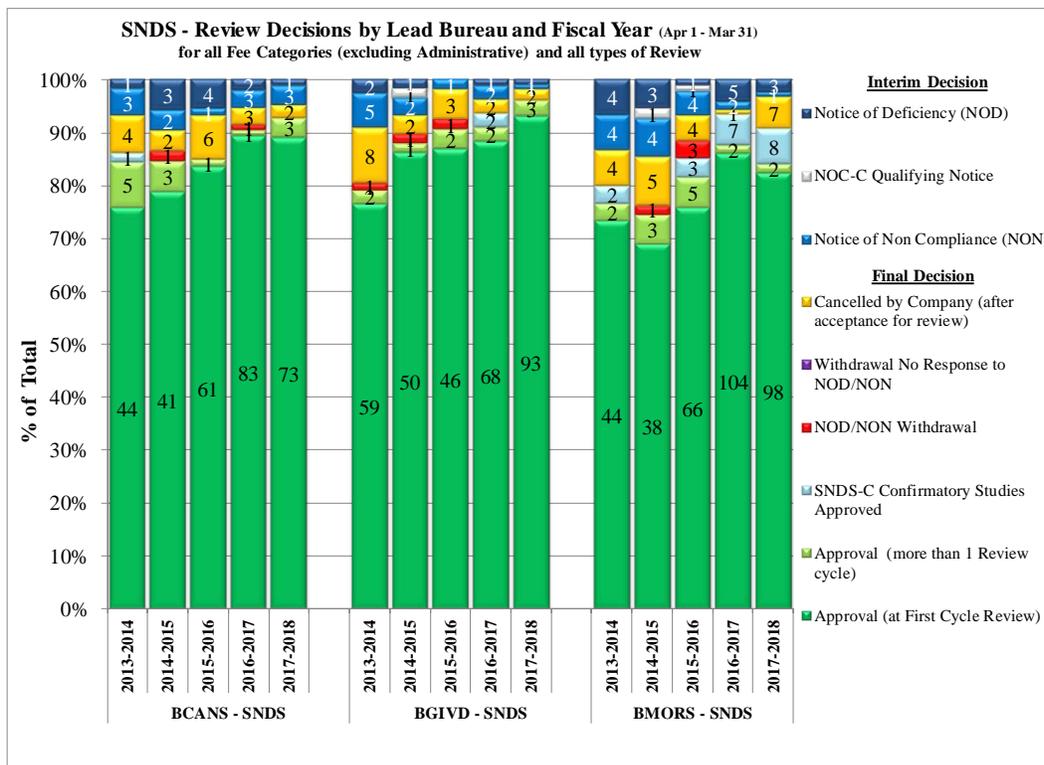


REVIEW DECISIONS by Lead Bureau

NDS Review Decisions by Lead Bureau

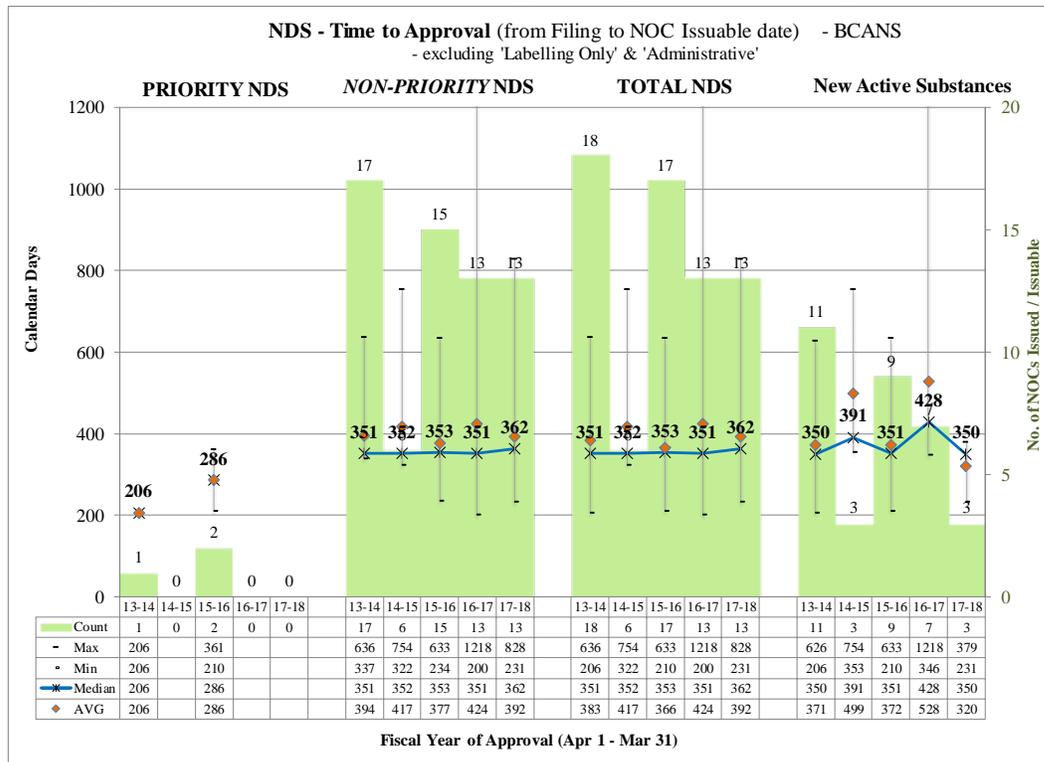


SNDS Review Decisions by Lead Bureau

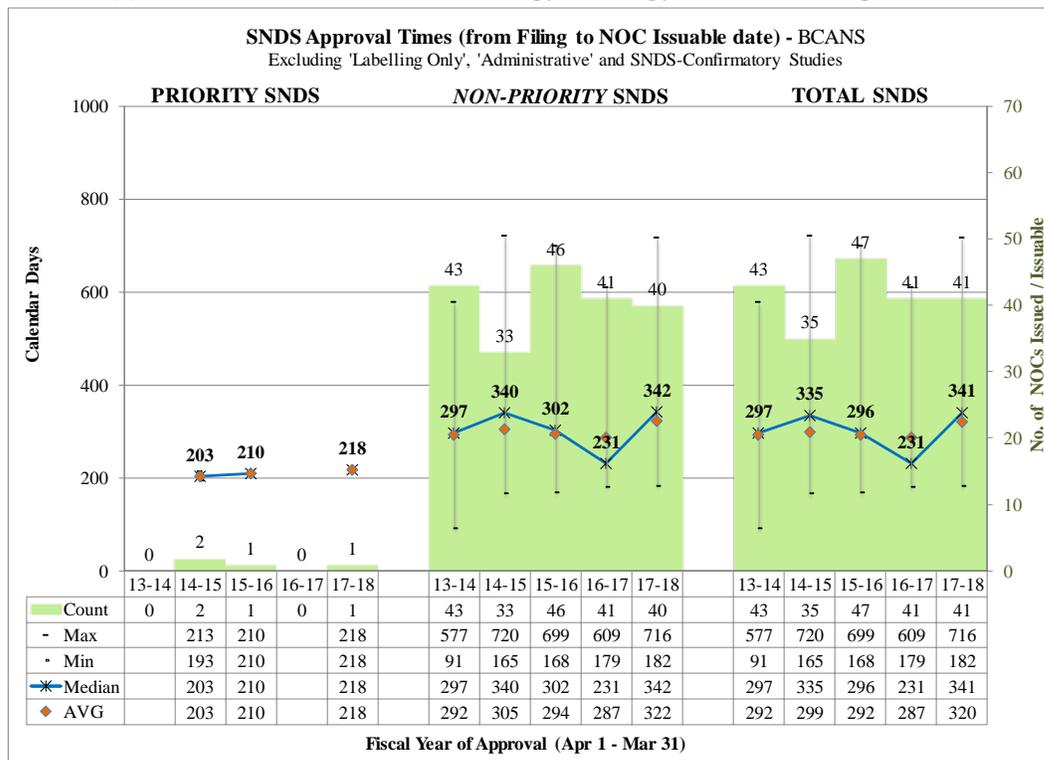


**APPROVALS by Lead Bureau**

**NDS Approvals – Bureau of Cardiology, Allergy and Neurological Sciences (BCANS)**

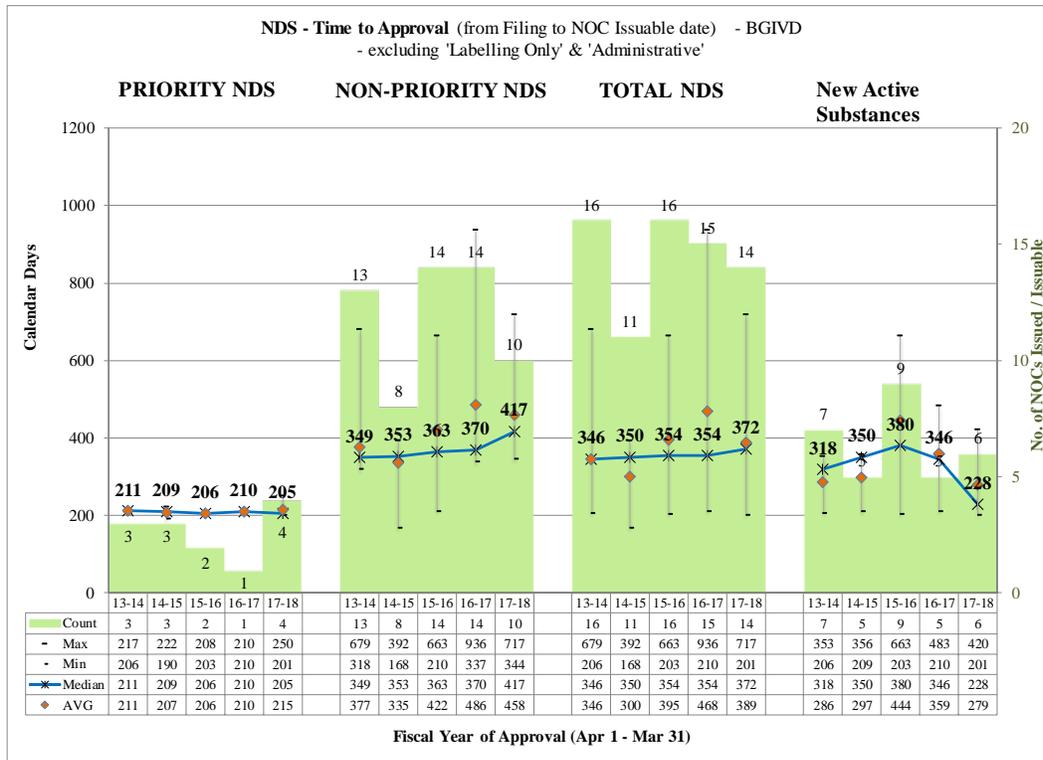


**SNDS Approvals – Bureau of Cardiology, Allergy and Neurological Sciences (BCANS)**

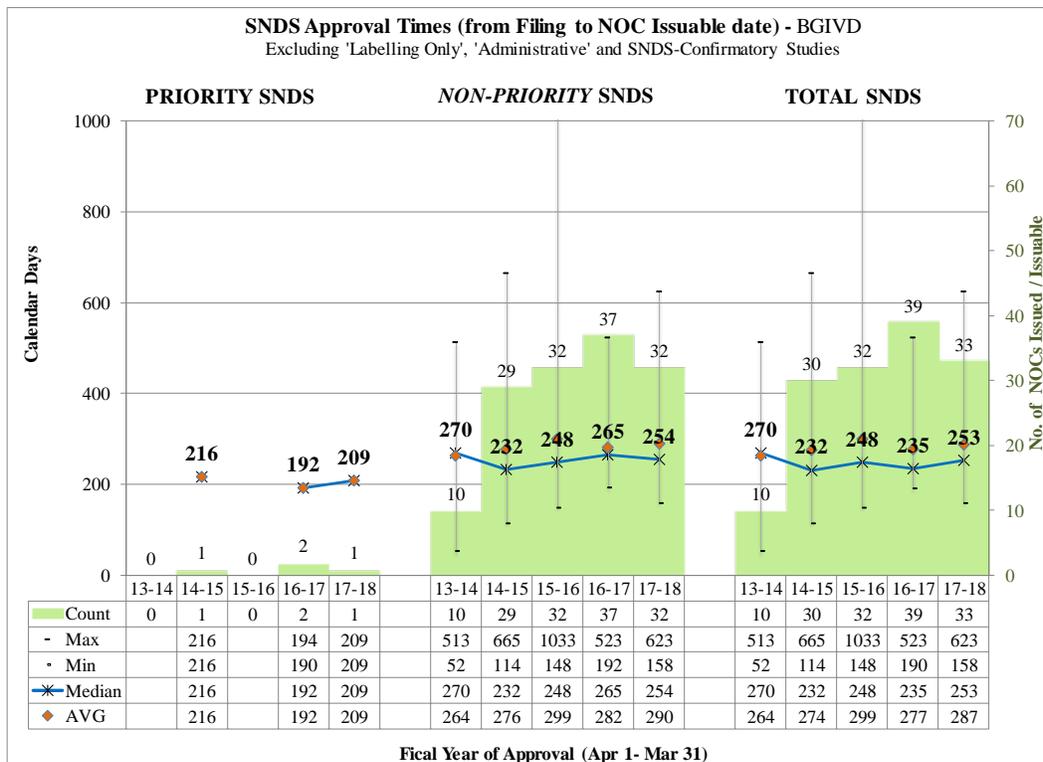


Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

NDS Approvals – Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD)

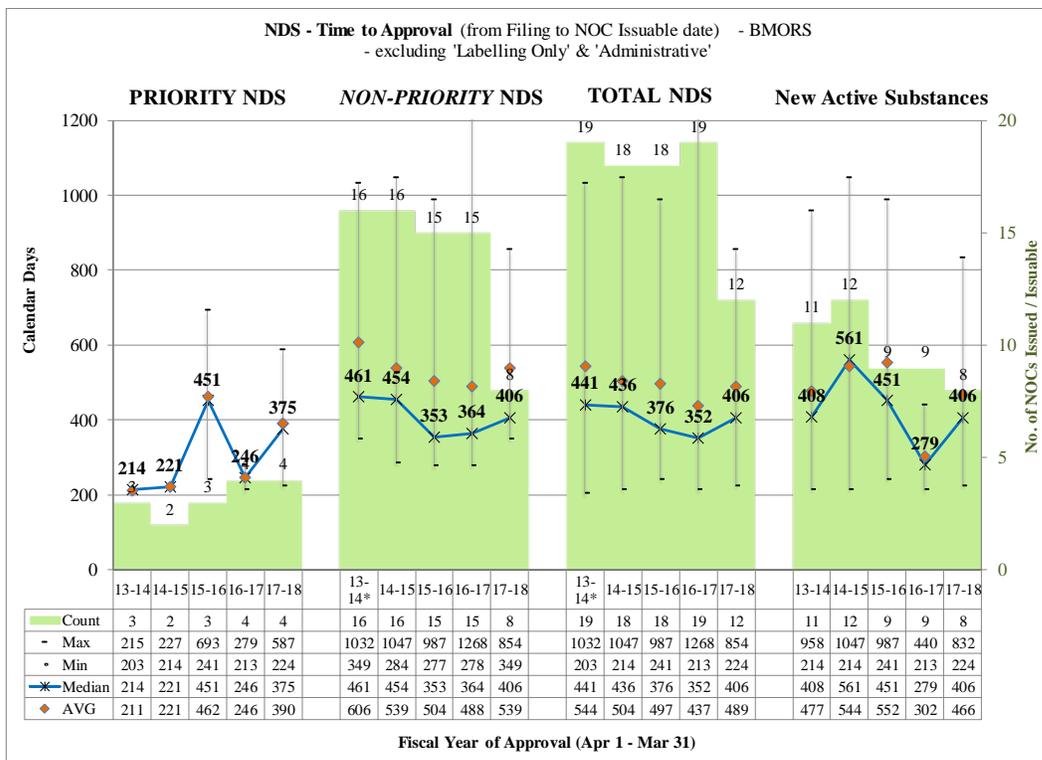


SNDS Approvals – Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD)



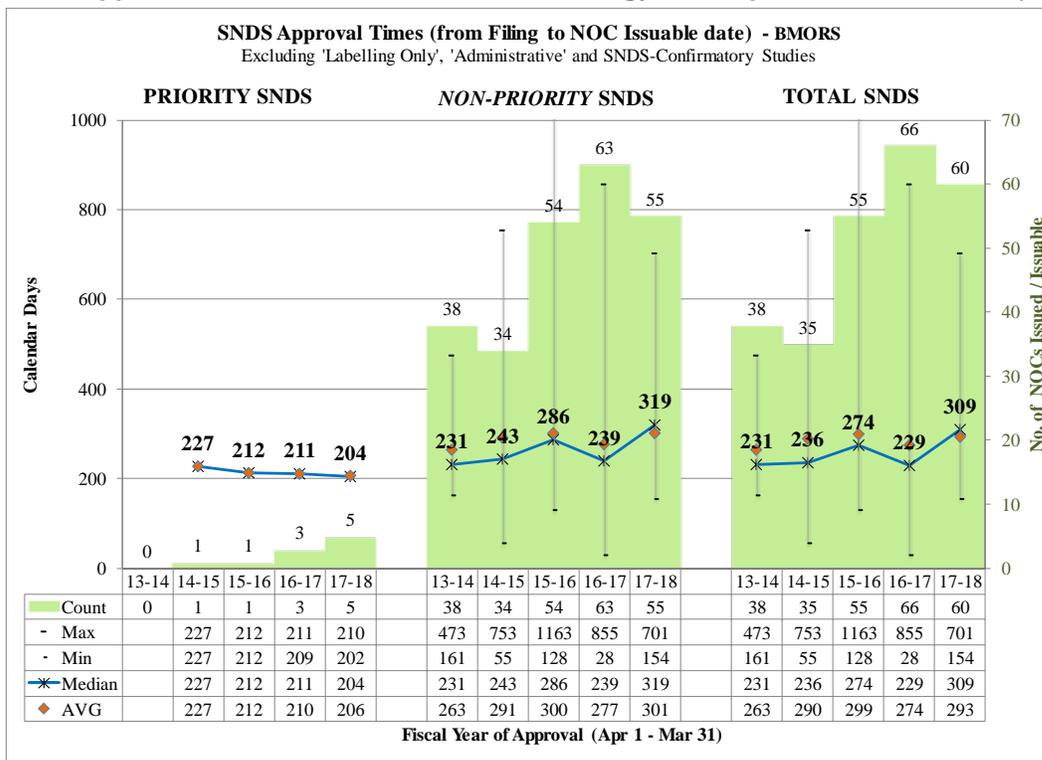
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

NDS Approvals – Bureau of Metabolism, Oncology & Reproductive Sciences (BMORS)



\*One outlier for fiscal year 2013-14 is included. The NDS was in rejected status for over 4 years but following a judicial review decision, screening was resumed. For this “outlier NDS”, the dates used to calculate the time to approval are the date the screening resumed and the date the submission was placed on intellectual property hold.

SNDS Approvals – Bureau of Metabolism, Oncology and Reproductive Sciences (BMORS)

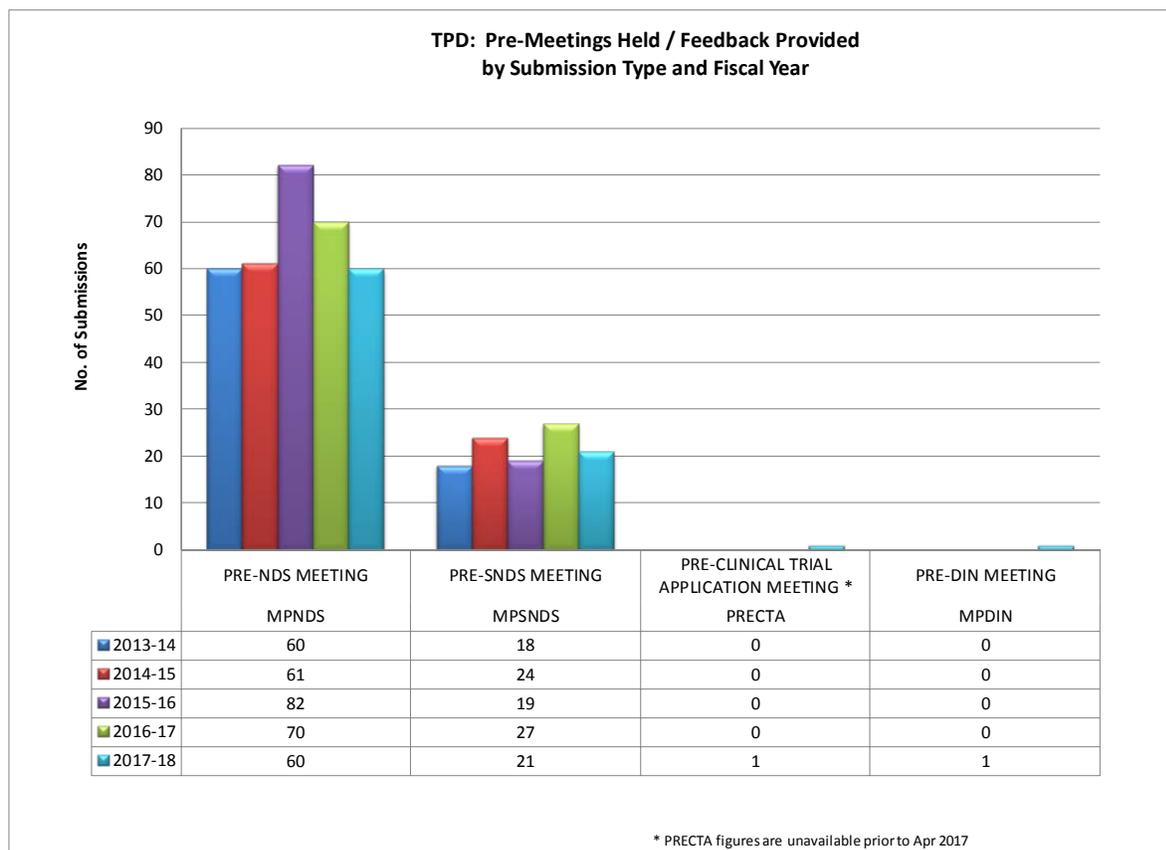


Approval Time is the total number of calendar days between a submission’s filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor

## Appendix B: Pre-submission Meetings

12

### Pre-submission Meetings Held / Feedback Provided



<sup>12</sup> Prior to filing a submission, a sponsor may request a pre-submission meeting to discuss the presentation of data in support of the submission: For further information, refer to the [Guidance for Industry: Management of Drug Submissions](#)

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