Health Products and Food Branch

Drug Submission Performance Annual Reports

Fiscal Year

2016-2017

April 1 2016- March 31 2017

Therapeutic Products Directorate and
Biologics and Genetic Therapies Directorate
Natural and Non-Prescription Health Products Directorate

Canada

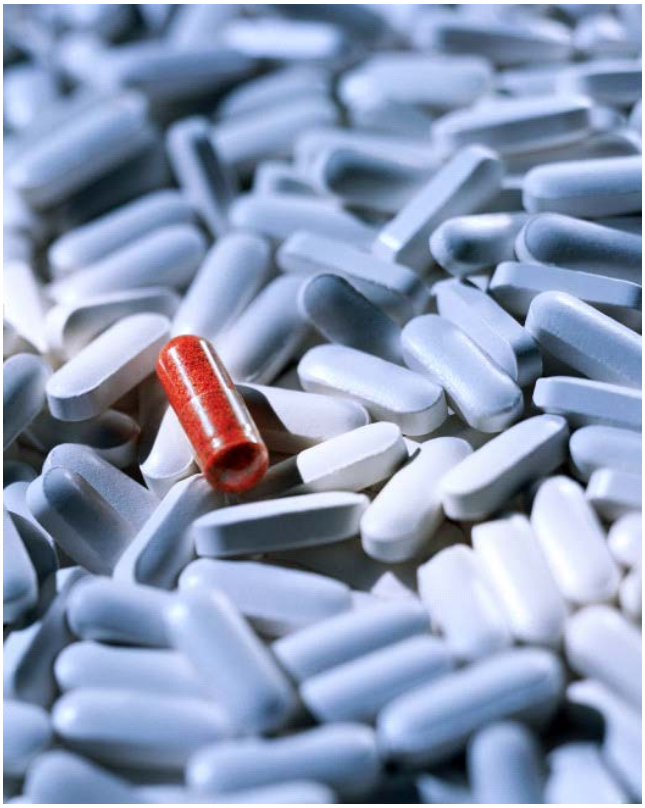
Therapeutic Products Directorate

Drug Submission Performance Annual Report

Fiscal Year

2016 – 2017

April 1 2016 – March 31 2017



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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 2012-2013 to 2016-2017.

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 2016-2017 fiscal year (from April 1 2016 to March 31 2017).

General Information

There are several steps involved in the drug submission review[1] and approval process:

- administrative processing,
- regulatory and scientific screening and
- in-depth scientific review.

When deficiencies or non-compliance issues are found, a company may submit responses before a final decision can be reached and thus multiple review cycles may be required. A submission's approval time can vary depending on the number and type of review cycles needed.

Submissions Received are counts of submissions received during the year using the filing date, 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.

Approvals are Notice of Compliances (NOC) Issued or Issuable. An NOC issuable is when a submission's NOC is placed "on hold" awaiting authorization to market, due to Patented Medicines (NOC) Regulations or due to changes from Prescription to Non-Prescription.

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

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

A **review cycle completion**[2] is counted upon the conclusion of an in-depth scientific review that then results in a decision of approval or non-approval. The time taken is compared to a set performance standard[2] 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” 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. # 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] 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.

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)* *This new NAS definition came into effect on April 1 2011*	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 *Food and Drug Regulations* (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[3]	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

[3] 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 being reported separately in the NNHPD Drug Submission Performance Annual Report.

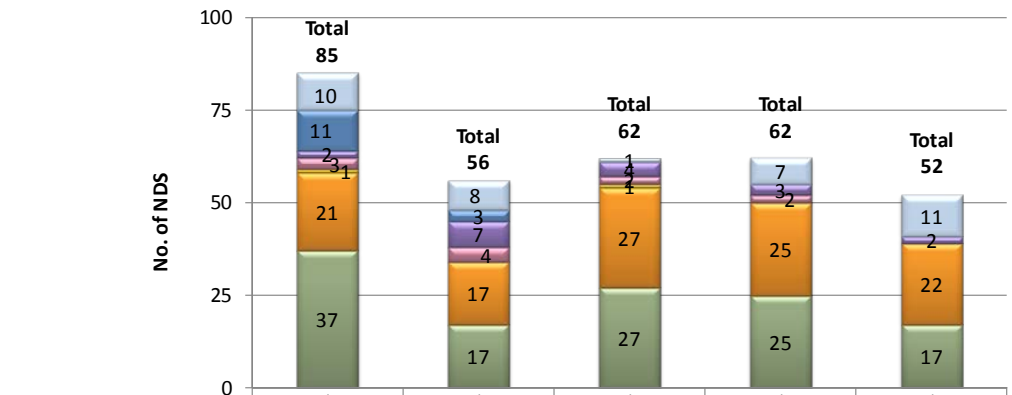
New Drug Submission (NDS)

&

Supplemental New Drug Submission (SNDS)

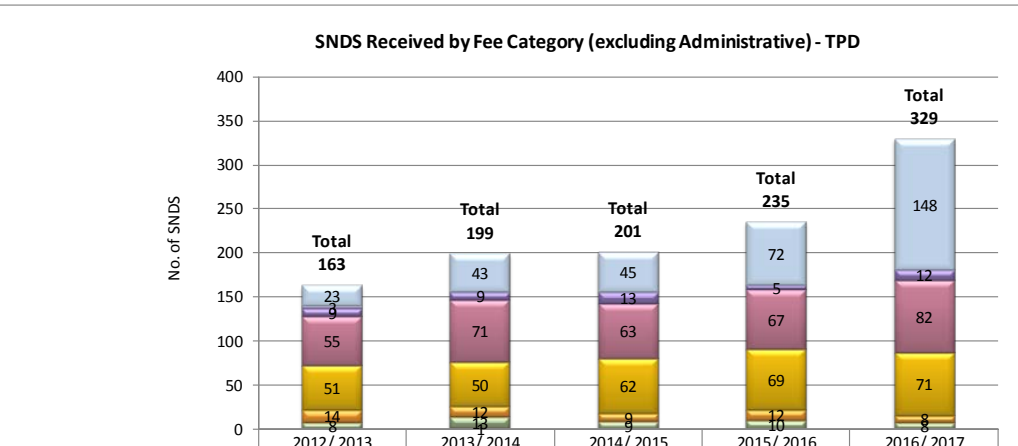
SUBMISSIONS RECEIVED[4]

New Drug Submissions (NDS) Received by Fee Category



	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Labelling Only	10	8	1	7	11
Disinfectants	11	3			
Comparative Studies	2	7	4	3	2
Chemistry & Manufacturing	3	4	2	2	
Clinical or Non-Clin Only	1		1		
Clinical or Non-Clin and C&M	21	17	27	25	22
New Active Substance	37	17	27	25	17
Total	85	56	62	62	52
Priority (subset)	7	6	8	8	5

Supplemental New Drug Submissions (SNDS) Received by Fee Category

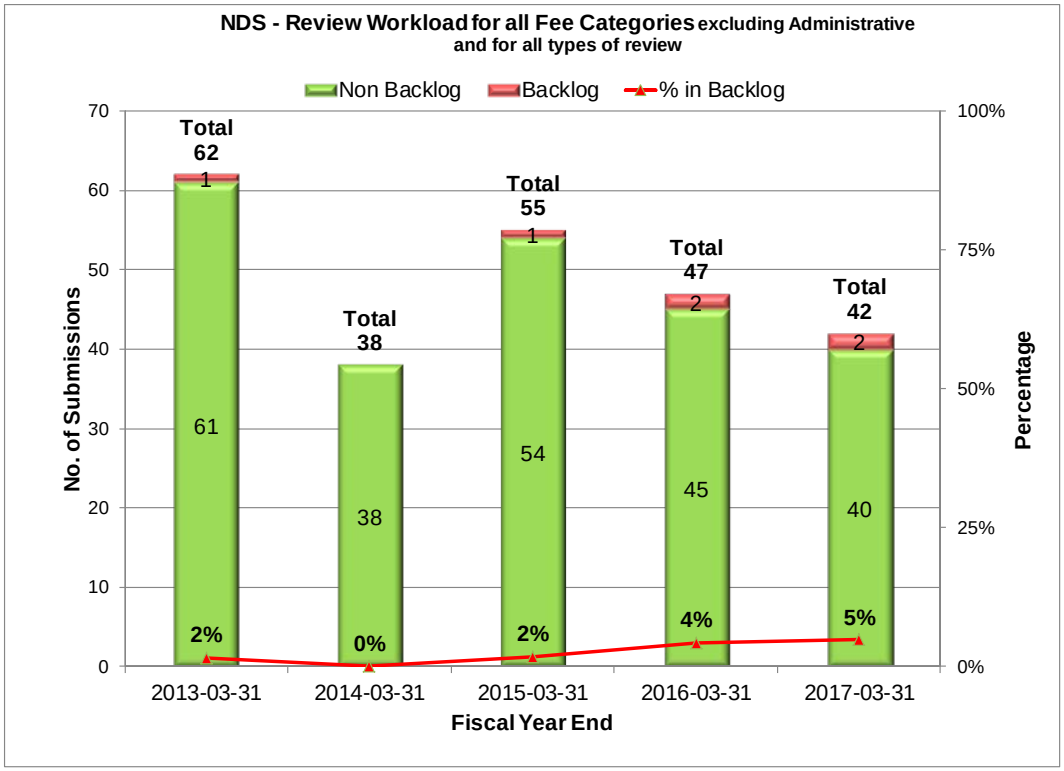


	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Labelling Only	23	43	45	72	148
Disinfectants	3				
Comparative Studies	9	9	13	5	12
Chemistry & Manufacturing	55	71	63	67	82
Clinical or Non-Clin Only	51	50	62	69	71
Clinical or Non-Clin and C&M	14	12	9	12	8
Published Data Only	8	13	9	10	8
Switch from Rx to OTC		1			
Total	163	199	201	235	329
Priority (subset)	0	2	4	5	5
*SNDS Confirmatory	2	1	3	6	9

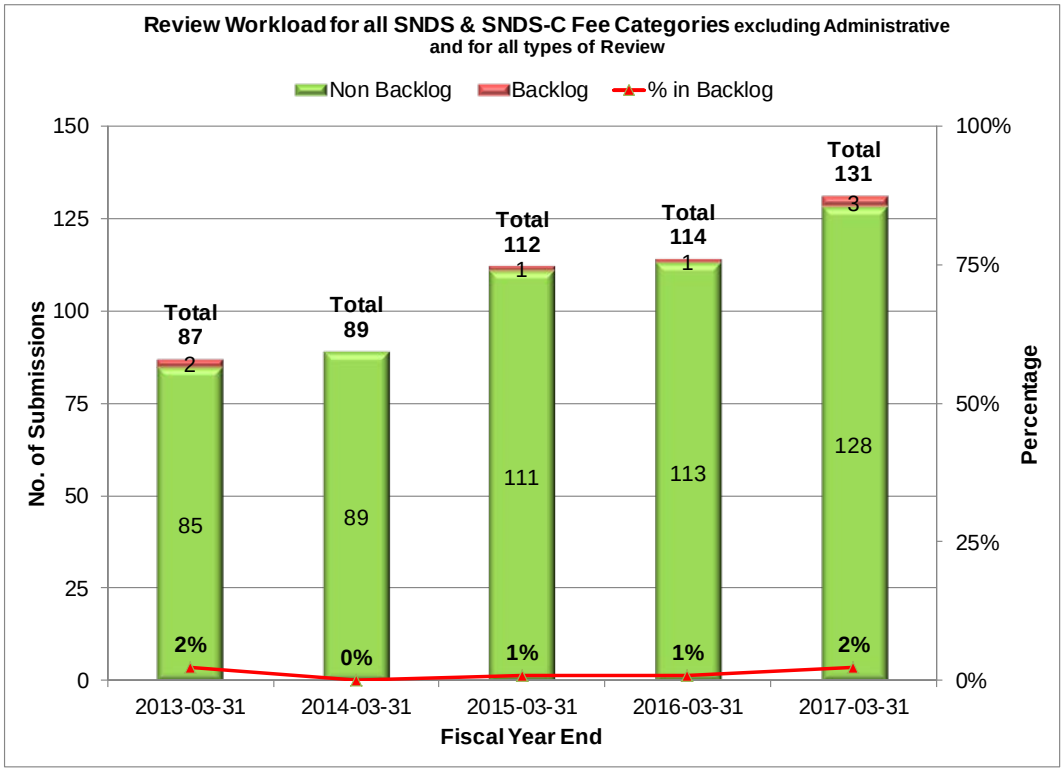
[4] TPD's non-prescription (or over-the-counter) and disinfectant drug review functions were moved to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013 and are now being reported separately in the NNHPD Drug Submission Performance Annual Report.

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

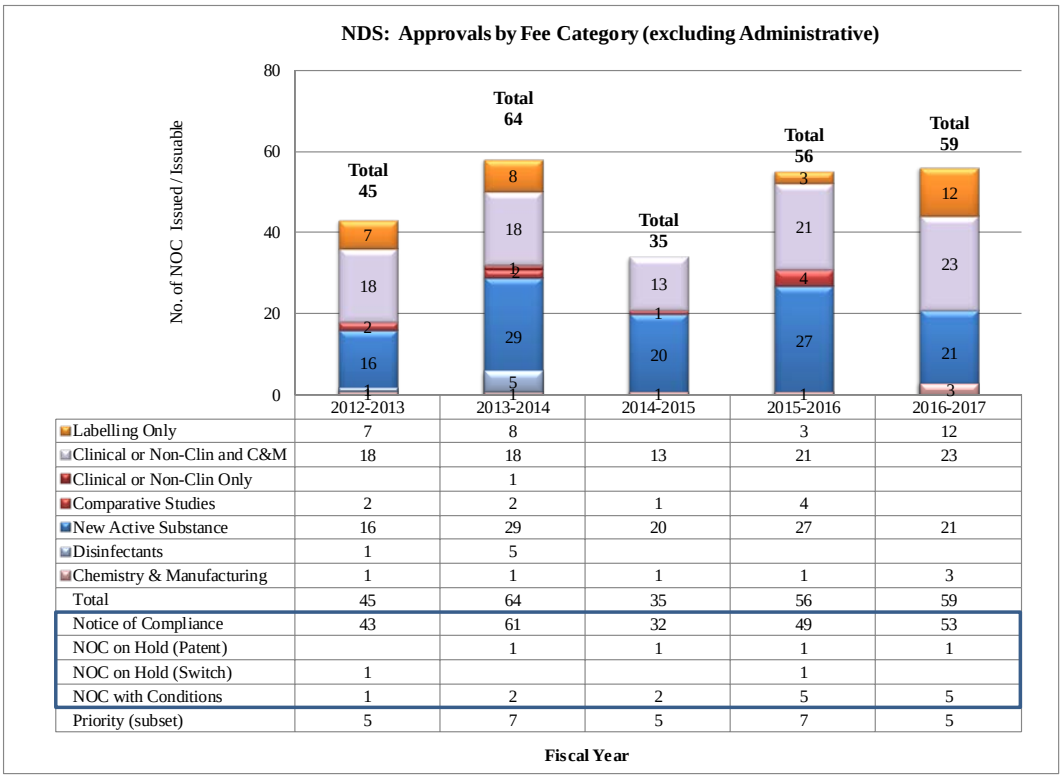
TPD NDS: All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2013-03-31	2014-03-31	2015-03-31	2016-03-31	2017-03-31
Labelling Only	1	0	1	3	1
Backlog	*0*	*0*	*0*	*0*	*0*
Disinfectant	4	3	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	0	3	2	0	3
Backlog	*0*	*0*	*1*	*0*	*0*
Chemistry & Manufacturing	2	3	2	3	0
Backlog	*0*	*0*	*0*	*2*	*0*
Clinical or Non-Clin Only	0	0	1	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	20	15	26	24	19
Backlog	*0*	*0*	*0*	*0*	*1*
New Active Substance	35	14	23	17	19
Backlog	*1*	*0*	*0*	*0*	*1*
Total	**62**	**38**	**55**	**47**	**42**
Non Backlog	**61**	**38**	**54**	**45**	**40**
Backlog	**1**	**0**	**1**	**2**	**2**
% in Backlog	**2%**	**0%**	**2%**	**4%**	**5%**
Priority (subset)	**5**	0	**4**	**4**	**6**
Backlog	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					
	2013-03-31	2014-03-31	2015-03-31	2016-03-31	2017-03-31
Labelling Only	**1**	**7**	**9**	**13**	**22**
Backlog	*0*	*0*	*0*	*1*	*1*
Comparative Studies	**2**	**4**	**8**	**1**	**7**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**29**	**22**	**29**	**31**	**34**
Backlog	*2*	*0*	*1*	*0*	*0*
Clinical or Non-Clin Only	**39**	**39**	**51**	**50**	**53**
Backlog	*0*	*0*	*0*	*0*	*2*
Clinical or Non-Clin and C&M	**11**	**10**	**9**	**12**	**8**
Backlog	*0*	*0*	*0*	*0*	*0*
Disinfectants	**1**	**0**	**0**	**0**	**0**
Backlog	**0**	**0**	**0**	**0**	**0**
Switch from Rx to OTC	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data Only	**5**	**7**	**6**	**7**	**7**
Backlog	0	0	0	0	0
Total	**87**	**89**	**112**	**114**	**131**
Non Backlog	**85**	**89**	**111**	**113**	**128**
Backlog	**2**	**0**	**1**	**1**	**3**
% in Backlog	**2%**	**0%**	**1%**	**1%**	**2%**
Priority (subset)	0	1	2	5	4
Backlog	0	0	0	0	0
***SNDS-C (Confirmatory)**	1	0	3	6	6
Backlog	0	0	0	0	0

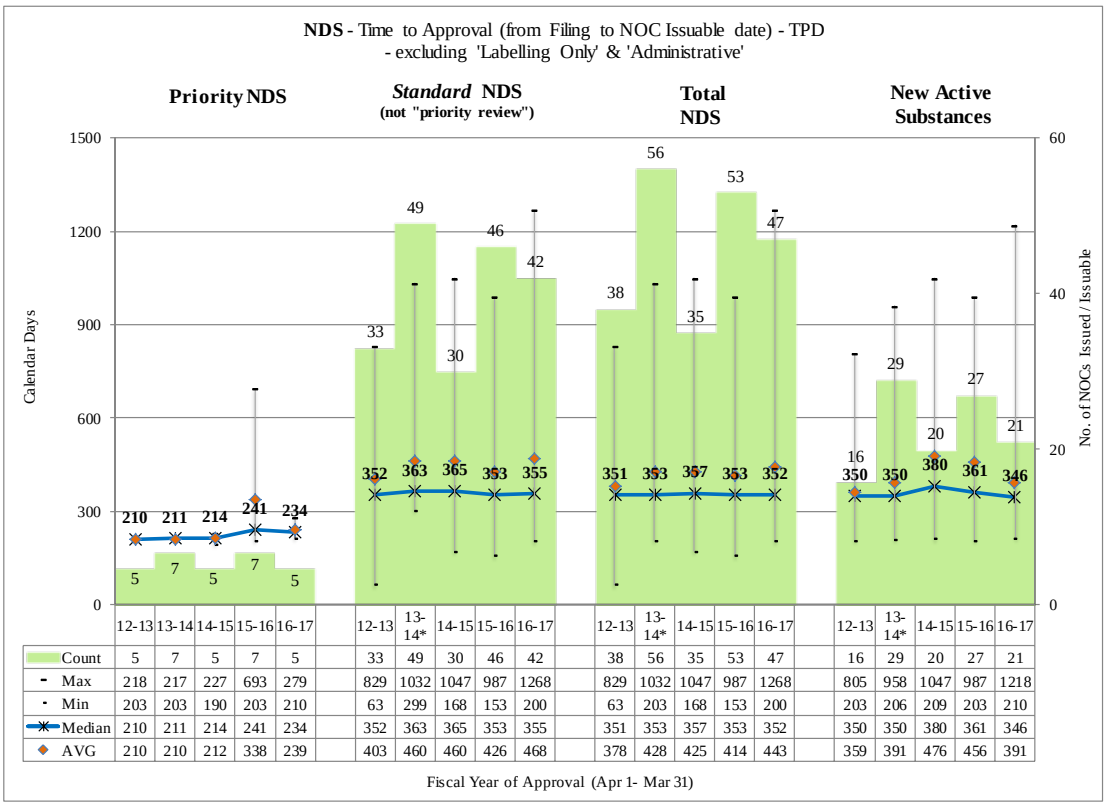
APPROVALS

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



	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
Labelling Only	7	8		3	12
Clinical or Non-Clin and C&M	18	18	13	21	23
Clinical or Non-Clin Only		1			
Comparative Studies	2	2	1	4	
New Active Substance	16	29	20	27	21
Disinfectants	1	5			
Chemistry & Manufacturing	1	1	1	1	3
Total	45	64	35	56	59
Notice of Compliance	43	61	32	49	53
NOC on Hold (Patent)		1	1	1	1
NOC on Hold (Switch)	1			1	
NOC with Conditions	1	2	2	5	5
Priority (subset)	5	7	5	7	5

NDS Approval Times

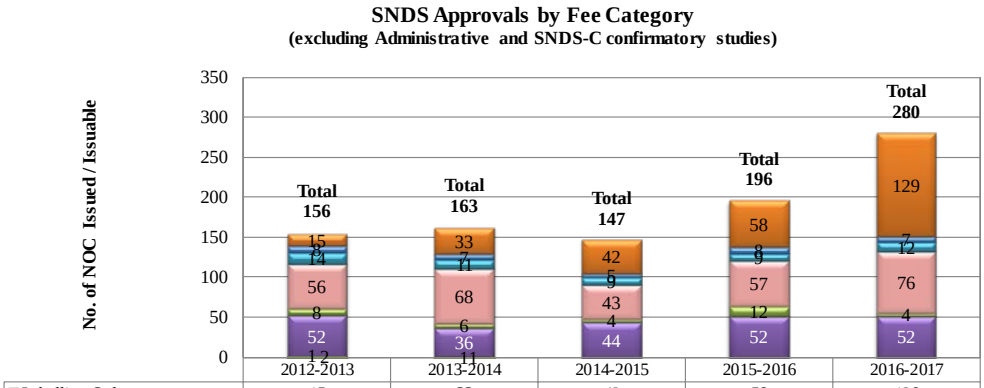


	12-13	13-14	14-15	15-16	16-17	12-13	13-14*	14-15	15-16	16-17	12-13	13-14*	14-15	15-16	16-17	12-13	13-14*	14-15	15-16	16-17
Count	5	7	5	7	5	33	49	30	46	42	38	56	35	53	47	16	29	20	27	21
Max	218	217	227	693	279	829	1032	1047	987	1268	829	1032	1047	987	1268	805	958	1047	987	1218
Min	203	203	190	203	210	63	299	168	153	200	63	203	168	153	200	203	206	209	203	210
Median	210	211	214	241	234	352	363	365	353	355	351	353	357	353	352	350	350	380	361	346
AVG	210	210	212	338	239	403	460	460	426	468	378	428	425	414	443	359	391	476	456	391

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.

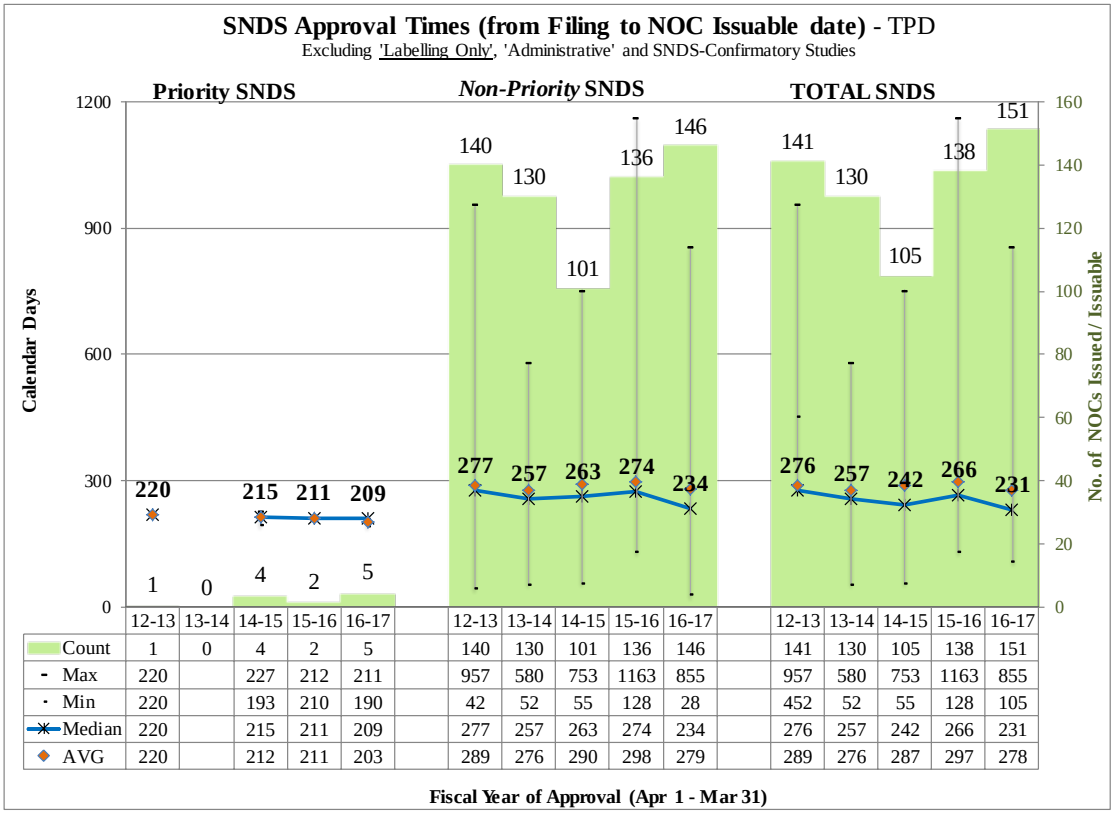
*One outlier is included for fiscal year 2013-14. The NDS was in rejected status for over 4 years but following a judicial review decision, screening was resumed. For this "outlier NDS", the dates used to calculate the time to approval are the date the screening resumed and the date the submission was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

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



	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
Labelling Only	15	33	42	58	129
Published Data Only	8	7	5	8	7
Clinical or Non-Clin and C&M	14	11	9	9	12
Chemistry & Manufacturing	56	68	43	57	76
Comparative Studies	8	6	4	12	4
Clinical or Non-Clin Only	52	36	44	52	52
Switch from Rx to OTC	1	1			
Disinfectants	2	1			
Total	156	163	147	196	280
Notice of Compliance	152	156	141	190	279
NOC on Hold (Patent)		1	1	1	
NOC on Hold (Switch)	3	4			
NOC with Conditions	1	2	5	5	1
Priority (subset)	1	0	4	0	5

SNDS Approval Times



	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17
Count	1	0	4	2	5	140	130	101	136	146	141	130	105	138	151
Max	220		227	212	211	957	580	753	1163	855	957	580	753	1163	855
Min	220		193	210	190	42	52	55	128	28	452	52	55	128	105
Median	220		215	211	209	277	257	263	274	234	276	257	242	266	231
AVG	220		212	211	203	289	276	290	298	279	289	276	287	297	278

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.

New Active Substance (NAS) Approvals

And

Priority Submission Approvals

New Active Substance (NAS) Approvals - TPD - Fiscal Year 2016-2017

New Active Substance Approvals – TPD Fiscal Year 2016-2017 (April 1 2016 – March 31 2017)				
Brand Name (Active Ingredient(s) - Indication(s))	**Class**	**Company**	**Filing (CR[5]) Date**	**Approval Date (dd-mon-yy)**
ALECENSARO (Alectinib as Alectinib Hydrochloride) - is indicated as monotherapy for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib.	NOC-C NAS	Hoffmann-La Roche Limited	12-Nov-15	29-Sep-16 NOC-C
BEPREVE (Bepotastine Besilate) - is indicated for the treatment of itching associated with allergic conjunctivitis.	NAS	Bausch & Lomb Inc.	19-Aug-15	27-Jul-16
BLEXTEN (Bilastine) - Seasonal Allergic Rhinitis: is indicated for the symptomatic relief of nasal and non-nasal symptoms of seasonal allergic rhinitis (SAR) in patients 12 years of age and older. Chronic Spontaneous Urticaria: is indicated for the relief of the symptoms associated with chronic spontaneous urticaria (CSU) (e.g. pruritus and hives), in patients 18 years of age and older.	NAS	Aralez Pharmaceuticals Trading Dac	11-May-15	21-Apr-16
BRINAVESS (Vernakalant Hydrochloride) - is indicated for rapid conversion of recent onset atrial fibrillation (AF) to sinus rhythm, for: non-surgery patients, with duration of AF ≤ 7 days, and post-cardiac surgery patients, with duration of AF ≤ 3 days. BRINAVESS is NOT recommended for conversion of atrial flutter (AFL) to sinus rhythm.	NAS	Cardiome UK Limited	4-Jan-16	13-Mar-17
DOTAREM (Gadoterate Meglumine) - is indicated in adults and pediatrics (2-18 years of age) for: contrast enhancement during cranial and spinal MRI investigations.	NAS	Guerbet	31-Jul-15	25-Nov-16
EPCLUSA (Sofosbuvir, Velpatasvir) - is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults without cirrhosis or with compensated cirrhosis and, in combination with ribavirin, for the treatment of chronic hepatitis C virus (HCV) infection in adults with decompensated cirrhosis.	PRIORITY-NAS	Gilead Sciences Canada Inc.	14-Dec-15	11-Jul-16

[5] The CR date is the date the submission is received and considered administratively complete by Health Canada.

New Active Substance Approvals – TPD
Fiscal Year 2016-2017
(April 1 2016 – March 31 2017)

Brand Name (Active Ingredient(s) - Indication(s))	Class	Company	Filing (CR[5]) Date	Approval Date (dd-mon-yy)
LANCORA (Ivabradine as Ivabradine Hydrochloride) - is indicated for the treatment of stable chronic heart failure with reduced left ventricular ejection fraction (≤ 35%) in adult patients with NYHA Classes II or III who are in sinus rhythm with a resting heart rate ≥ 77 beats per minute, to reduce the incidence of cardiovascular mortality and hospitalisations for worsening heart failure. LANCORA should be administered in combination with standard chronic heart failure therapies.	NAS	Servicer Canada Inc.	23-Aug-13	23-Dec-16
LIXIANA (Edoxaban) - is indicated for: prevention of stroke and systemic embolic events in patients with atrial fibrillation, in whom anticoagulation is appropriate and for treatment of venous thromboembolism (VTE) (deep vein thrombosis [DVT], pulmonary embolism [PE]) and the prevention of recurrent DVT and PE.	NAS	Daiichi Sankyo Inc.	3-Sep-15	4-Nov-16
LYNPARZA (Olaparib) - is indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline or somatic) high grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy. Platinum sensitivity is defined as disease progressing at least 6 months after completion of the penultimate platinum chemotherapy.	NAS	Astrazeneca Canada Inc.	16-Mar-15	29-Apr-16 NOC-C
MDK-NITISINONE (Nitisinone) - is indicated for the treatment of patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.	PRIORITY-NAS	Mendelikabs Inc.	16-Dec-15	20-Sep-16
MICTORYL (Propiverine Hydrochloride) - is indicated for symptomatic treatment of urinary incontinence and/or increased urinary frequency and urgency in patients with overactive bladder (OAB).	NAS	Duchesnay Inc.	23-Oct-15	5-Jan-17
NINLARO (Ixazomib as Ixazomib Citrate) - in combination with lenalidomide and dexamethasone is indicated for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.	PRIORITY-NAS	Takeda Canada Inc.	14-Dec-15	4-Aug-16

New Active Substance Approvals – TPD
Fiscal Year 2016-2017
(April 1 2016 – March 31 2017)

Brand Name (Active Ingredient(s) - Indication(s))	Class	Company	Filing (CR[5]) Date	Approval Date (dd-mon-yy)
NITISINONE TABLETS (Nitisinone) - are indicated for the treatment of hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.	PRIORITY-NAS	Cycle Pharmaceuticals Ltd.	5-Apr-16	4-Nov-16
ORFADIN (Nitisinone) - is indicated for the treatment of patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.	PRIORITY-NAS	Swedish Orphan Biovitrum AB (publ)	30-Mar-16	13-Dec-16
RAPIVAB (Peramivir) - is indicated for the treatment of acute uncomplicated influenza in patients 18 years and older, who have been symptomatic for no more than 2 days.	NAS	Biocryst Pharmaceuticals Inc.	25-Jan-16	5-Jan-17
REXULTI (Brexpiprazole) - is indicated for treatment of schizophrenia in adults.	NAS	Otsuka Pharmaceuticals Co. Ltd.	26-Feb-16	16-Feb-17
RUPATADINE (Rupatadine as Rupatadine Fumarate) - Allergic Rhinitis: is indicated for the symptomatic relief of nasal and non-nasal symptoms of seasonal allergic rhinitis (SAR) and perennial allergic rhinitis (PAR) in patients 2 years of age and older. Chronic Spontaneous Urticaria: is indicated for the relief of the symptoms associated with chronic spontaneous urticaria (CSU), e.g. pruritus and hives, in patients 2 years of age and older.	NAS	Pediapharm Inc.	4-Aug-15	20-Jul-16
TAGRISSO (Osimertinib as Osimertinib Mesylate) - is indicated for the treatment of patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC) who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy. A validated test is required to identify EGFR T790M mutation-positive status prior to treatment.	NOC-C NAS	Astrazeneca Canada Inc.	1-Oct-15	5-Jul-16 NOC-C
VENCLEXTA (Venetoclax) - is indicated as monotherapy for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion who have received at least one prior therapy, or patients with CLL without 17p deletion who have received at least one prior therapy and for whom there are no other available treatment options.	NOC-C NAS	Abbvie Corporation	21-Dec-15	30-Sep-16 NOC-C

New Active Substance Approvals – TPD Fiscal Year 2016-2017 (April 1 2016 – March 31 2017)				
Brand Name (Active Ingredient(s) - Indication(s))	**Class**	**Company**	**Filing (CR[5]) Date**	**Approval Date (dd-mon-yy)**
VIBERZI (Eluxadoline) - is indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.	NAS	Allergan Pharma Co.	11-Dec-15	26-Jan-17
ZONTIVITY (Vorapaxar Sulfate) – co-administered with acetylsalicylic acid (ASA) with or without clopidogrel, according to their standard of care, is indicated for the reduction of atherothrombotic events in adult high-risk patients with a history of myocardial infarction (MI).	NAS	Merck Canada Inc.	31-Oct-14	13-May-16

Priority Submission Approvals - TPD - Fiscal Year 2016-2017

Priority Submission Approvals – TPD Fiscal Year 2016-2017 (April 1 2016 – March 31 2017)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR) Date**	**Approval Date**
AFINITOR (Everolimus) New indication: For the treatment of unresectable, locally advanced or metastatic, well differentiated, non-functional neroendocrine tumours (NET) of gastrointestinal or lung origin in adults with progressive disease.	Priority-CLIN Only	Novartis Pharmaceuticals Canada Inc.	19-Oct-15	17-May-16
DAKLINZA (Daclatasvir) Revised indications: For use in combination with other agents for the treatment of chronic hepatitis C (CHC) in adult patients with hepatitis C virus (HCV) genotypes 1, 2 or 3 including • patients with HCV/HIV-1 coinfection, • patients with compensated or decompensated cirrhosis (Child-Pugh score A, B or C, and • patients with HCV recurrence after liver transplantation	Priority-CLIN Only	Bristol-Myers Squibb Canada	5-Nov-15	17-May-16
EPCLUSA (Sofosbuvir, Velpatasvir) - is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults without cirrhosis or with compensated cirrhosis and, in combination with ribavirin, for the treatment of chronic hepatitis C virus (HCV) infection in adults with decompensated cirrhosis.	Priority-NAS	Gilead Sciences Canada Inc.	14-Dec-15	11-Jul-16
HARVONI (Ledipasvir, Sofosbuvir) Revised indication: Use of Harvoni in patients 1) with HCV genotype 1 infection and decompensated cirrhosis 2) with hepatitis C recurrence after liver transplantation, and 3) patients with HCV/human immunodeficiency virus 1 co-infection.	Priority-CLIN Only	Gilead Sciences Canada Inc.	7-Dec-15	14-Jun-16
IMBRUVICA (Ibrutinib) – To broaden the existing indication for chronic lymphocytic leukemia (CLL) to include all previously untreated patients.	Priority-CLIN Only	Janssen Inc.	21-Dec-15	19-Jul-16

Priority Submission Approvals – TPD Fiscal Year 2016-2017 (April 1 2016 – March 31 2017)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR) Date**	**Approval Date**
JARDIANCE (Empagliflozin) New indication: Add-on combination in patients with established cardiovascular disease: As an adjunct to diet, exercise and standard care therapy to reduce the incidence of cardiovascular death in patients with type 2 diabetes mellitus and established cardiovascular disease who have inadequate glycemic control. Update to the product monograph based on the results of the EMPA-REG Cardiovascular outcomes Trial.	Priority-CLIN Only	Boehringer Ingelheim (Canada) Ltd Ltée	31-Dec-15	27-Jul-16
MDK-NITISINONE (Nitisinone) - is indicated for the treatment of patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.	Priority-NAS	Mendelikabs Inc.	16-Dec-15	20-Sep-16
NINLARO (Ixazomib as Ixazomib Citrate) - in combination with lenalidomide and dexamethasone is indicated for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.	Priority-NAS	Takeda Canada Inc.	14-Dec-15	4-Aug-16
NITISINONE TABLETS (Nitisinone) - are indicated for the treatment of hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.	Priority-NAS	Cycle Pharmaceuticals Ltd.	5-Apr-16	4-Nov-16
ORFADIN (Nitisinone) - is indicated for the treatment of patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.	Priority-NAS	Swedish Orphan Biovitrum AB (publ)	30-Mar-16	13-Dec-16

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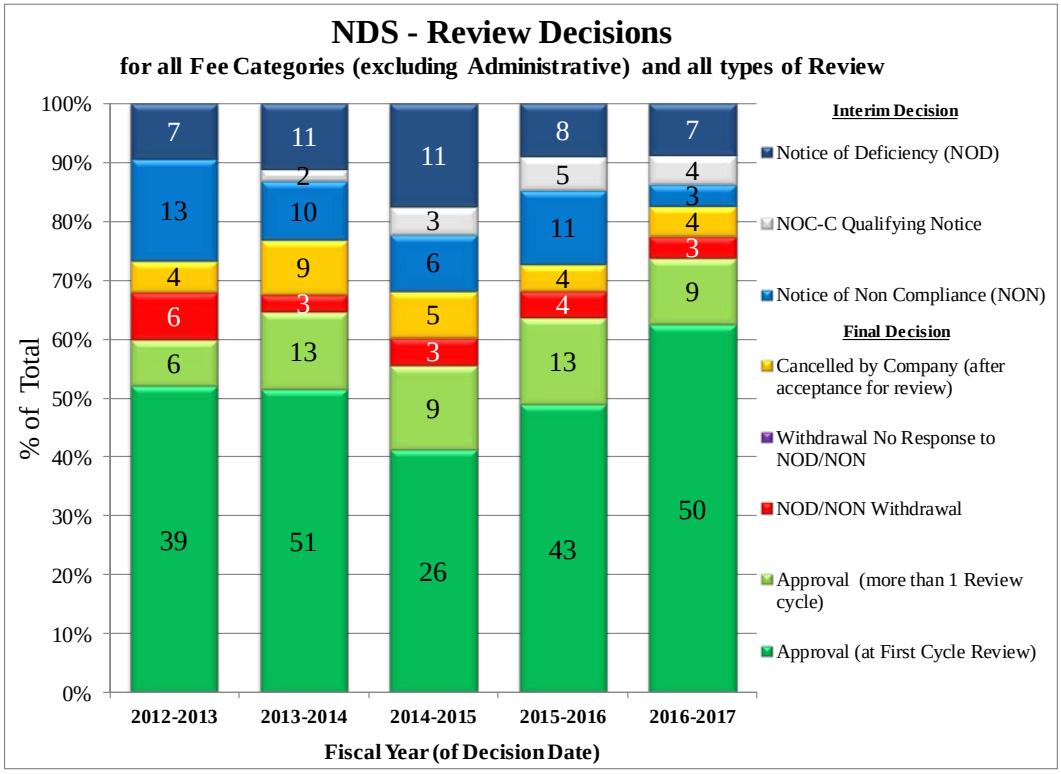
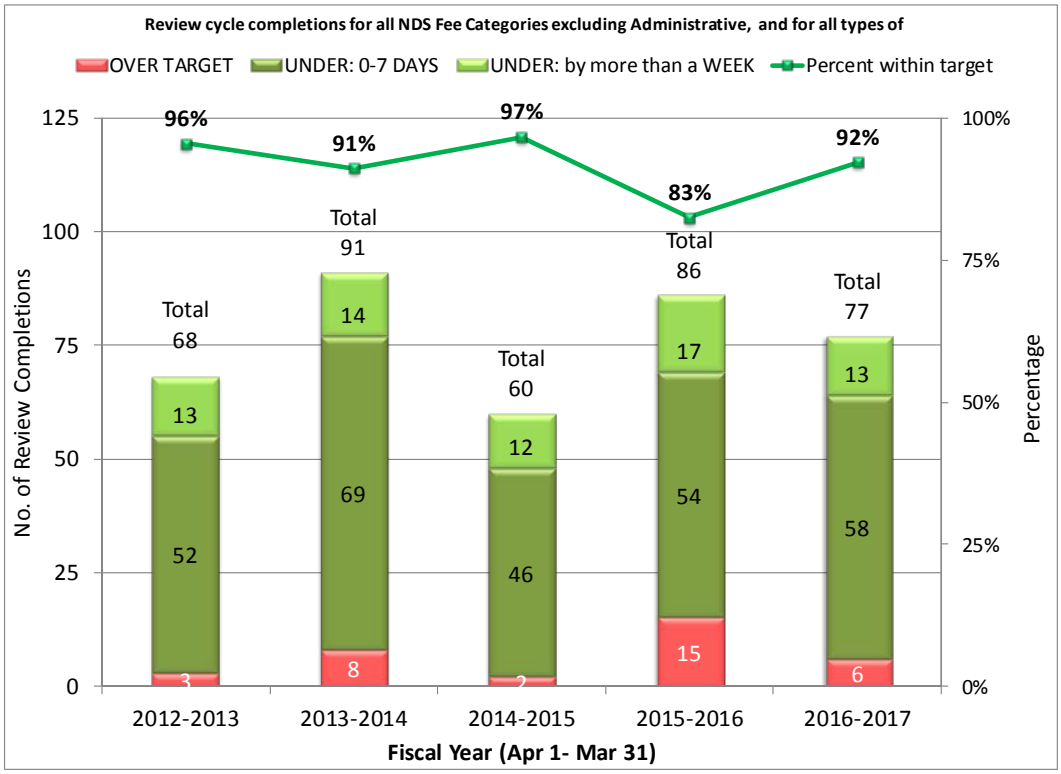
REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

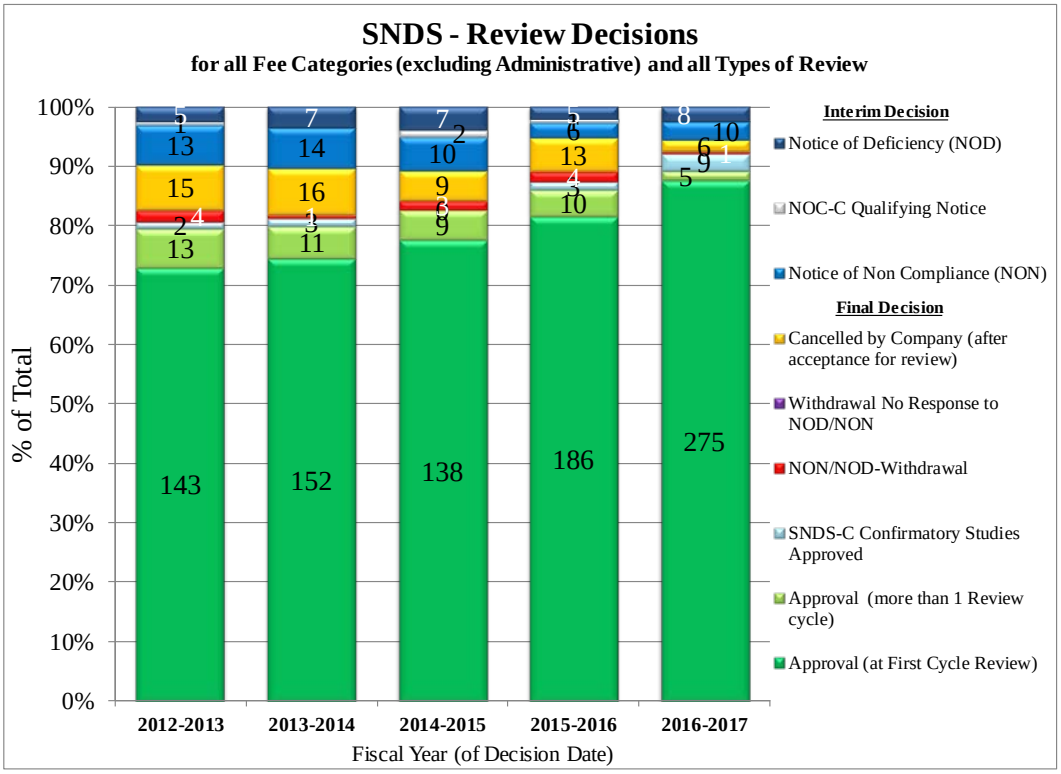


NDS - Review Cycle Completions Showing Percentage Within Target

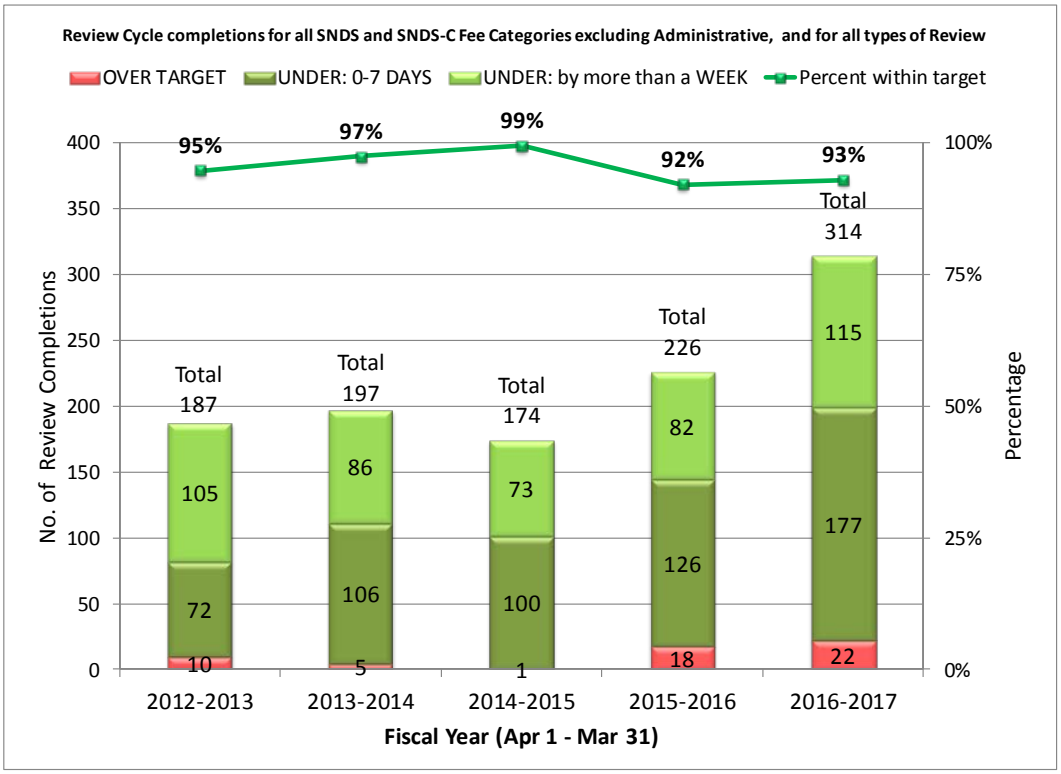


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

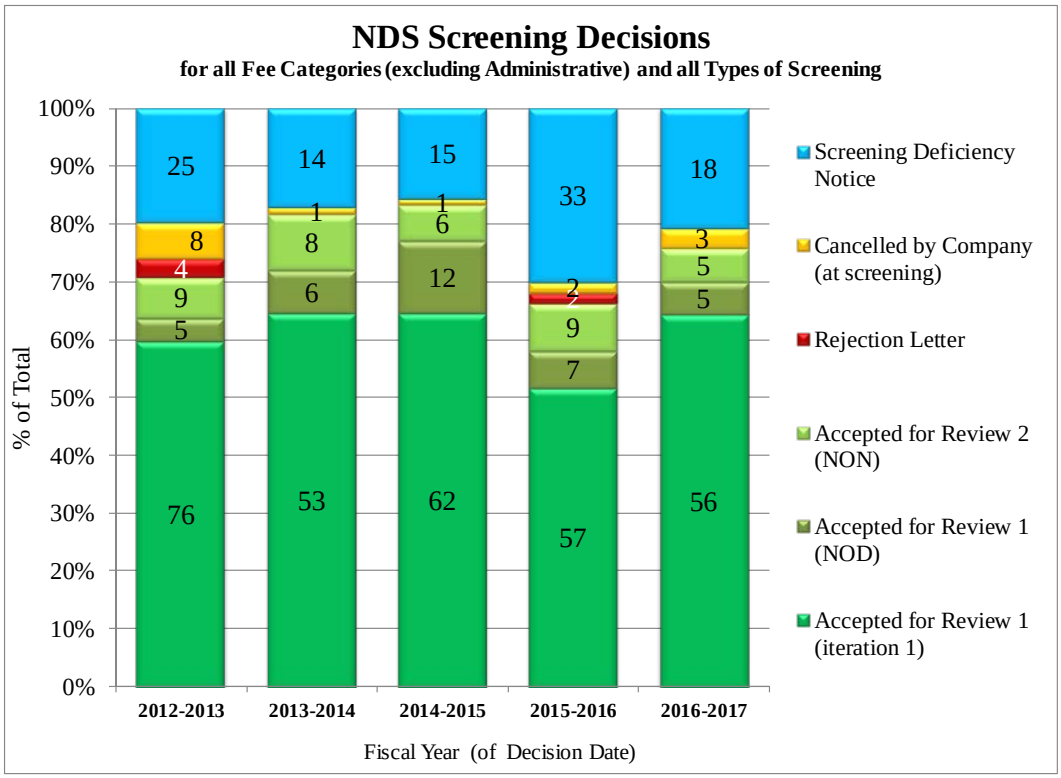


SNDS - Review Cycle Completions Showing Percentage Within Target

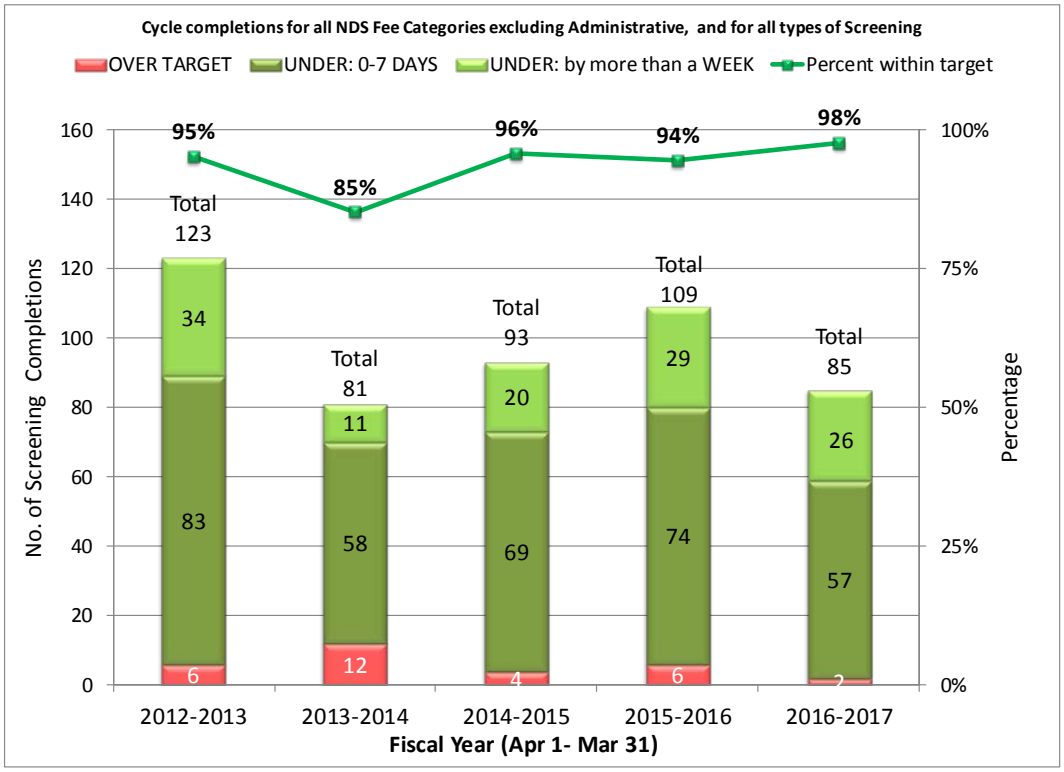


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

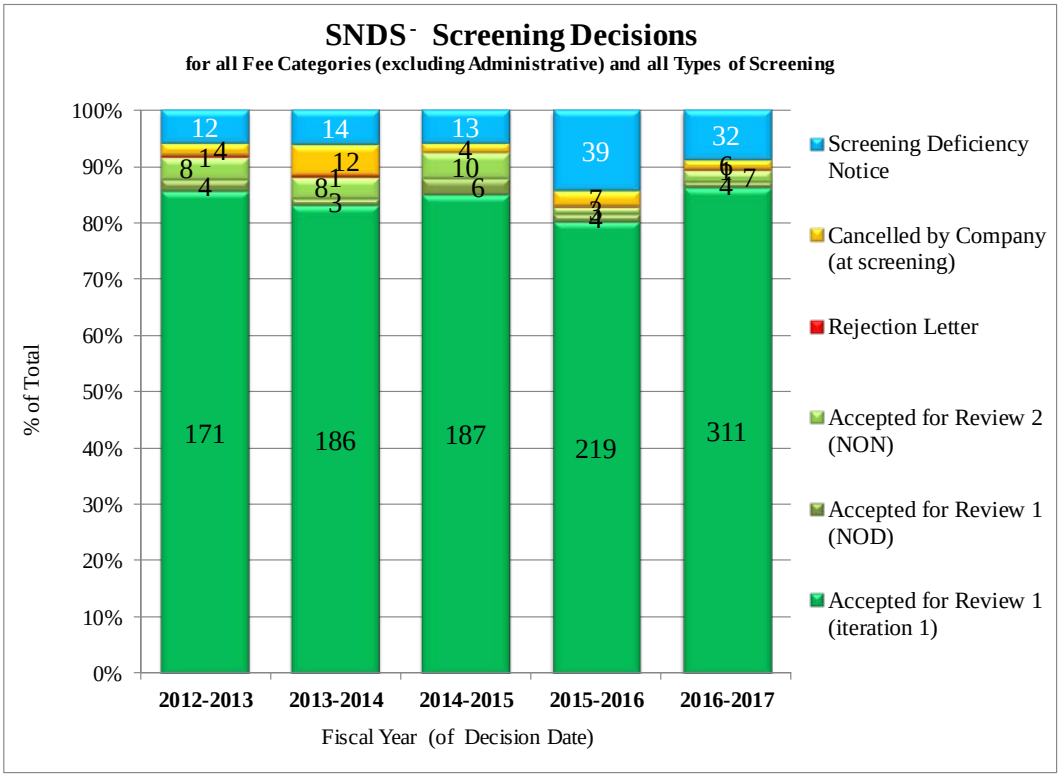


NDS - Screening Cycle Completions Showing Percentage Within Target

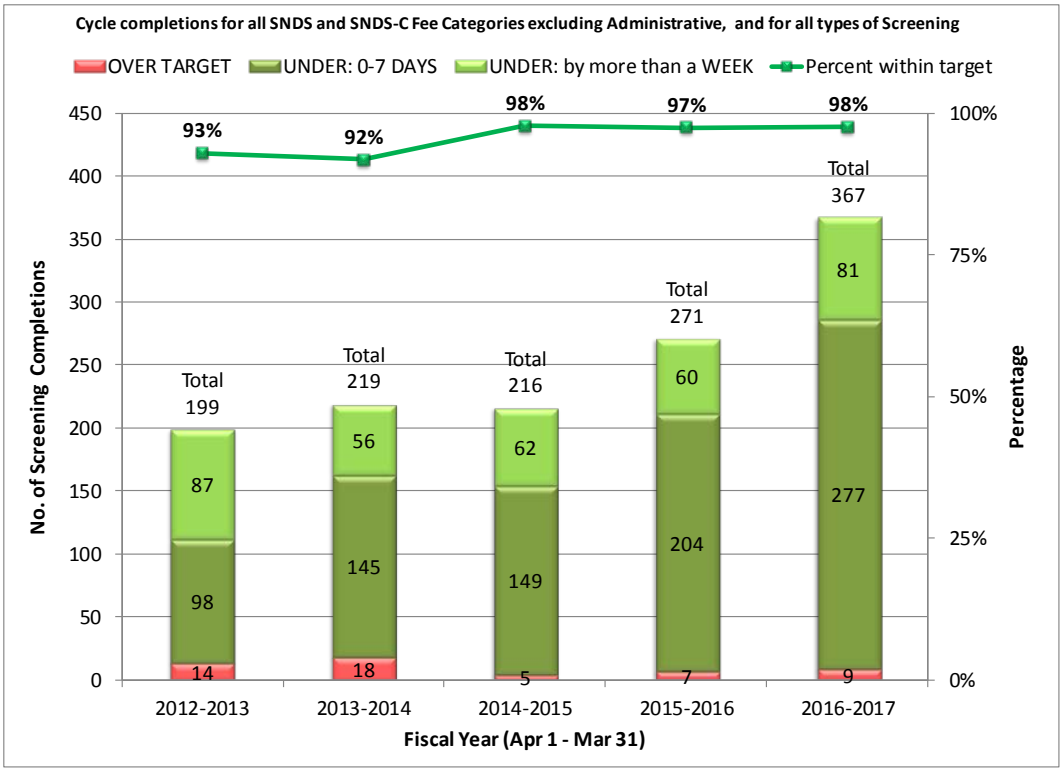


SCREENING CYCLE DECISIONS

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)

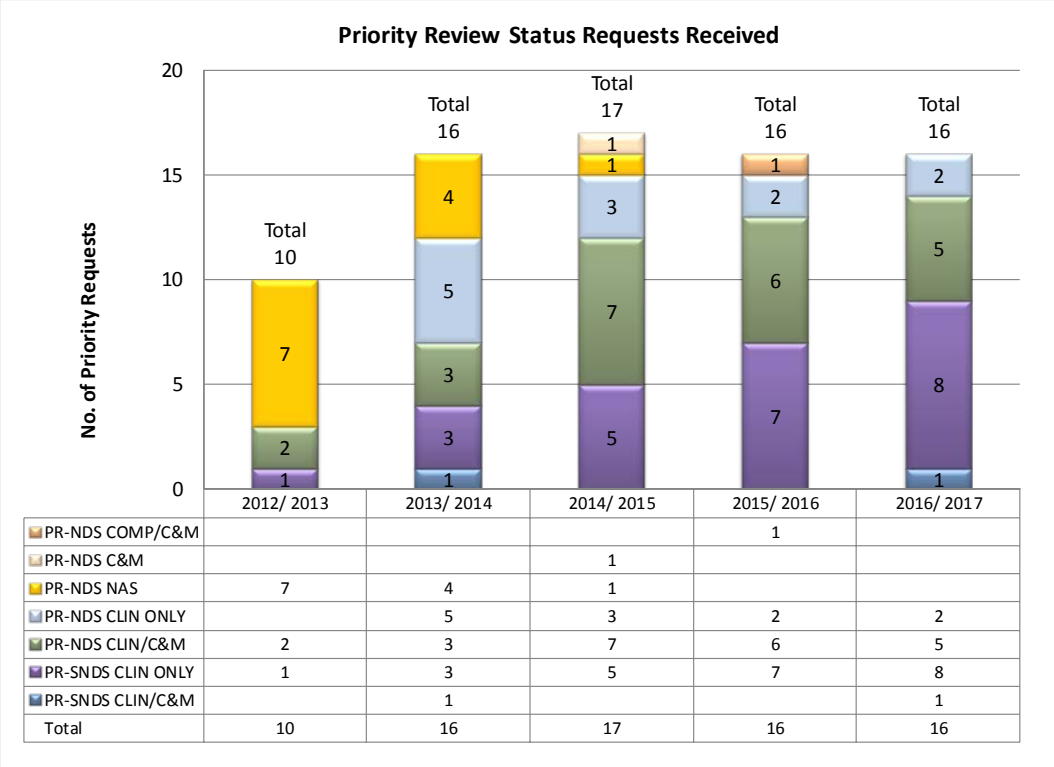
NDS - Reconsideration of Final Decisions Requests Received Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	**12-13**	**13-14**	**14-15**	**15-16**	**16-17**	**Final Decision in Dispute**	**NDS Status (as of May 12 2017)**
Total Received	**2**	**1**	**0**	**2**	**1**		
Total Pending	***0***	***0***	***0***	***0***	***0***		
PENDING						NOD-Withdrawal	Under Reconsideration
Total Granted	***1***	***1***	***0***	***1***	***0***		
GRANTED		1				NON-Withdrawal	Cleared
GRANTED	1					NON-Withdrawal	Cleared
GRANTED				*1*		NOD-Withdrawal	Cleared
Total Denied	***1***	***0***	***0***	***1***	***1***		
DENIED				1		NOD-Withdrawal	Withdrawn
DENIED	1					Screening Rejection Letter	Rejected
DENIED					1	NOD-Withdrawal	Withdrawn

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

SNDS - Reconsideration of Final Decisions Requests Received Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	**12-13**	**13-14**	**14-15**	**15-16**	**16-17**	**Final Decision in Dispute**	**SNDS Status (as of May12 2017)**
Total Received	**2**	**0**	**1**	**2**	**0**		
Total Pending				***1***		NOD-Withdrawal	Under Reconsideration
Total Granted			***1***			NOD-Withdrawal	Withdrawn
Total Denied	***2***			***1***		NOD-Withdrawal	Withdrawn

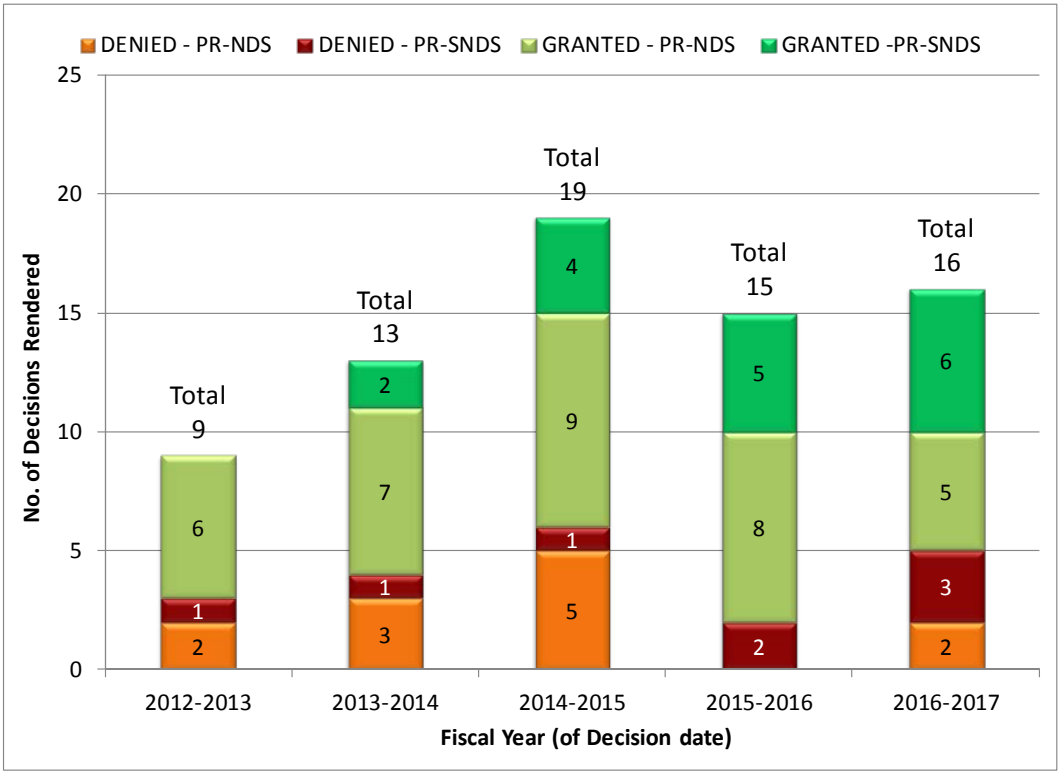
PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests Received



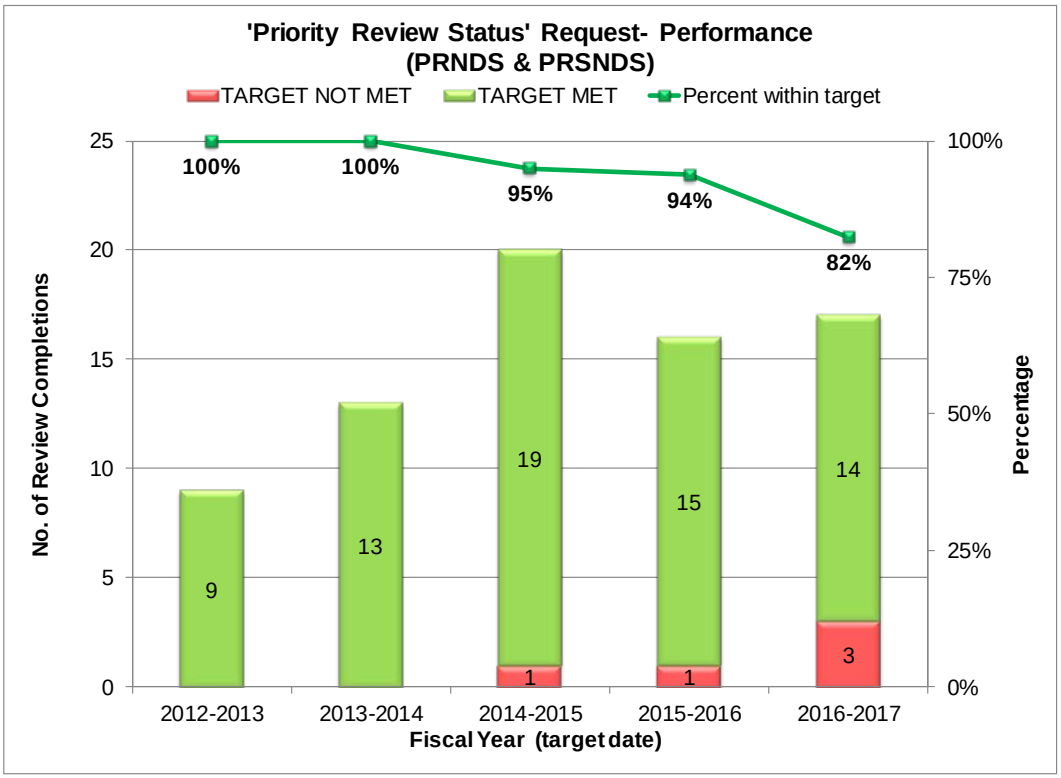
	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
PR-NDS COMP/C&M				1	
PR-NDS C&M			1		
PR-NDS NAS	7	4	1		
PR-NDS CLIN ONLY		5	3	2	2
PR-NDS CLIN/C&M	2	3	7	6	5
PR-SNDS CLIN ONLY	1	3	5	7	8
PR-SNDS CLIN/C&M		1			1
Total	10	16	17	16	16

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	**12-13**	**13-14**	**14-15**	**15-16**	**16-17**	**Final Decision in Dispute**	**Submission Status (as of May 12 2017)**
Total Received	**0**	**0**	**0**	**0**	**0**		

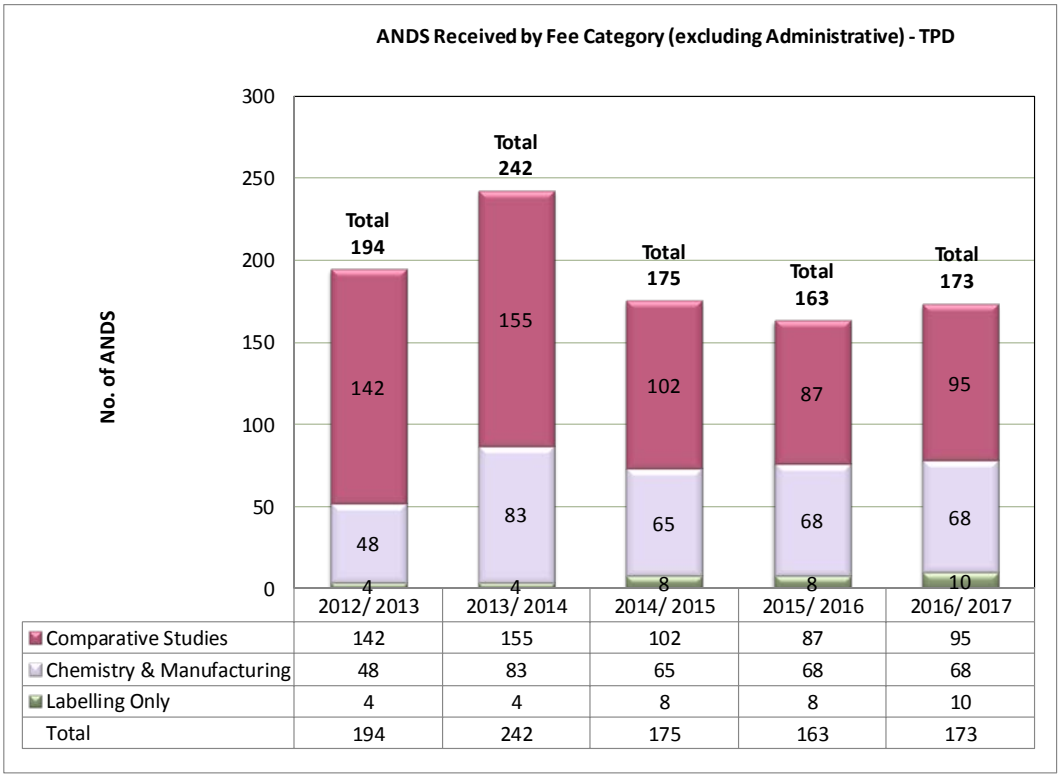
Abbreviated New Drug Submissions (ANDS)

&

Supplemental Abbreviated New Drug Submissions (SANDS)

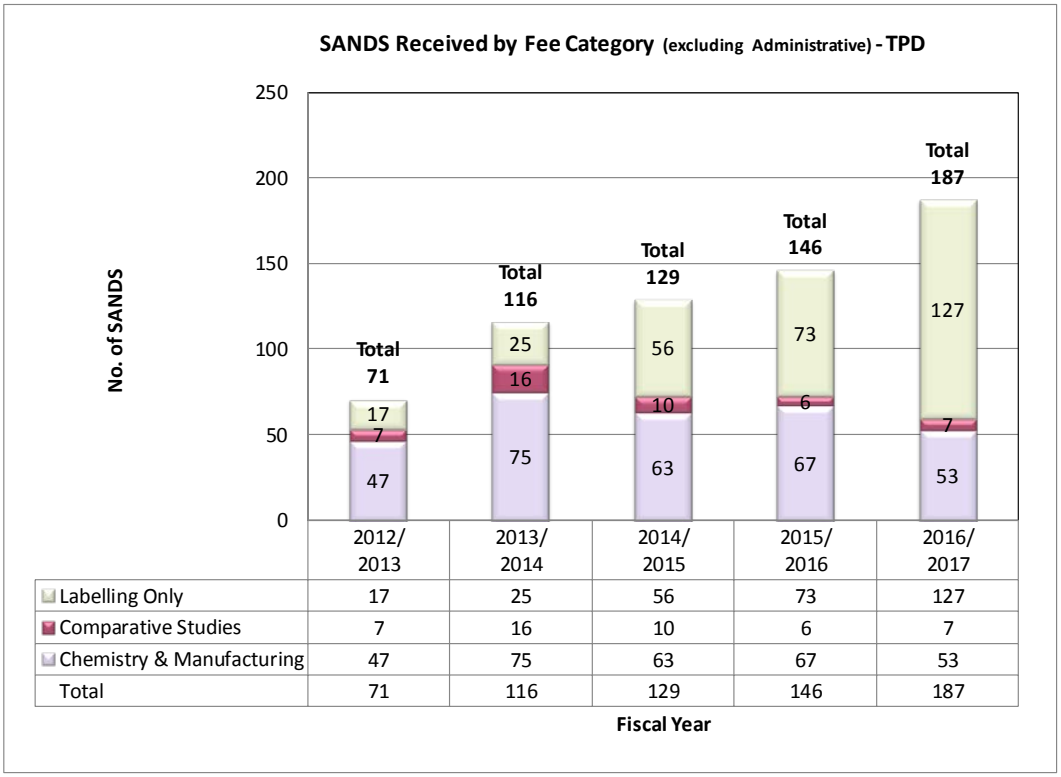
SUBMISSIONS RECEIVED

Abbreviated New Drug Submissions (ANDS) Received by Fee Category



	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Comparative Studies	142	155	102	87	95
Chemistry & Manufacturing	48	83	65	68	68
Labelling Only	4	4	8	8	10
Total	194	242	175	163	173

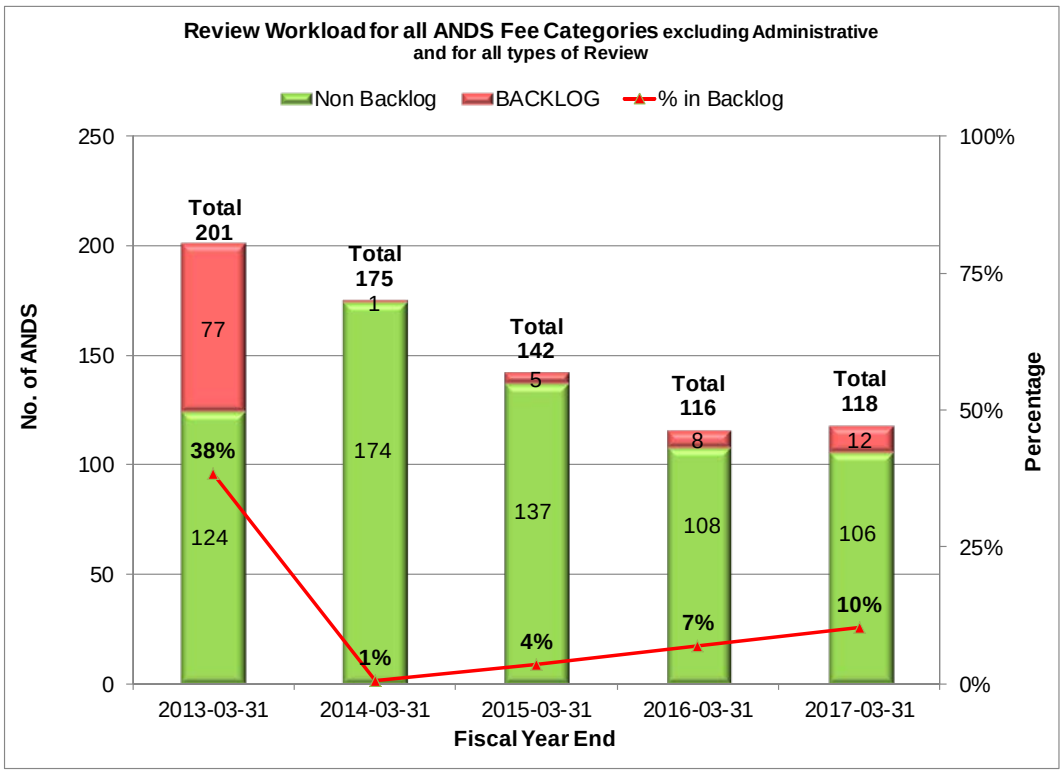
Supplemental Abbreviated New Drug Submission (SANDS) Received by Fee Category



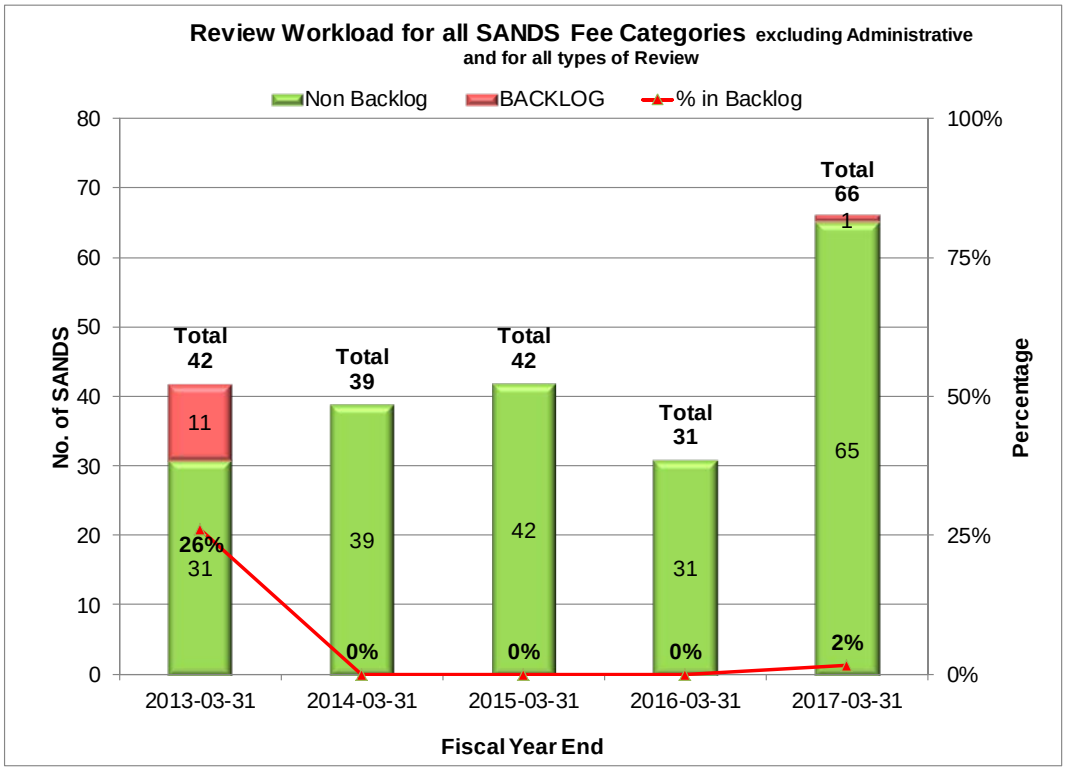
	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Labelling Only	17	25	56	73	127
Comparative Studies	7	16	10	6	7
Chemistry & Manufacturing	47	75	63	67	53
Total	71	116	129	146	187

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

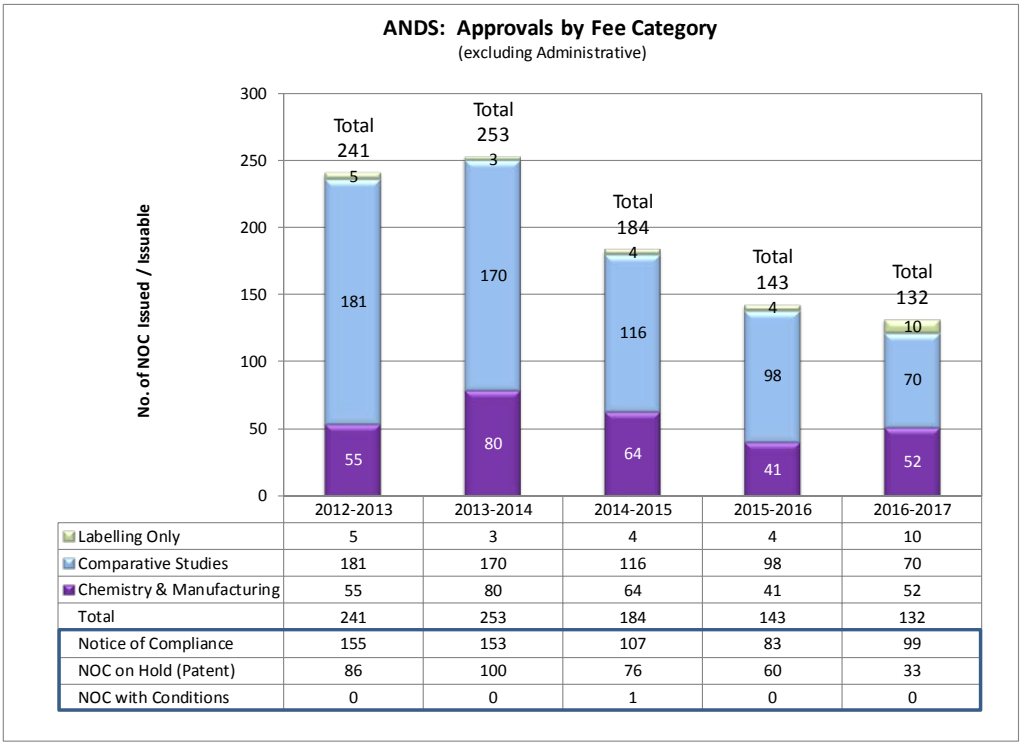
TPD ANDS All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2013-03-31	2014-03-31	2015-03-31	2016-03-31	2017-03-31
Chemistry & Manufacturing	**79**	**58**	**59**	**49**	**46**
Backlog	*44*	*1*	*1*	*1*	*5*
Comparative Studies	**122**	**117**	**83**	**65**	**71**
Backlog	*33*	*0*	*4*	*7*	*7*
Labelling Only	**0**	**0**	**0**	**2**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**201**	**175**	**142**	**116**	**118**
Non Backlog	**124**	**174**	**137**	**108**	**106**
BACKLOG	**77**	**1**	**5**	**8**	**12**
% in Backlog	**38%**	**1%**	**4%**	**7%**	**10%**

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					
	2013-03-31	2014-03-31	2015-03-31	2016-03-31	2017-03-31
Chemistry & Manufacturing	**33**	**27**	**27**	**24**	**32**
Backlog	*9*	*0*	*0*	*0*	*1*
Clinical or Non-Clin Only	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**6**	**10**	**7**	**2**	**4**
Backlog	*2*	*0*	*0*	*0*	*0*
Labelling Only	**3**	**2**	**8**	**5**	**30**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**42**	**39**	**42**	**31**	**66**
Non Backlog	**31**	**39**	**42**	**31**	**65**
BACKLOG	**11**	**0**	**0**	**0**	**1**
% in Backlog	**26%**	**0%**	**0%**	**0%**	**2%**

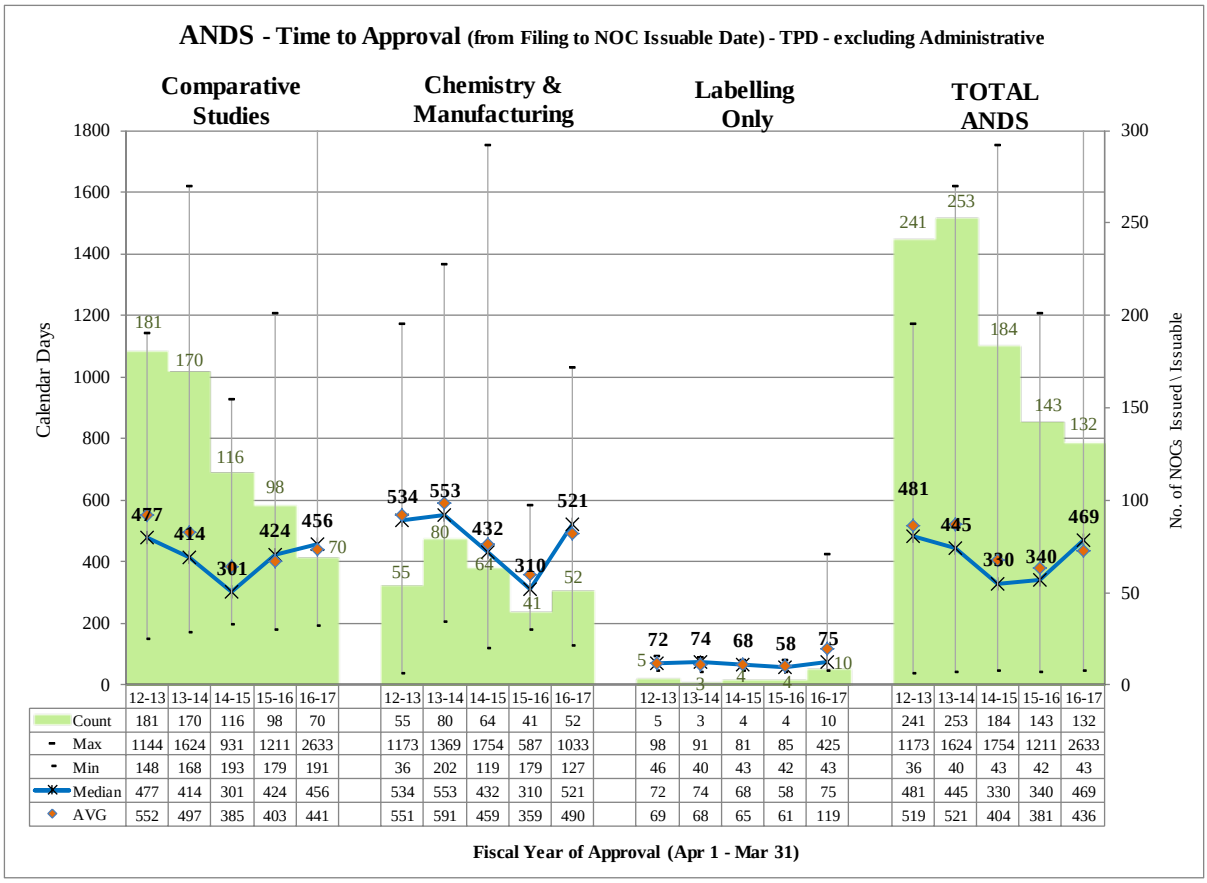
APPROVALS

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



	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
Labelling Only	5	3	4	4	10
Comparative Studies	181	170	116	98	70
Chemistry & Manufacturing	55	80	64	41	52
Total	241	253	184	143	132
Notice of Compliance	155	153	107	83	99
NOC on Hold (Patent)	86	100	76	60	33
NOC with Conditions	0	0	1	0	0

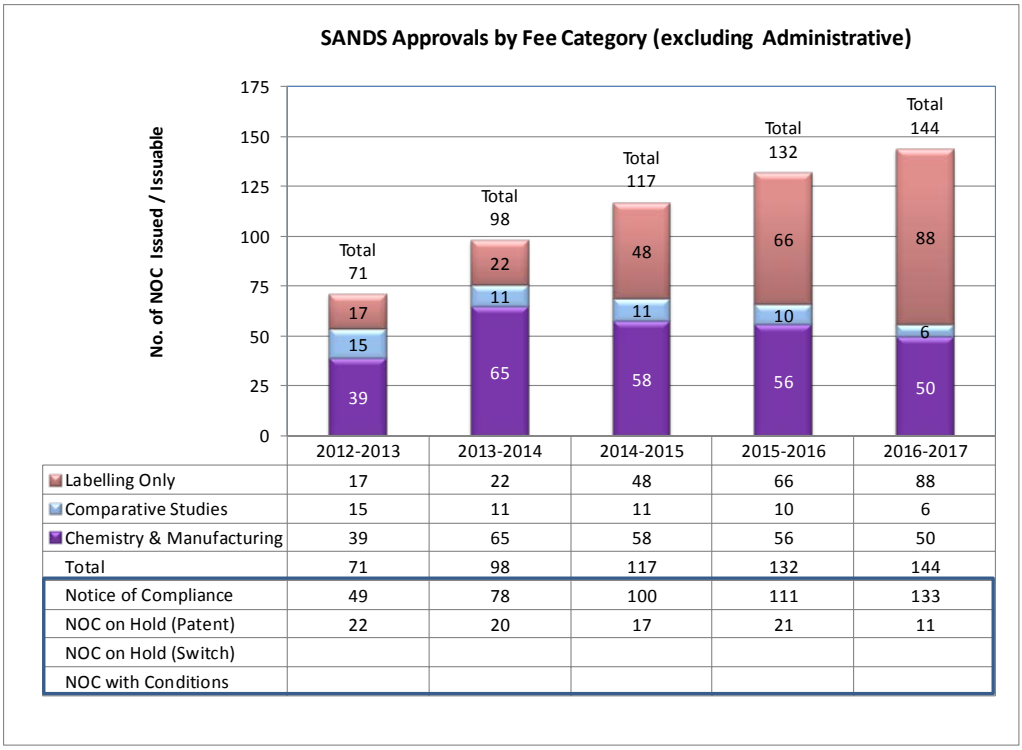
ANDS Approval Times



	Comparative Studies					Chemistry & Manufacturing					Labelling Only					TOTAL ANDS				
	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17
Count	181	170	116	98	70	55	80	64	41	52	5	3	4	4	10	241	253	184	143	132
Max	1144	1624	931	1211	2633	1173	1369	1754	587	1033	98	91	81	85	425	1173	1624	1754	1211	2633
Min	148	168	193	179	191	36	202	119	179	127	46	40	43	42	43	36	40	43	42	43
Median	477	414	301	424	456	534	553	432	310	521	72	74	68	58	75	481	445	330	340	469
AVG	552	497	385	403	441	551	591	459	359	490	69	68	65	61	119	519	521	404	381	436

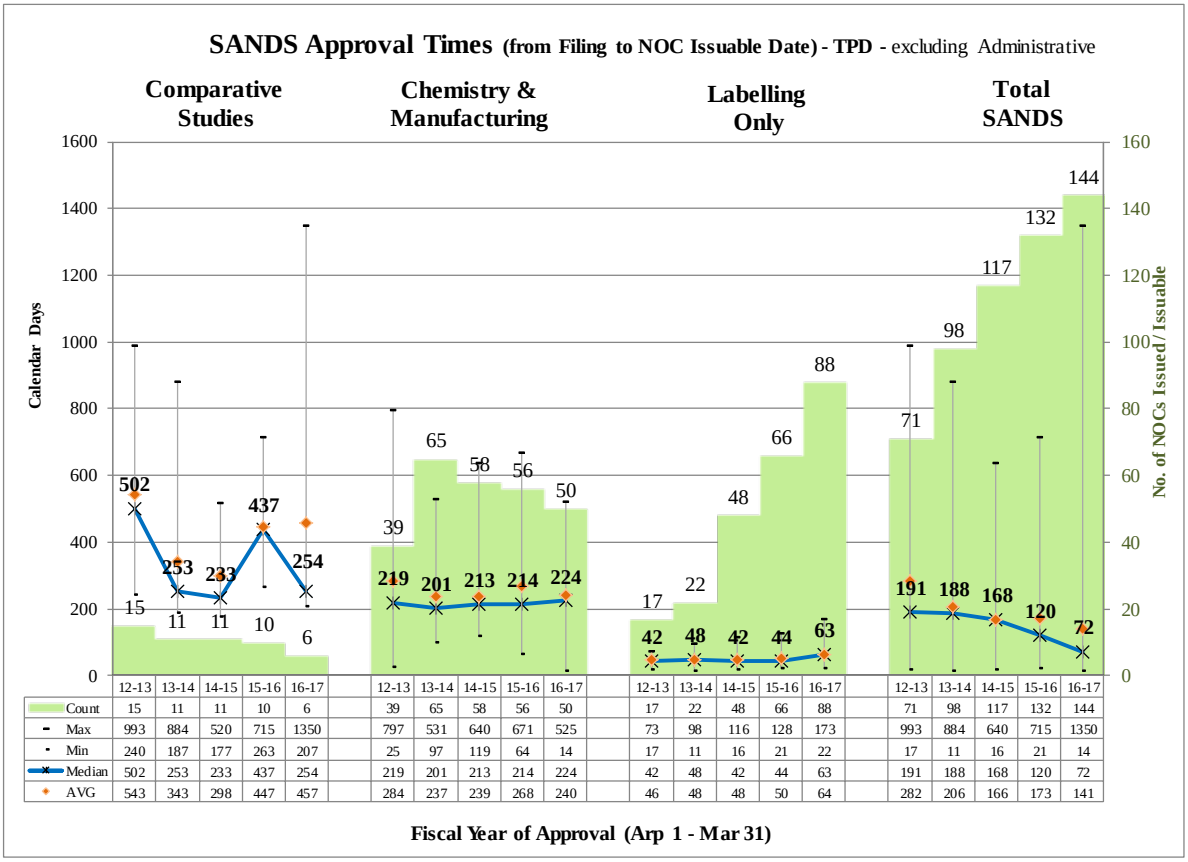
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

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



	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
Labelling Only	17	22	48	66	88
Comparative Studies	15	11	11	10	6
Chemistry & Manufacturing	39	65	58	56	50
Total	71	98	117	132	144
Notice of Compliance	49	78	100	111	133
NOC on Hold (Patent)	22	20	17	21	11
NOC on Hold (Switch)					
NOC with Conditions					

SANDS Approval Times

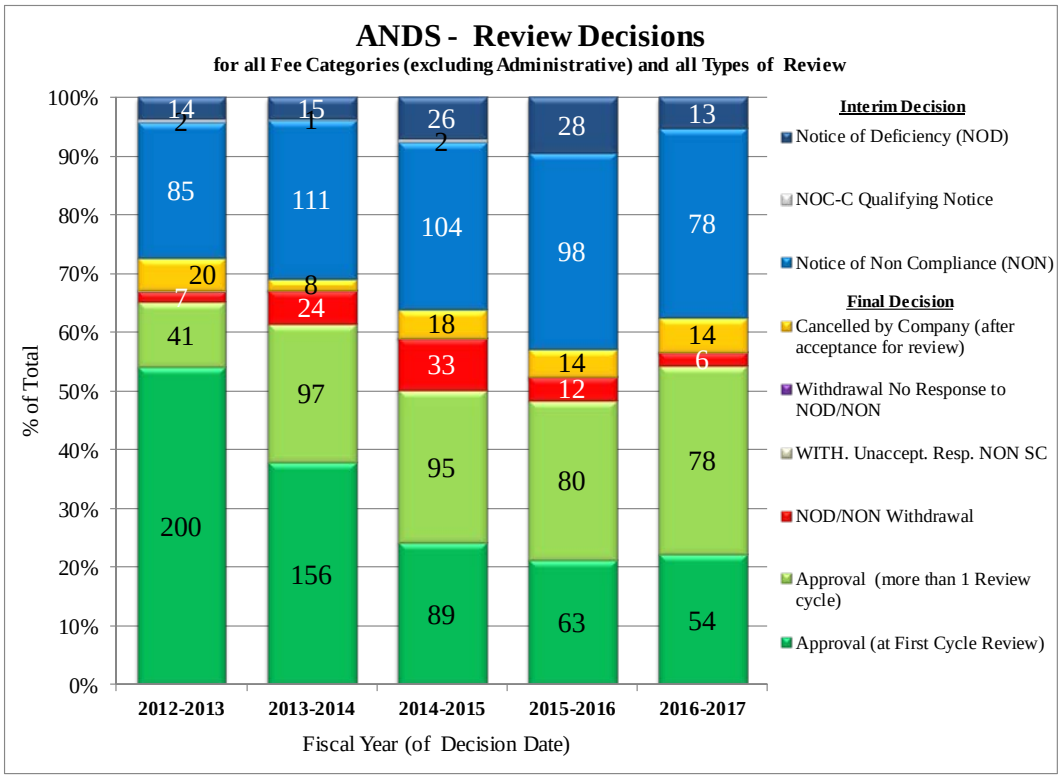


	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17
Count	15	11	11	10	6	39	65	58	56	50	17	22	48	66	88	71	98	117	132	144
Max	993	884	520	715	1350	797	531	640	671	525	73	98	116	128	173	993	884	640	715	1350
Min	240	187	177	263	207	25	97	119	64	14	17	11	16	21	22	17	11	16	21	14
Median	502	253	233	437	254	219	201	213	214	224	42	48	42	44	63	191	188	168	120	72
AVG	543	343	298	447	457	284	237	239	268	240	46	48	48	50	64	282	206	166	173	141

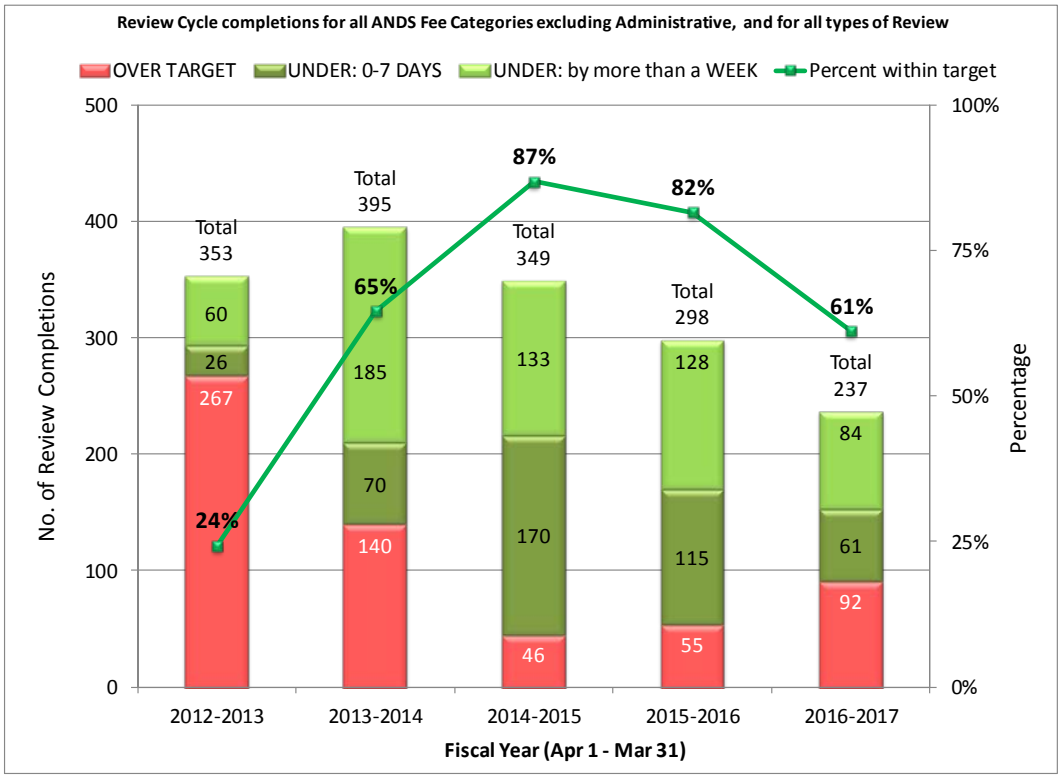
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

REVIEW CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Review Decisions

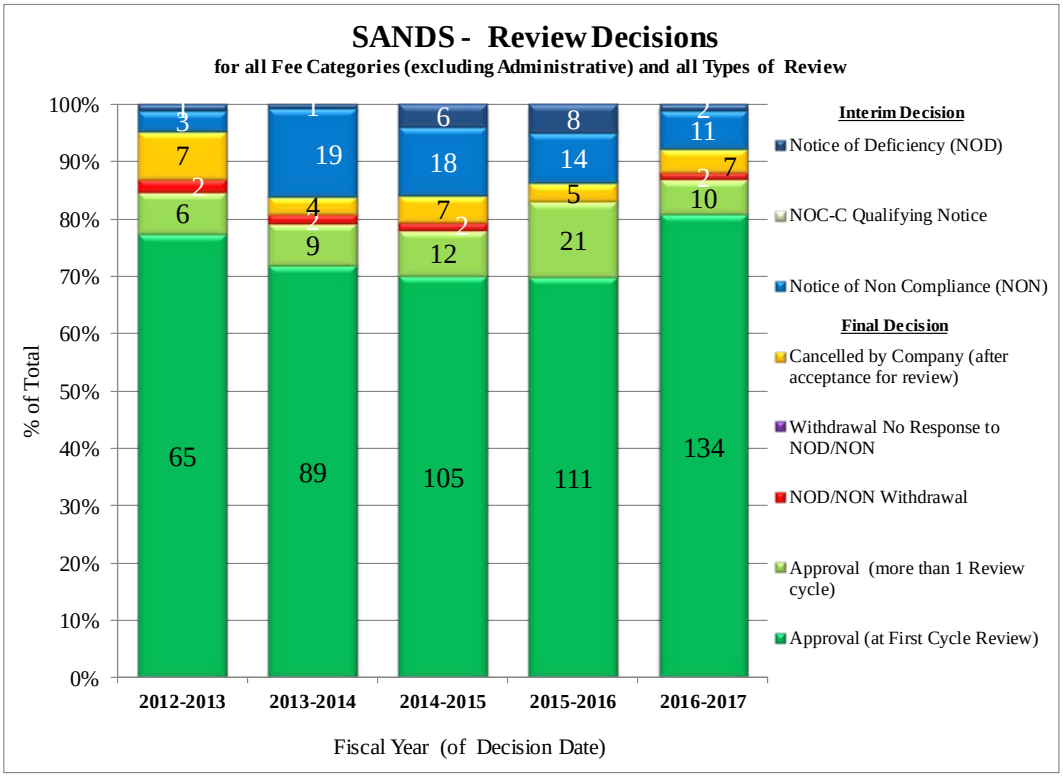


ANDS - Review Cycle Completions Showing Percentage Within Target

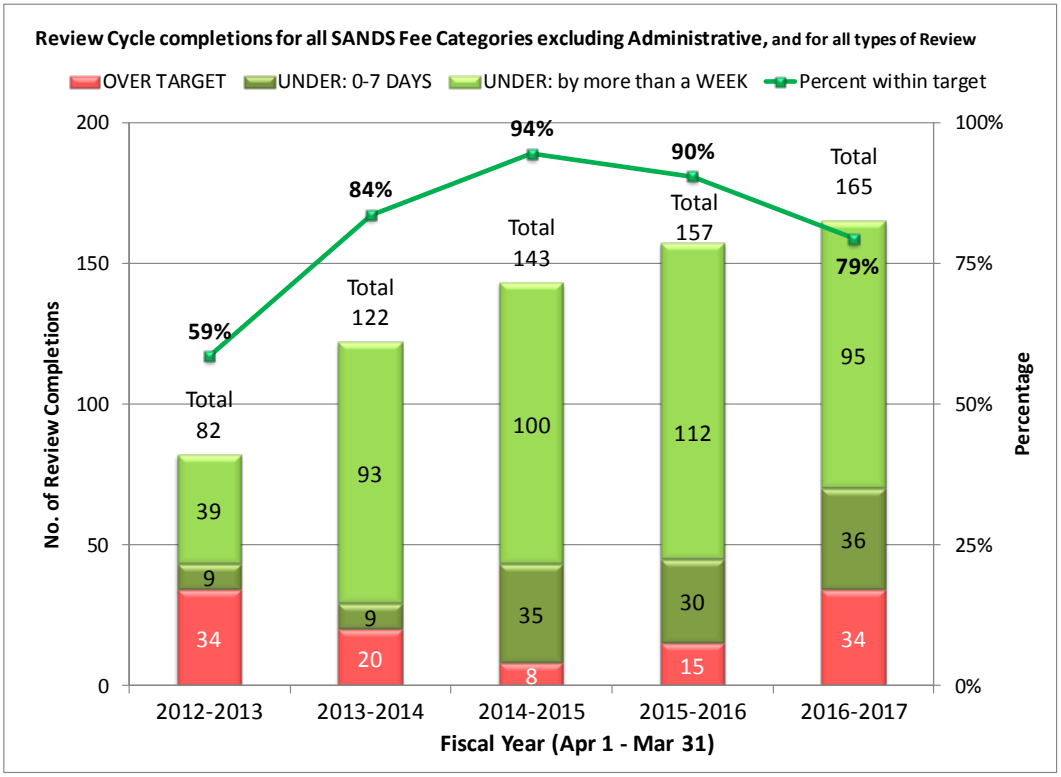


REVIEW CYCLE DECISIONS

Supplemental Abbreviated New Drug Submission (SANDS) Review Decisions

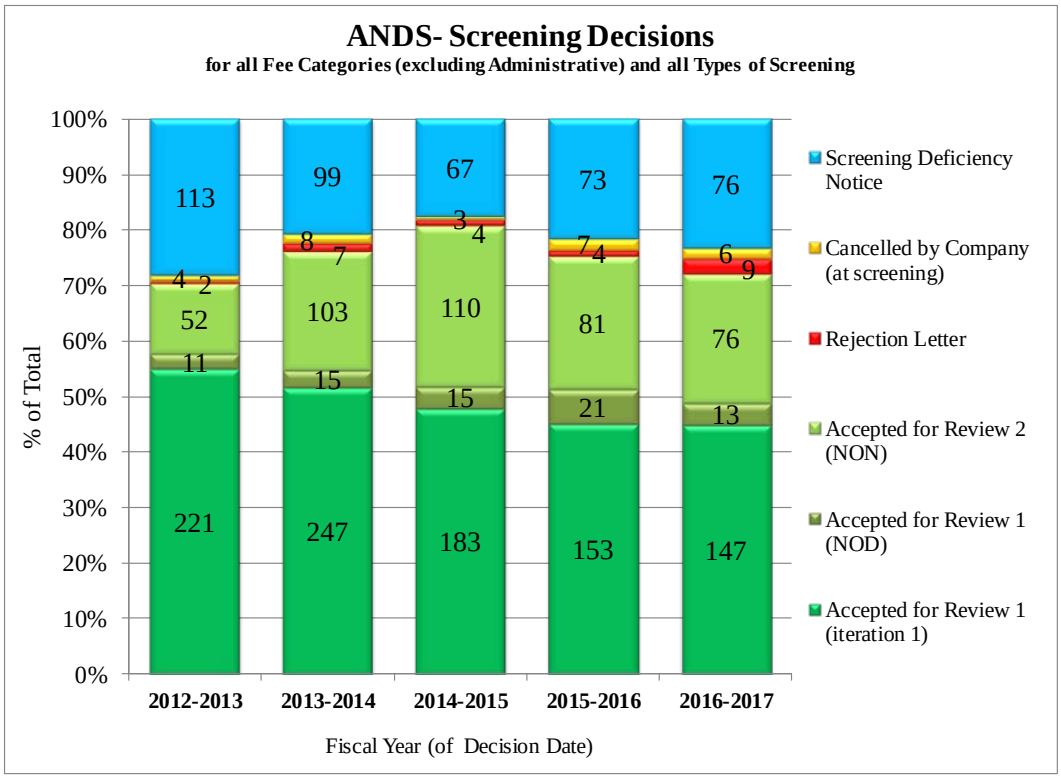


SANDS - Review Cycle Completions Showing Percentage Within Target

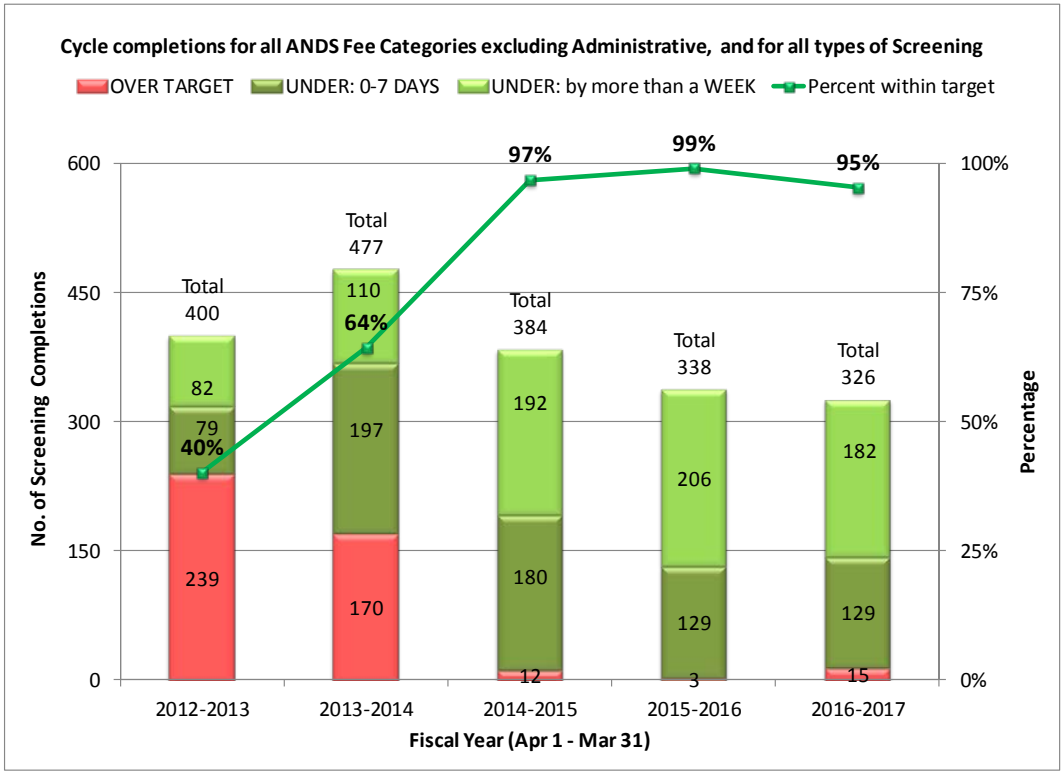


SCREENING CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Screening Decisions

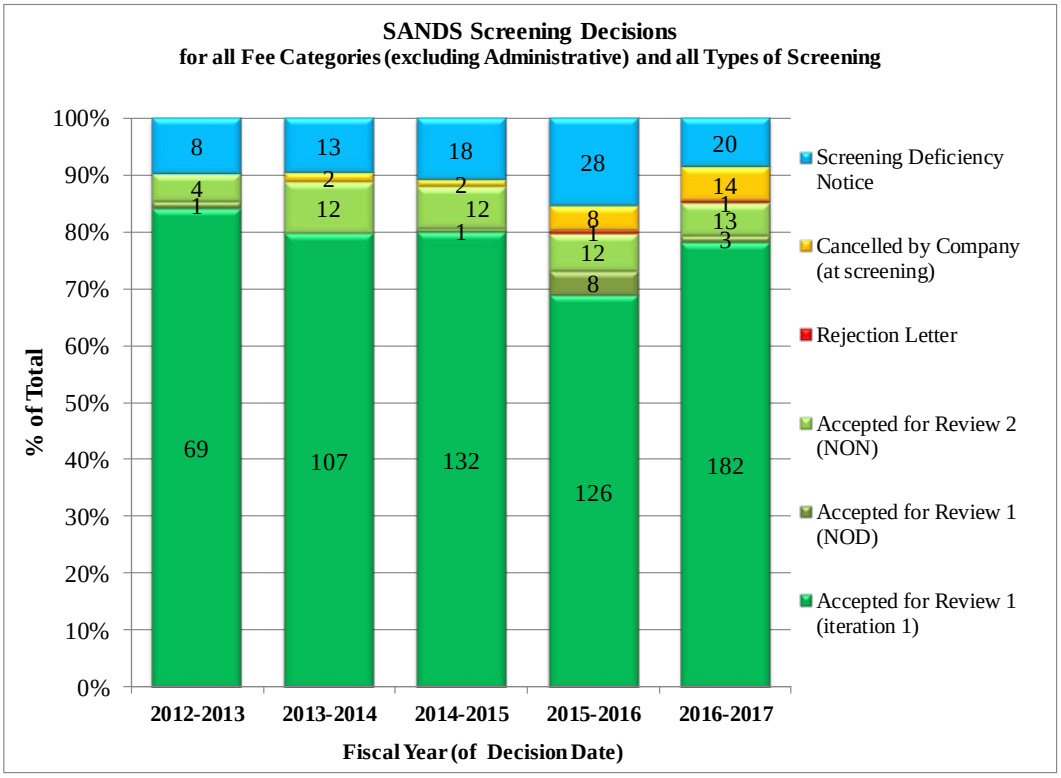


ANDS - Screening Cycle Completions Showing Percentage Within Target

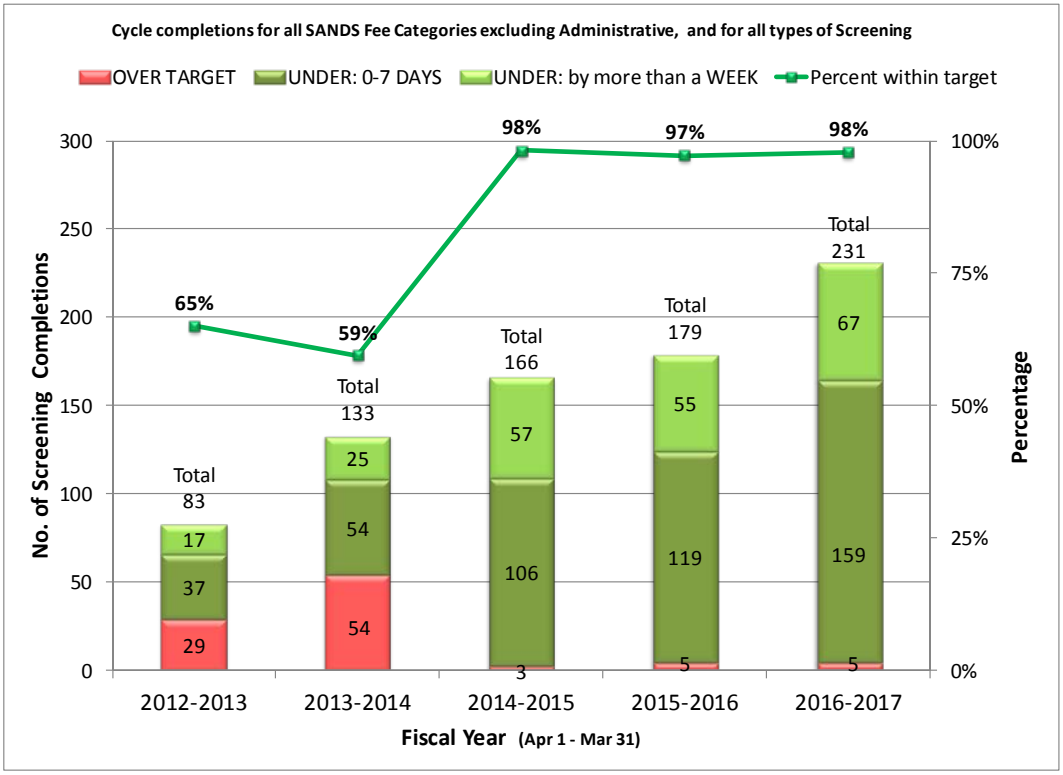


SCREENING CYCLE DECISIONS

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)

ANDS - Reconsideration of Final Decisions Requests Received

Fiscal Year of Request (April 1 - March 31)

Breakdown by Reconsideration Decision	12-13	13-14	14-15	15-16	16-17	Final Decision in Dispute	ANDS Status (as of May 12 2017)
TOTAL Received	**0**	**8**	**8**	**3**	**2**		
Total Pending	***0***	***0***	***0***	***1***	***0***		
Pending				1		NON-Withdrawal	Under Reconsideration
Total Granted	***0***	***1***	***3***	***1***	***1***		
Granted		1	3			NON-Withdrawal	Cleared
Granted				1		NON-Withdrawal	Cleared
Granted					1	Rejection at Screening	Review 1
Total Denied	***0***	***3***	***1***	***1***	***0***		
Denied		2				NOD-Withdrawal	Withdrawn
Denied		1	1	1		NON-Withdrawal	Withdrawn
Total Cancelled	***0***	***4***	***4***	***0***	***1***		
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)

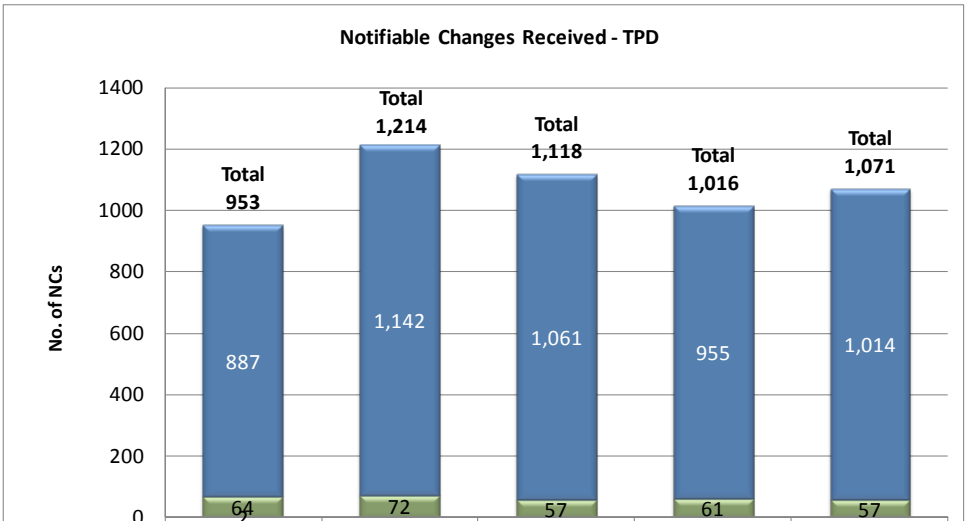
SANDS - Reconsideration of Final Decisions Requests Received

Fiscal Year of Request (April 1 - March 31)

Breakdown by Reconsideration Decision	12-13	13-14	14-15	15-16	16-17	Final Decision in Dispute	SANDS Status (as of May 12 2017)
Total Received	**0**	**0**	**0**	**1**	**1**		
Total Granted	***0***	***0***	***0***	***1***	***0***		
						NON-Withdrawal	Cleared
				1		NOD-Withdrawal	Cleared
Total Cancelled	***0***	***0***	***0***	***0***	***1***		
Cancelled by Health Canada					1	NOD-Withdrawal	Cleared

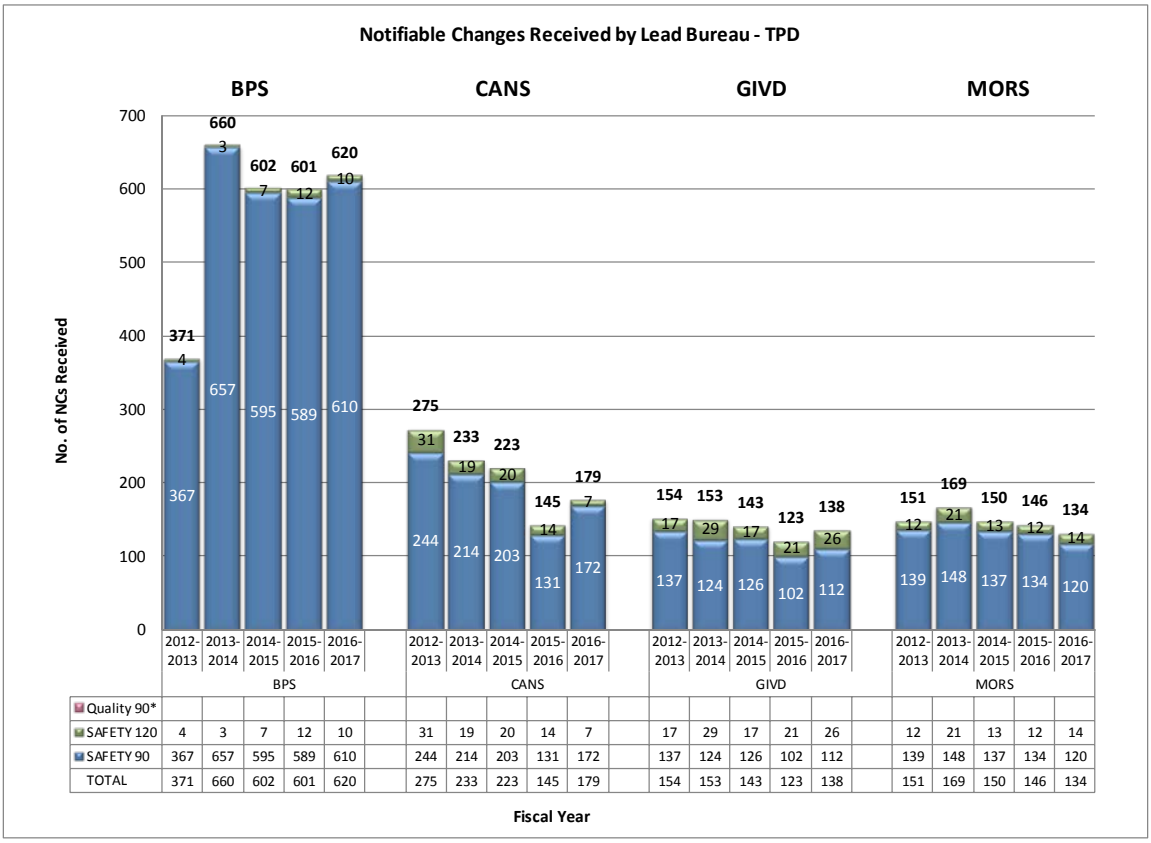
NOTIFIABLE CHANGES (NC)

Number Received - Notifiable Changes (NC)



	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Safety (90)	887	1142	1061	955	1014
Safety (120)	64	72	57	61	57
Quality (90)	2	0	0	0	0
Total	953	1214	1118	1016	1071

Number Received by Lead Bureau- Notifiable Changes (NC)

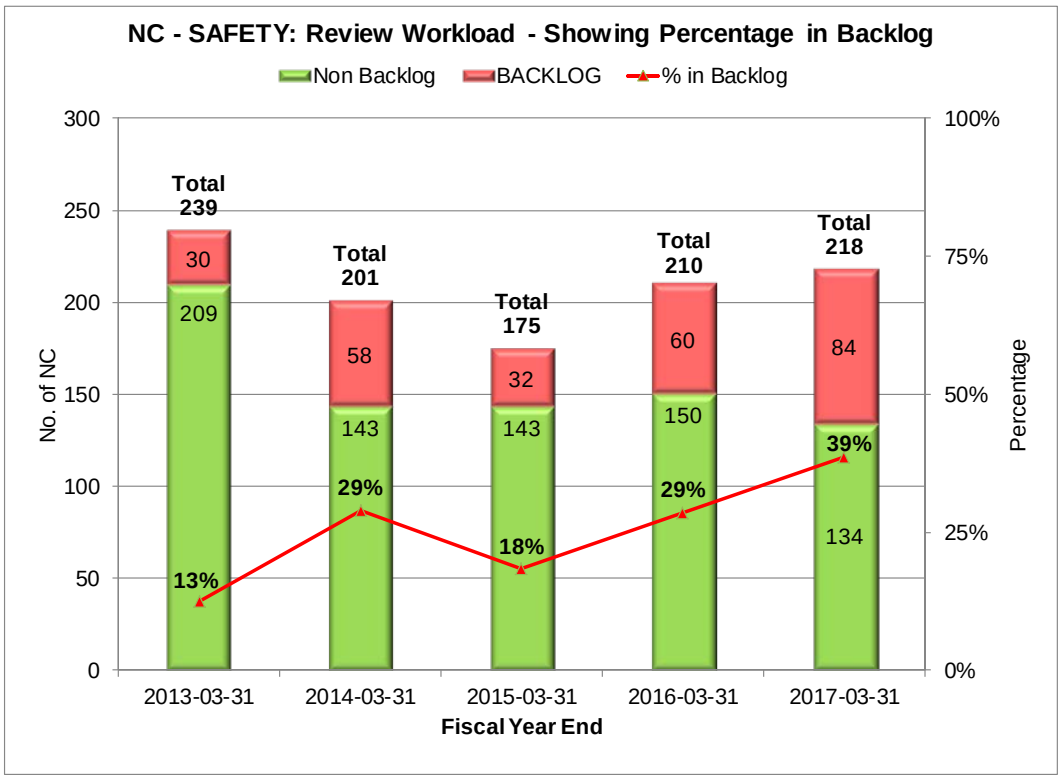


	BPS					CANS					GIVD					MORS				
	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
Quality 90*																				
SAFETY 120	4	3	7	12	10	31	19	20	14	7	17	29	17	21	26	12	21	13	12	14
SAFETY 90	367	657	595	589	610	244	214	203	131	172	137	124	126	102	112	139	148	137	134	120
TOTAL	371	660	602	601	620	275	233	223	145	179	154	153	143	123	138	151	169	150	146	134

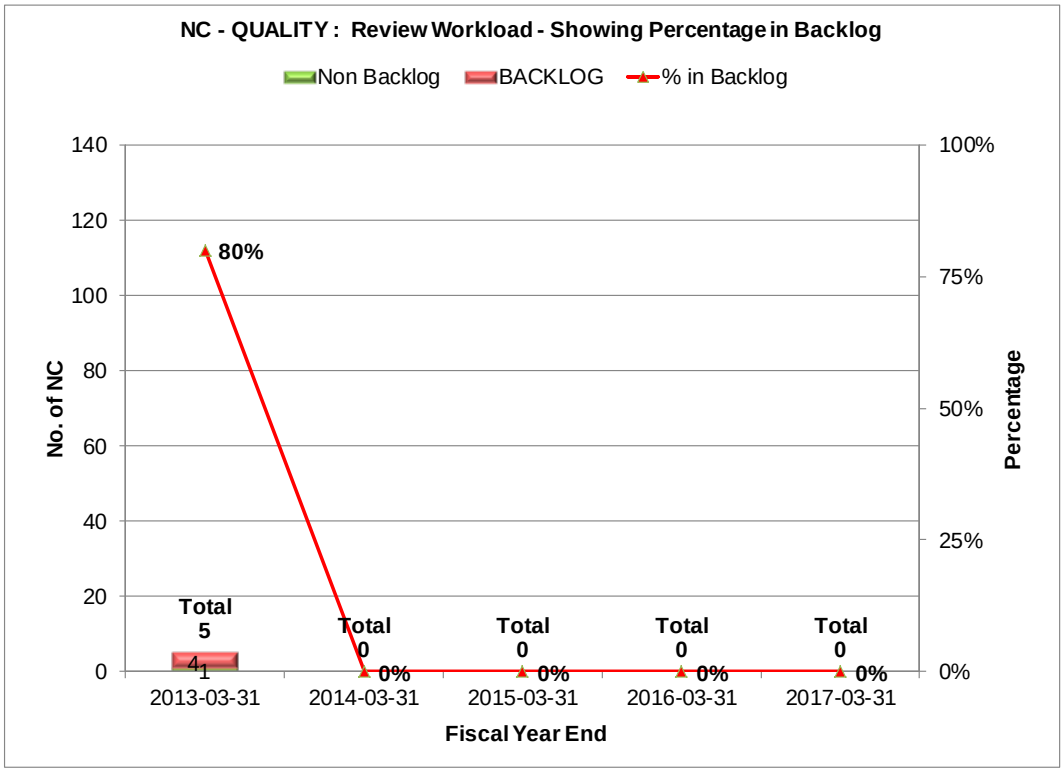
In February 2013 the Safety Labelling Changes to the Product Monographs of Brand Name Pharmaceutical Drug Products process was introduced to inform generic drug manufacturers about new safety information for pharmaceutical drug products so that they can update their PMs for health care professionals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

WORKLOAD

Notifiable Change (NC) SAFETY: Review Workload / Backlog



Notifiable Change (NC) QUALITY: Review Workload / Backlog



WORKLOAD

Notifiable Change (NC) SAFETY: Review Workload by Class

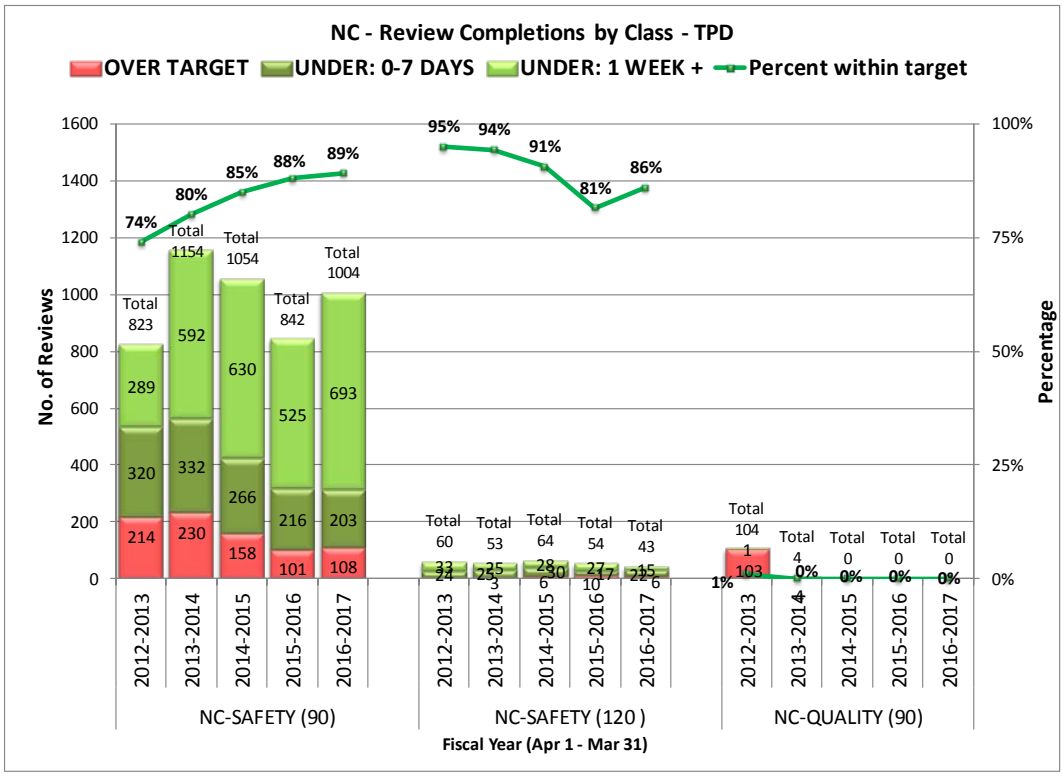
TPD NC- SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2013-03-31	2014-03-31	2015-03-31	2016-03-31	2017-03-31
SAFETY - 90 day	227	177	156	194	188
Backlog	*29*	*57*	*32*	*60*	*78*
SAFETY - 120 day	12	24	19	16	30
Backlog	*1*	*1*	*0*	*0*	*6*
Total	239	201	175	210	218
Non Backlog	209	143	143	150	134
BACKLOG	30	58	32	60	84
% in Backlog	13%	29%	18%	29%	39%

Notifiable Change (NC) QUALITY: Review Workload by Class

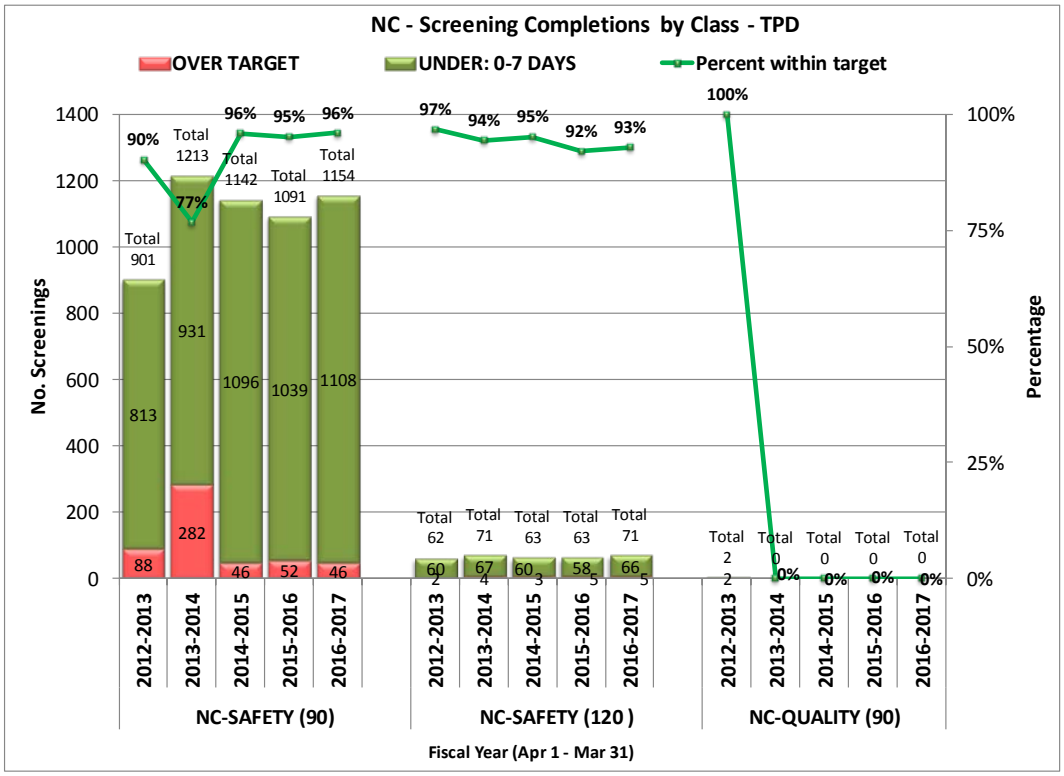
TPD NC- QUALITY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2013-03-31	2014-03-31	2015-03-31	2016-03-31	2017-03-31
QUALITY - 90 day	5	0	0	0	0
Backlog	*4*	*0*	*0*	*0*	*0*
Total	5	0	0	0	0
Non Backlog	1	0	0	0	0
BACKLOG	4	0	0	0	0
% in Backlog	80%	0%	0%	0%	0%

PERFORMANCE

REVIEW Completions by Class - Notifiable Changes (NC)



SCREENING Completions by Class - Notifiable Changes (NC)



DECISIONS

Decision Documents by Class - Notifiable Change (NC) Safety

NC - SAFETY (90)					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER	797	1098	1065	834	954
CANCELLED BY COMPANY	34	42	49	62	65
NC - HOLD (PATENT)	45	72	34	45	69
SCREEN. DEFICIENCY NOTICE	27	91	85	197	136
REJECTION LETTER (SCR)	1	5	6	3	2
NOT SATISFACTORY NOTICE	7	2	5	1	2
SPONSOR SUB CHANGE ACCEPT				1	

NC - SAFETY (120)					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER	60	49	63	54	43
NOT SATISFACTORY NOTICE		1	1		
SCREENING DEFICIENCY NOTICE		1	3	6	11
CANCELLED BY COMPANY	1	7	1	6	4
REJECTION LETTER (SCR)		1		1	

Decision Documents by Class - Notifiable Change (NC) Quality

NC - QUALITY (90)					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER	105	8	6	-	-
SCREEN. DEFICIENCY NOTICE				-	-
CANCELLED BY COMPANY	6			-	-
REJECTION LETTER (SCR)				-	-
NC - HOLD (PATENT)				-	-
NOT SATISFACTORY NOTICE	2			-	-

REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – Notifiable Changes (NC)

Notifiable Changes - Requests for Reconsideration of Final Decisions Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	**12-13**	**13-14**	**14-15**	**15-16**	**16-17**	**Final Decision in Dispute**	**NC's Status (as of May 12 2017)**
Total Received	**0**	**0**	**0**	**0**	**0**		
Total Granted	***0***	***0***	***0***	***0***	***0***		
Total Denied	***0***	***0***	***0***	***0***	***0***		

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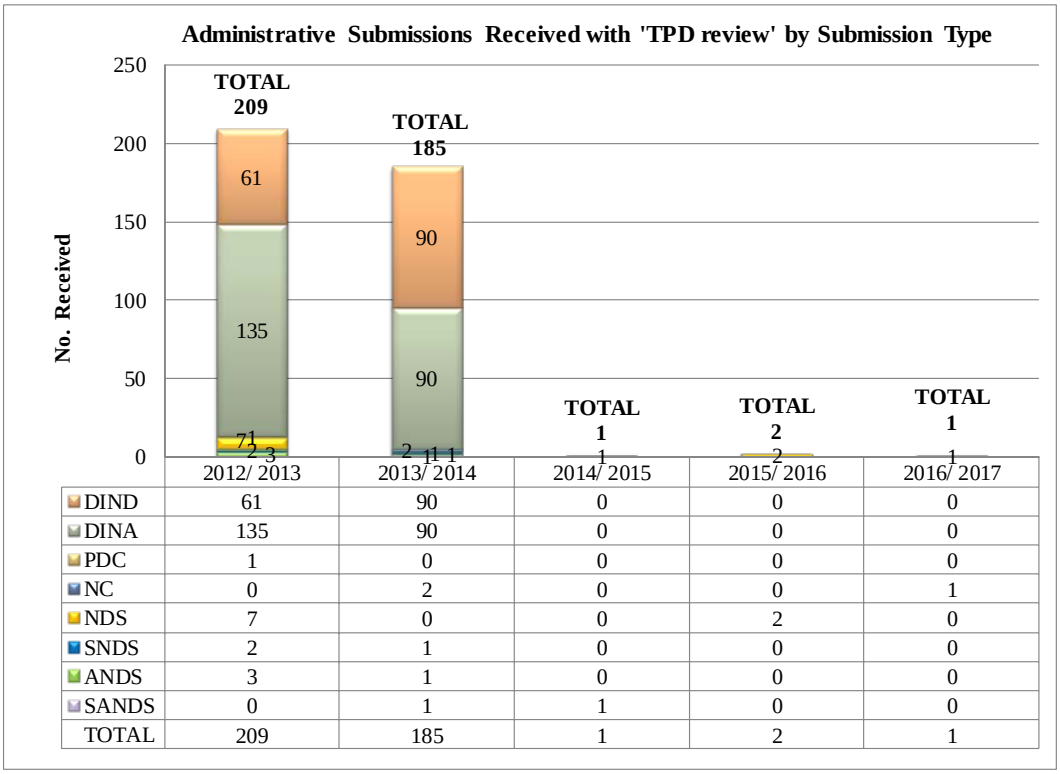
Administrative Submissions

Submissions in support of a manufacturer or product name change.

ADMINISTRATIVE SUBMISSIONS with TPD review

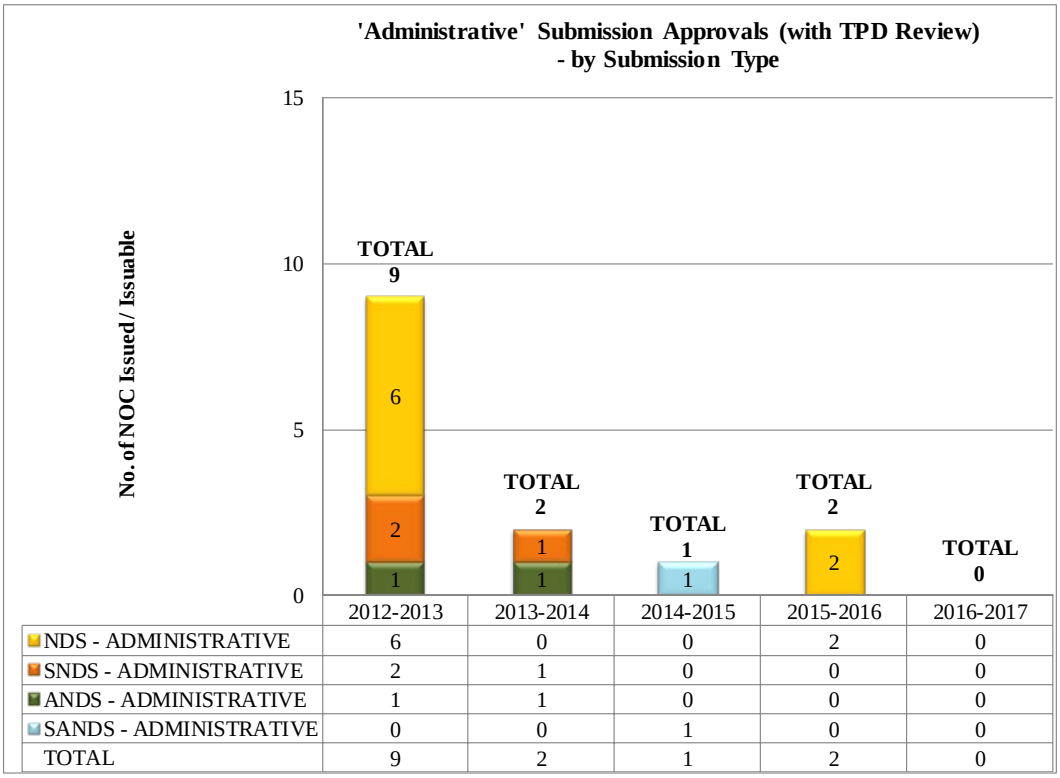
(such as product name change that requires a drug name review)

Administrative Submissions Received (with TPD review)



	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
DIND	61	90	0	0	0
DINA	135	90	0	0	0
PDC	1	0	0	0	0
NC	0	2	0	0	1
NDS	7	0	0	2	0
SNDS	2	1	0	0	0
ANDS	3	1	0	0	0
SANDS	0	1	1	0	0
TOTAL	209	185	1	2	1

Administrative Submission Approvals (with TPD Review)

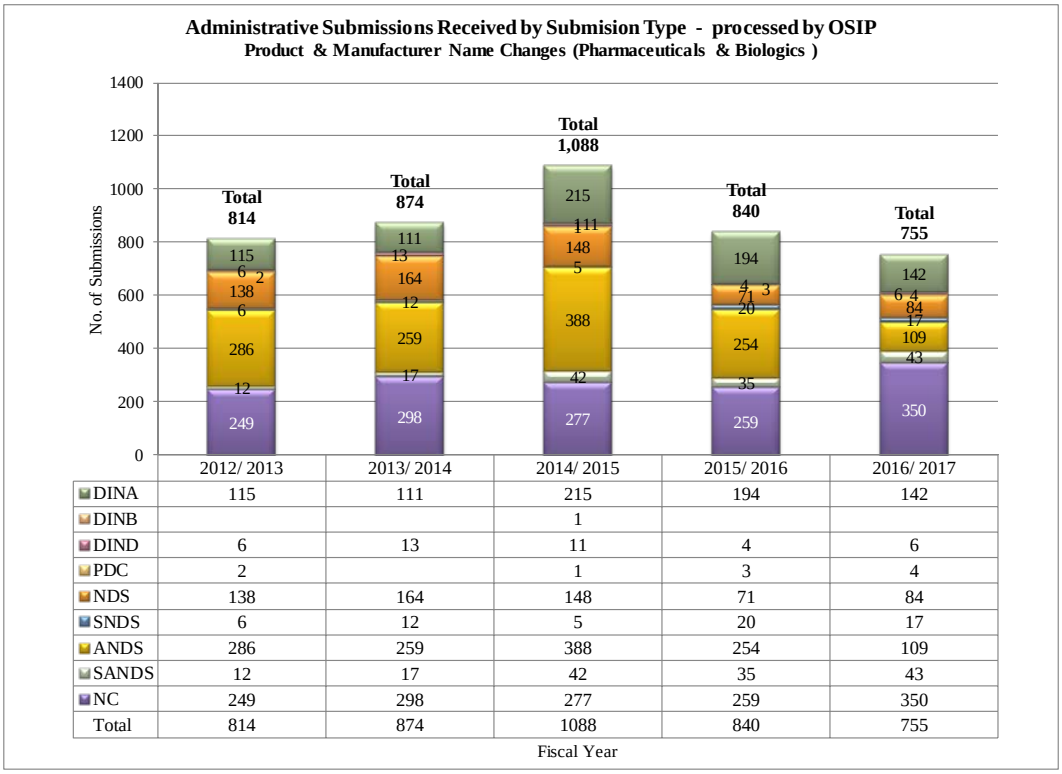


	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
NDS - ADMINISTRATIVE	6	0	0	2	0
SNDS - ADMINISTRATIVE	2	1	0	0	0
ANDS - ADMINISTRATIVE	1	1	0	0	0
SANDS - ADMINISTRATIVE	0	0	1	0	0
TOTAL	9	2	1	2	0

ADMINISTRATIVE SUBMISSIONS (Processed by OSIP)

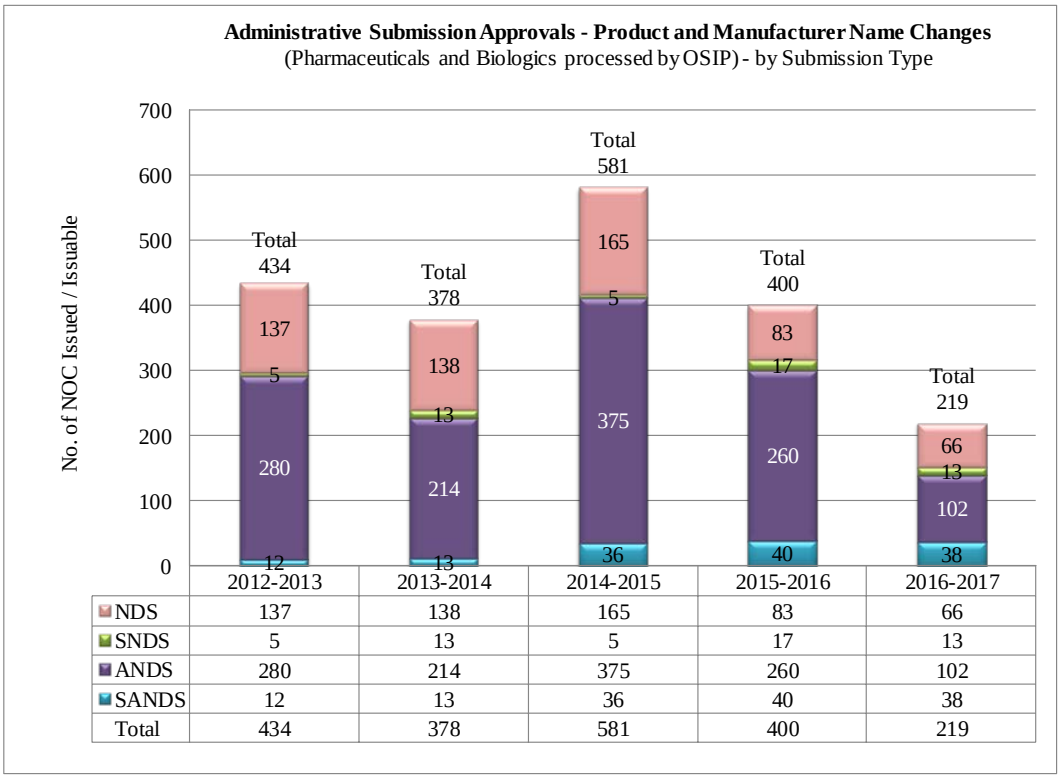
(Product & Manufacturer Name Changes)
(Admin Ncs are for cross-referenced changes)

Administrative Submissions Received by Submission Type (OSIP)



	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
DINA	115	111	215	194	142
DINB			1		
DIND	6	13	11	4	6
PDC	2		1	3	4
NDS	138	164	148	71	84
SNDS	6	12	5	20	17
ANDS	286	259	388	254	109
SANDS	12	17	42	35	43
NC	249	298	277	259	350
Total	814	874	1088	840	755

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



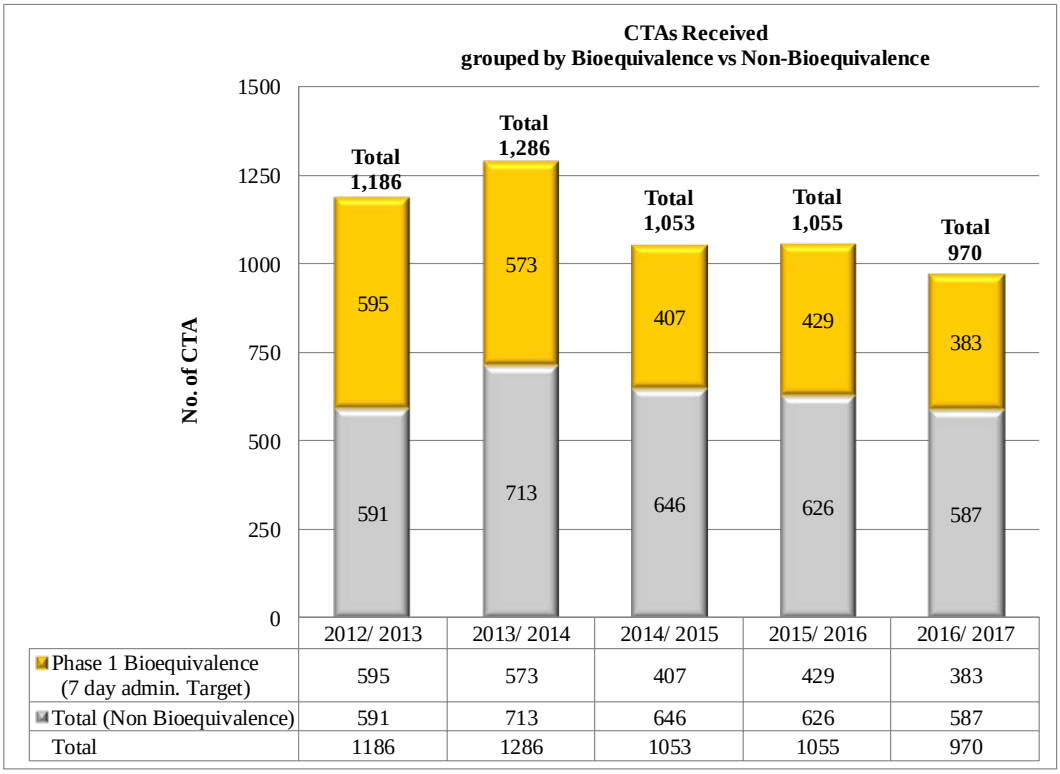
	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
NDS	137	138	165	83	66
SNDS	5	13	5	17	13
ANDS	280	214	375	260	102
SANDS	12	13	36	40	38
Total	434	378	581	400	219

Clinical Trial Applications and Amendments

(CTA & CTA-A)

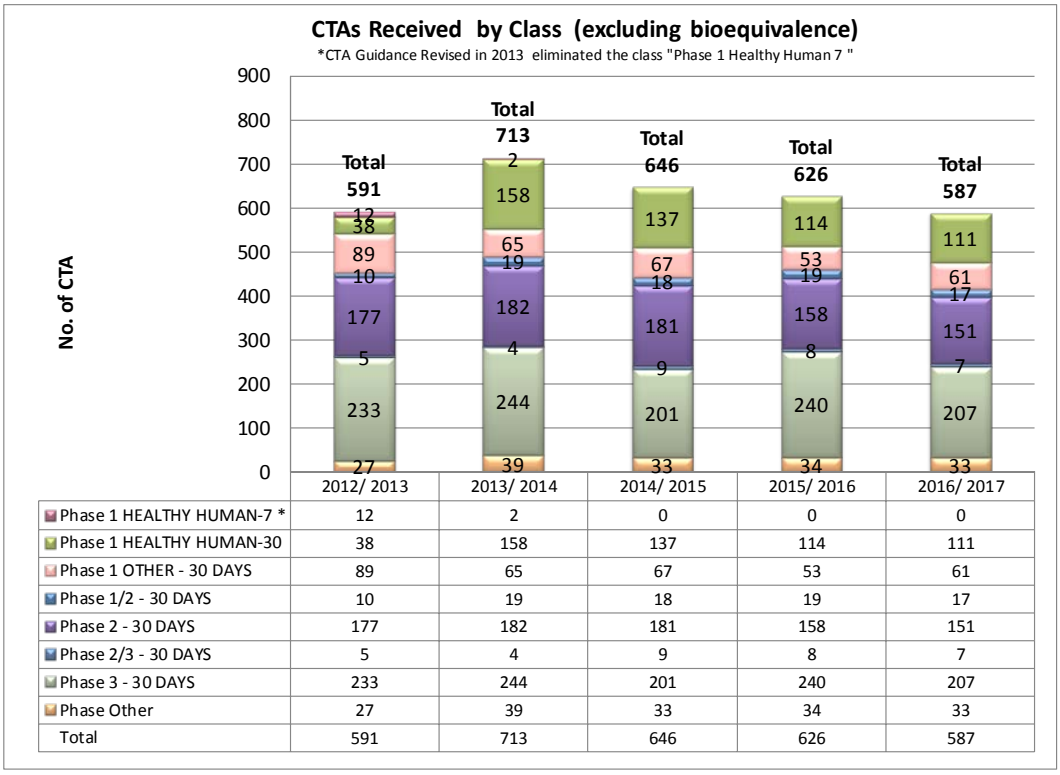
CLINICAL TRIAL APPLICATIONS

Number Received - Clinical Trial Application (CTA)



	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Phase 1 Bioequivalence (7 day admin. Target)	595	573	407	429	383
Total (Non Bioequivalence)	591	713	646	626	587
Total	1186	1286	1053	1055	970

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



	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Phase 1 HEALTHY HUMAN-7 *	12	2	0	0	0
Phase 1 HEALTHY HUMAN-30	38	158	137	114	111
Phase 1 OTHER - 30 DAYS	89	65	67	53	61
Phase 1/2 - 30 DAYS	10	19	18	19	17
Phase 2 - 30 DAYS	177	182	181	158	151
Phase 2/3 - 30 DAYS	5	4	9	8	7
Phase 3 - 30 DAYS	233	244	201	240	207
Phase Other	27	39	33	34	33
Total	591	713	646	626	587

DECISION DOCUMENTS

Decision Documents - Clinical Trial Application (CTA)

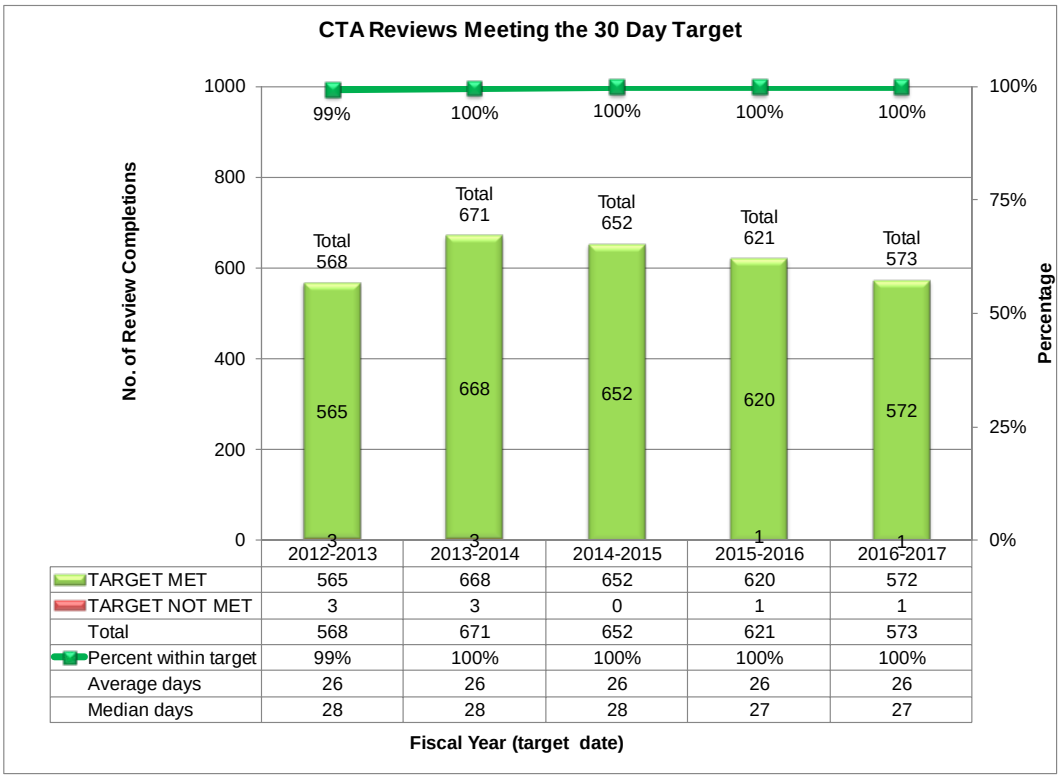
CTA (Total)					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER	1139	1186	1021	994	926
CANCELLED BY COMPANY DURING REVIEW	39	54	48	44	36
CANCELLED BY COMPANY AT PROCESSING	0	17	7	8	4

CTA (7 day administrative target*)	*Phase 1 Bioequivalence (Class Phase 1 Healthy Human 7 eliminated in 2013)				
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER	596	553	410	405	386
CANCELLED BY COMPANY DURING REVIEW	13	16	6	12	3
CANCELLED BY COMPANY AT PROCESSING	0	2	0	0	0

CTA (30 day target)					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER	543	633	611	589	540
CANCELLED BY COMPANY DURING REVIEW	26	38	42	32	33
CANCELLED BY COMPANY AT PROCESSING	0	15	7	8	4

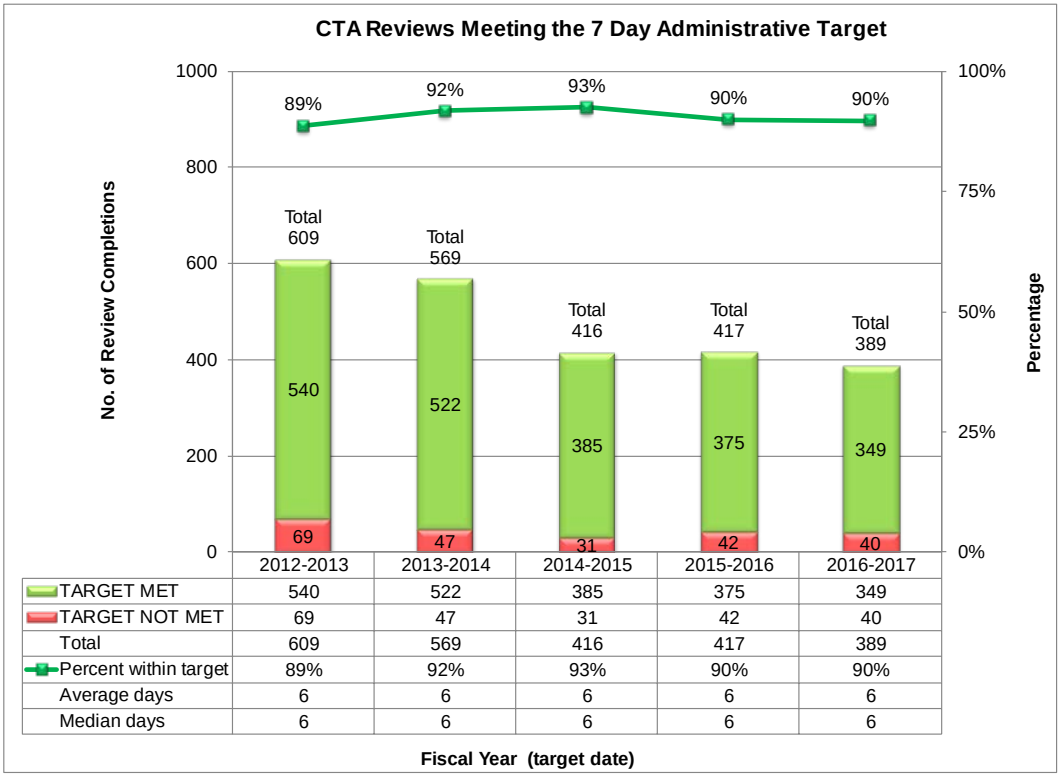
PERFORMANCE

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



	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
TARGET MET	565	668	652	620	572
TARGET NOT MET	3	3	0	1	1
Total	568	671	652	621	573
Percent within target	99%	100%	100%	100%	100%
Average days	26	26	26	26	26
Median days	28	28	28	27	27

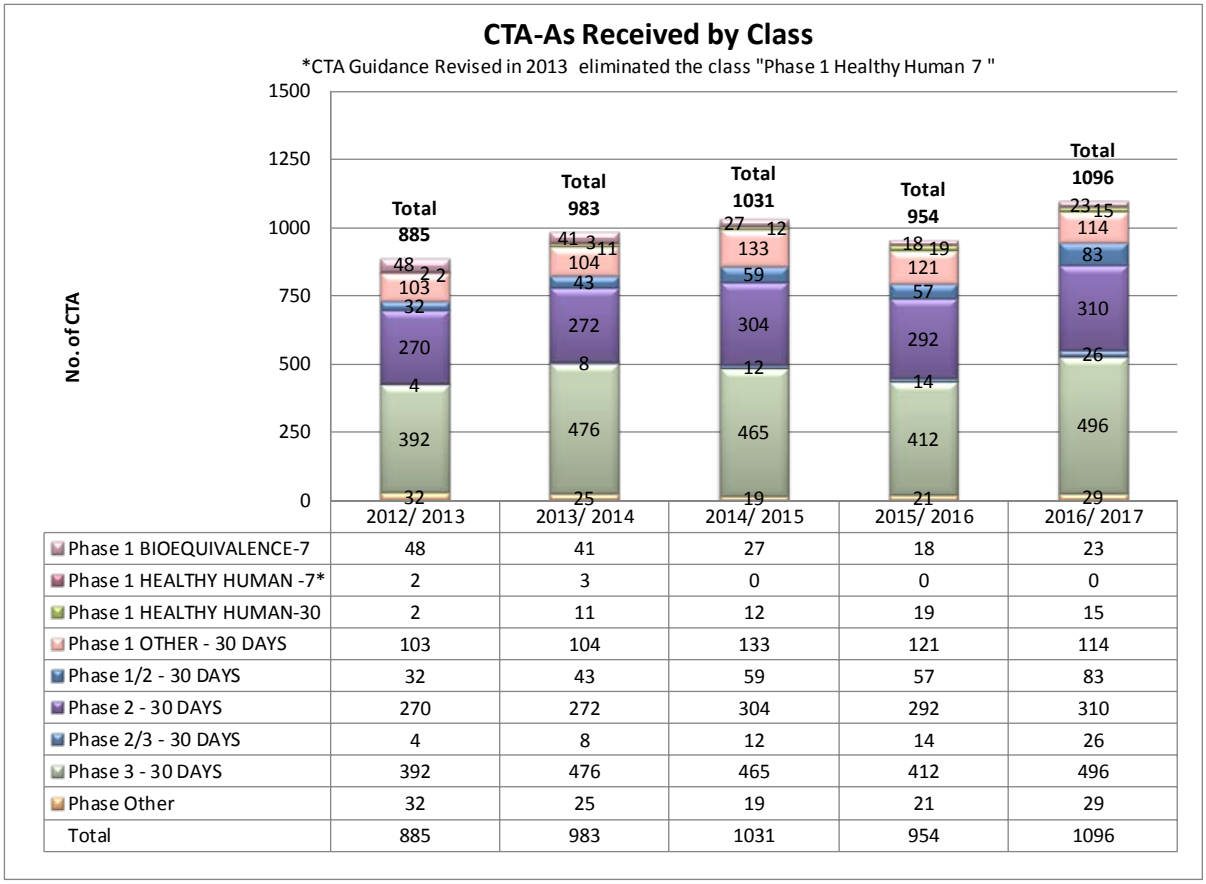
Performance – CTA Reviews Meeting the 7 Day Administrative Target



	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
TARGET MET	540	522	385	375	349
TARGET NOT MET	69	47	31	42	40
Total	609	569	416	417	389
Percent within target	89%	92%	93%	90%	90%
Average days	6	6	6	6	6
Median days	6	6	6	6	6

CLINICAL TRIAL APPLICATION-AMENDMENTS

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



	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Phase 1 BIOEQUIVALENCE-7	48	41	27	18	23
Phase 1 HEALTHY HUMAN -7*	2	3	0	0	0
Phase 1 HEALTHY HUMAN-30	2	11	12	19	15
Phase 1 OTHER - 30 DAYS	103	104	133	121	114
Phase 1/2 - 30 DAYS	32	43	59	57	83
Phase 2 - 30 DAYS	270	272	304	292	310
Phase 2/3 - 30 DAYS	4	8	12	14	26
Phase 3 - 30 DAYS	392	476	465	412	496
Phase Other	32	25	19	21	29
Total	885	983	1031	954	1096

DECISION DOCUMENTS

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

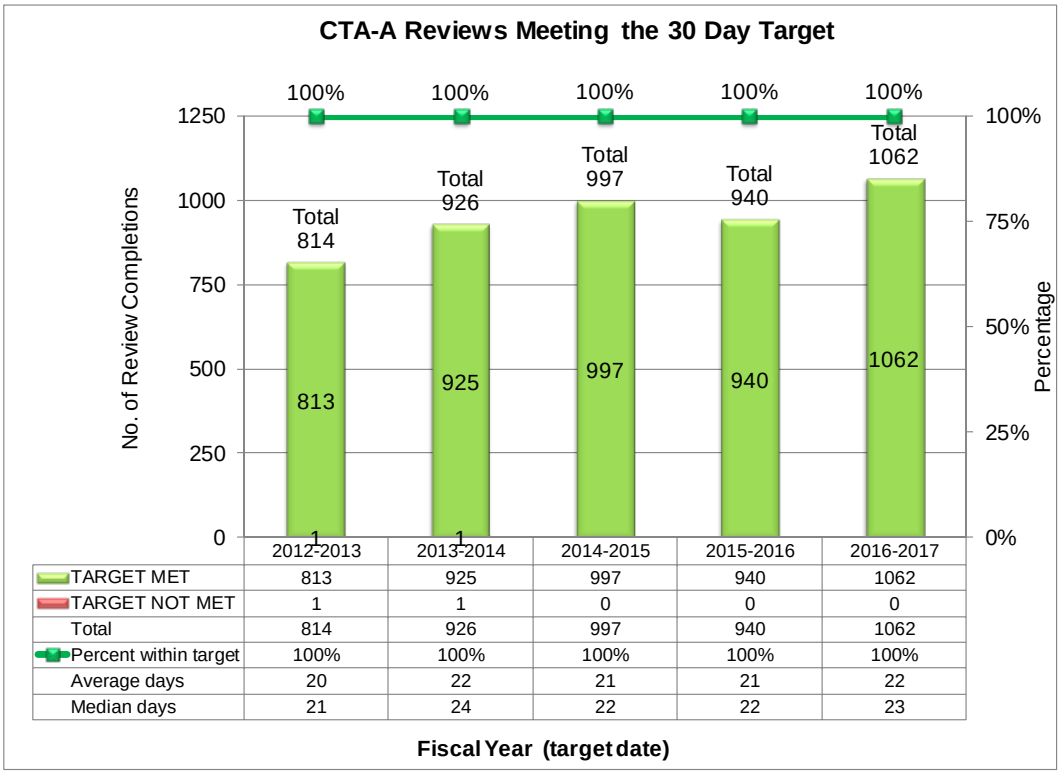
CTA-A (Total)					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER	859	963	1013	949	1070
CANCELLED BY COMPANY DURING REVIEW	5	8	11	9	15
CANCELLED BY COMPANY AT PROCESSING	5	0	4	0	0

CTA-A (7 day administrative target)					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER	49	43	26	18	23
CANCELLED BY COMPANY DURING REVIEW	1	0	0	0	0
CANCELLED BY COMPANY AT PROCESSING	0	0	0	0	0

CTA-A (30 day target)					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER	810	920	987	931	1047
CANCELLED BY COMPANY DURING REVIEW	4	8	11	9	15
CANCELLED BY COMPANY AT PROCESSING	5	0	4	0	0

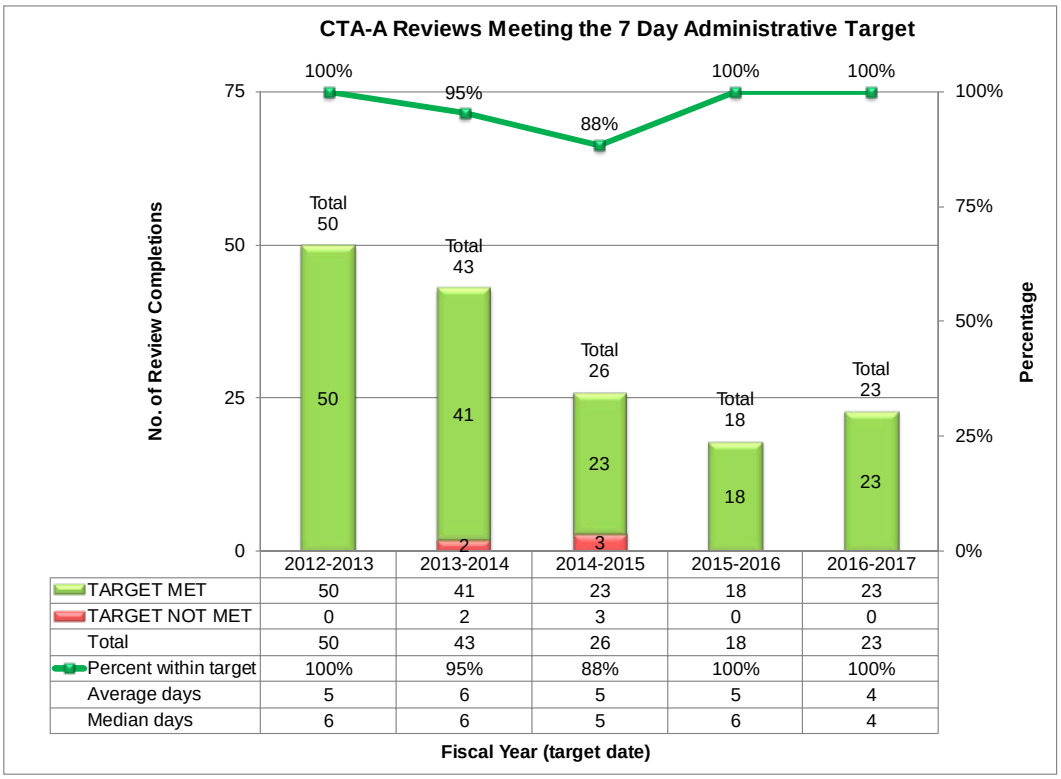
PERFORMANCE

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



	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
TARGET MET	813	925	997	940	1062
TARGET NOT MET	1	1	0	0	0
Total	814	926	997	940	1062
Percent within target	100%	100%	100%	100%	100%
Average days	20	22	21	21	22
Median days	21	24	22	22	23

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



	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
TARGET MET	50	41	23	18	23
TARGET NOT MET	0	2	3	0	0
Total	50	43	26	18	23
Percent within target	100%	95%	88%	100%	100%
Average days	5	6	5	5	4
Median days	6	6	5	6	4

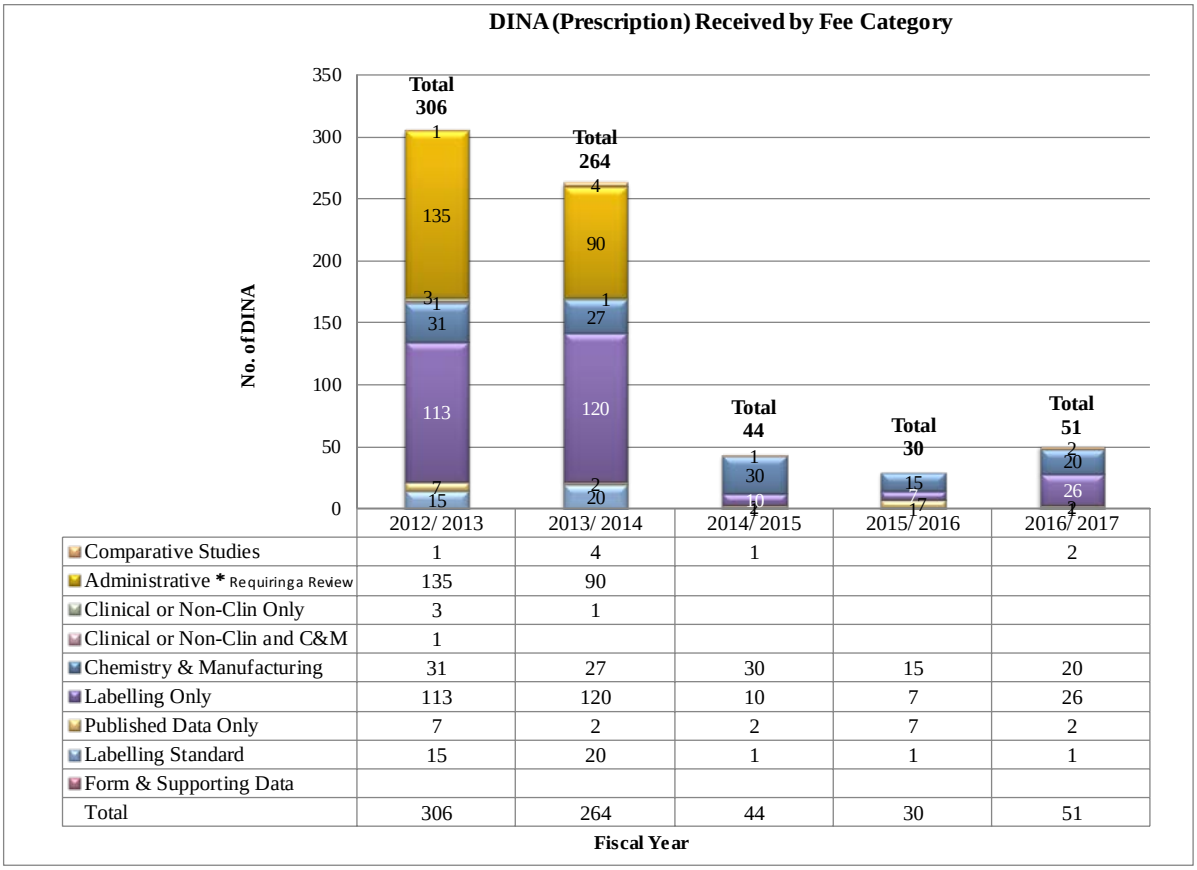
DINA (Prescription)

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 (Prescription): APPLICATION FOR A DRUG IDENTIFICATION NUMBER

DINA: Number Received

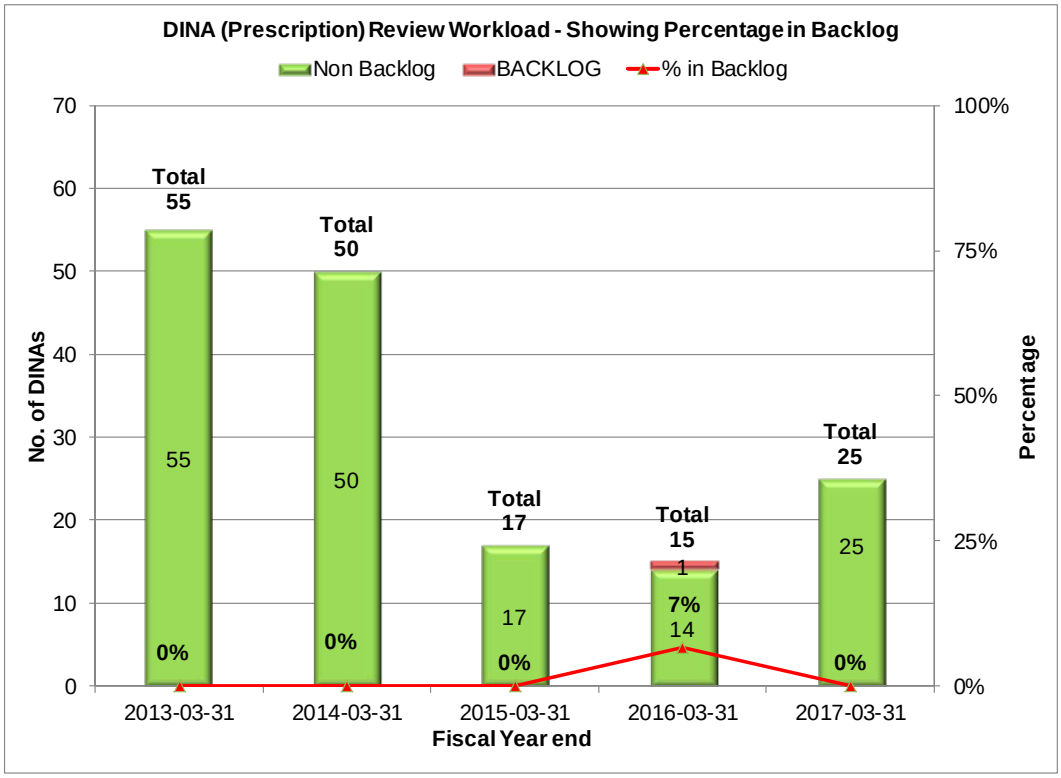


	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Comparative Studies	1	4	1		2
Administrative * Requiring a Review	135	90			
Clinical or Non-Clin Only	3	1			
Clinical or Non-Clin and C&M	1				
Chemistry & Manufacturing	31	27	30	15	20
Labelling Only	113	120	10	7	26
Published Data Only	7	2	2	7	2
Labelling Standard	15	20	1	1	1
Form & Supporting Data					
Total	306	264	44	30	51

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

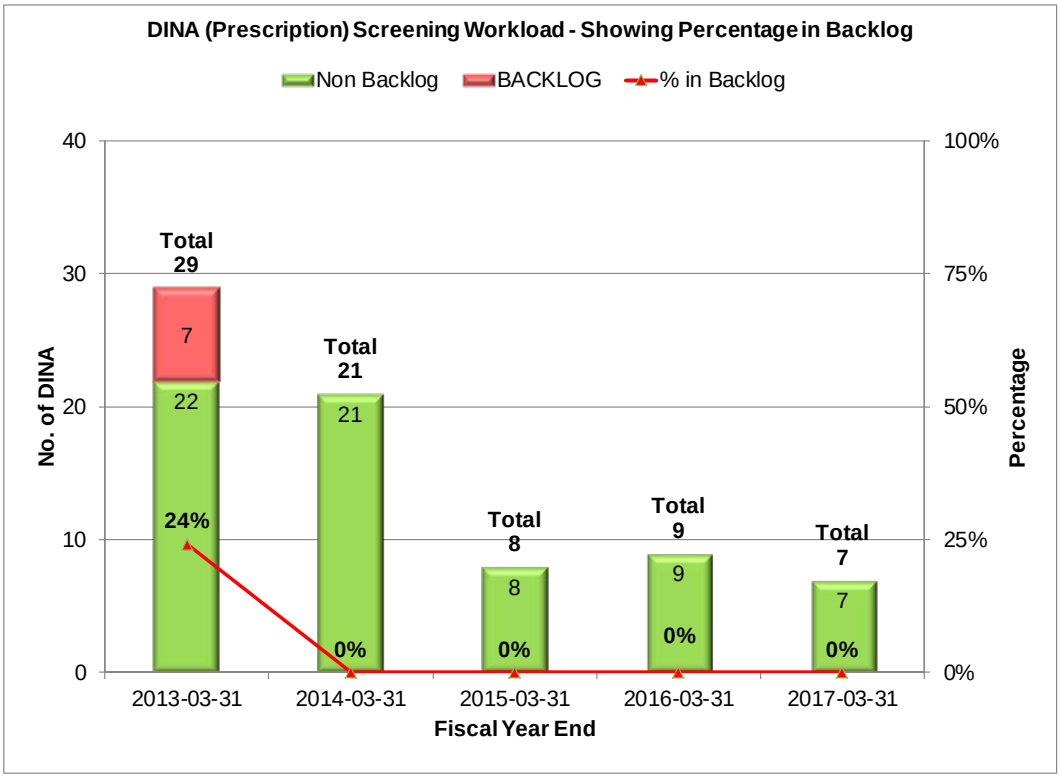


DINA: Review Workload by Class

TPD DINA (PRESCRIPTION) All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2013-03-31	2014-03-31	2015-03-31	2016-03-31	2017-03-31
Labelling Only	**44**	**32**	**2**	**4**	**13**
Backlog	*0*	*0*	*0*	*0*	*0*
Form and Supporting Data	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	**2**	**1**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**1**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**4**	**15**	**14**	**9**	**12**
Backlog	*0*	*0*	*0*	*1*	*0*
Published Data	**4**	**0**	**0**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**0**	**2**	**1**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**55**	**50**	**17**	**15**	**25**
Non Backlog	**55**	**50**	**17**	**14**	**25**
BACKLOG	**0**	**0**	**0**	**1**	**0**
% in Backlog	**0%**	**0%**	**0%**	**7%**	**0%**

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					
	2013-03-31	2014-03-31	2015-03-31	2016-03-31	2017-03-31
Labelling Only	**15**	**13**	**3**	**1**	**4**
Backlog	*1*	*0*	*0*	*0*	*0*
Form & Supporting Data	**1**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Standard	**1**	**4**	**0**	**0**	**0**
Backlog	*1*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**10**	**3**	**3**	**5**	**2**
Backlog	**5**	**0**	**0**	**0**	**0**
Clinical or Non-Clinical Only	*1*	*0*	*0*	*0*	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data Only	***2***	***0***	***1***	***3***	***0***
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**0**	**1**	**1**	**0**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**29**	**21**	**8**	**9**	**7**
Non Backlog	**22**	**21**	**8**	**9**	**7**
BACKLOG	**7**	**0**	**0**	**0**	**0**
% in Backlog	**24%**	**0%**	**0%**	**0%**	**0%**

DECISION DOCUMENTS

DINA: Decision Documents by Fee Category

CLASS	DOCUMENT TYPE	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
DINA - LABELLING ONLY	NOTIFICATION FORM/DIN ISSUED	54	92	4	1	3
	NO OBJECTION LETTER	11	21	6	5	4
	CANCELLED BY COMPANY	16	10		1	6
	DIN INCORR SUBTYPE-CLASS	20	17			
	NEW DRUG LETTER SCREEN	1	3			
	NON WITHDRAWAL LETTER	1				
	NOTICE OF DEFICIENCY	1		2		1
	NOTICE OF NON-COMPLIANCE	3	8			1
	REJECTION LETTER (SCREENING)	4				
	SCREENING DEFICIENCY NOTICE	30	17	4	2	9
	SPONSOR SUB CHANGE ACCEPT	12	10			
DINA - ADMINISTRATIVE	NOTIFICATION FORM/DIN ISSUED	90	87	-	-	-
	NO OBJECTION LETTER	1	1	-	-	-
	REJECTION LETTER (SCREENING)	31	10	-	-	-
	SCREENING DEFICIENCY NOTICE	6	6	-	-	-
	CANCELLED BY COMPANY	3	2	-	-	-
	NOT SATISFACTORY NOTICE					
DINA - LABELLING STANDARD	NOTIFICATION FORM/DIN ISSUED	10	16			
	NO OBJECTION LETTER	1				
	NEW DRUG LETTER SCREEN	1	1			
	REJECTION LETTER (SCREENING)					1
	SCREENING DEFICIENCY NOTICE	1	1	1		
	SPONSOR SUB CHANGE ACCEPT					
	DIN INCORR SUBTYPE-CLASS					
	CANCELLED BY COMPANY	2	1	1		
DINA - PUBLISHED DATA ONLY	NO OBJECTION LETTER	2			3	2
	NOTICE OF DEFICIENCY	1				
	REJECTION LETTER (SCREENING)			1		
	SCREENING DEFICIENCY NOTICE	2				
	CANCELLED BY COMPANY		2		1	1
	NOTICE OF NON-COMPLIANCE				1	1
	NOT SATISFACTORY NOTICE					1
DINA - CHEMISTRY & MANUFACTURING	NOTIFICATION FORM/DIN ISSUED	19	8	17	12	6
	NOD WITHDRAWAL LETTER	1				
	NOTICE OF DEFICIENCY	1		3	2	1
	REJECTION LETTER (SCREENING)	4	3			3
	SCREENING DEFICIENCY NOTICE	5	15	11	12	17
	CANCELLED BY COMPANY	1	5		3	4
	NO OBJECTION LETTER	6	3	8	6	5
	NEW DRUG LETTER SCREEN		1			
	NOTICE OF NON-COMPLIANCE		6	3	4	8
	NON WITHDRAWAL LETTER					1
DINA - CLINICAL OR NON-CLINICAL DATA	NOTIFICATION FORM/DIN ISSUED	1	1			
	NOTICE OF DEFICIENCY	1				
	NO OBJECTION LETTER		3			
DINA - COMPARATIVE STUDIES	NOTIFICATION FORM/DIN ISSUED	2	1	2	1	2
	NO OBJECTION LETTER		1			
	NOTICE OF DEFICIENCY		1	1	1	
	SCREENING DEFICIENCY NOTICE		1			1

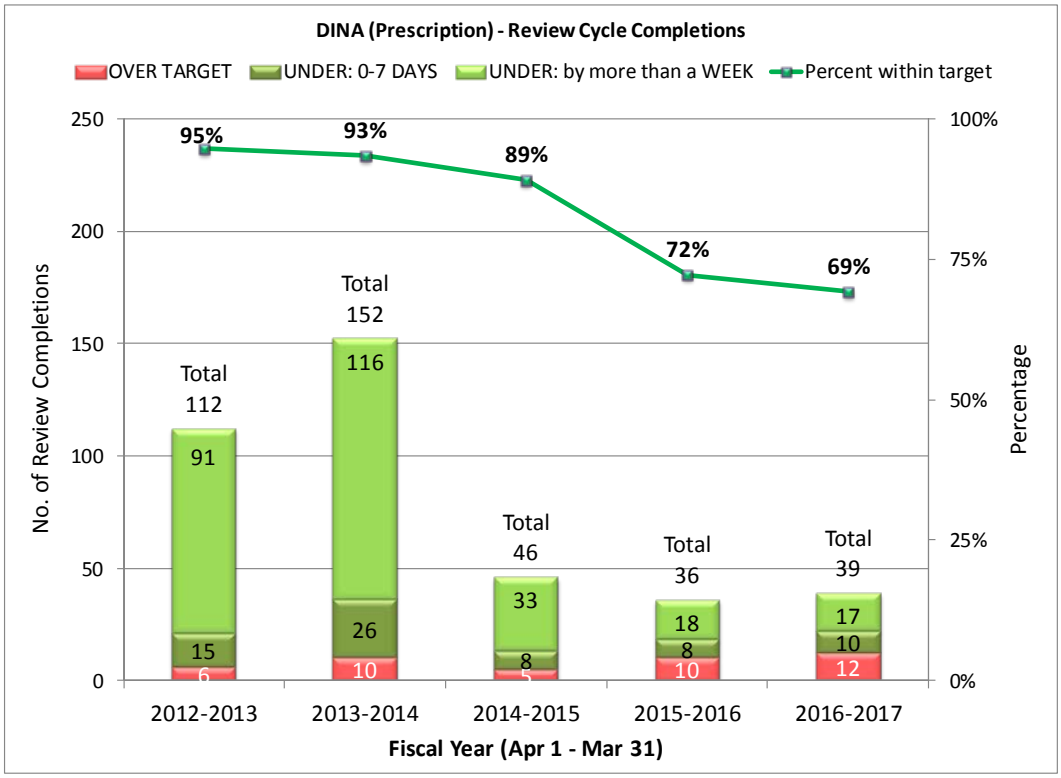
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

DINA: Requests for Reconsideration of Final Decisions

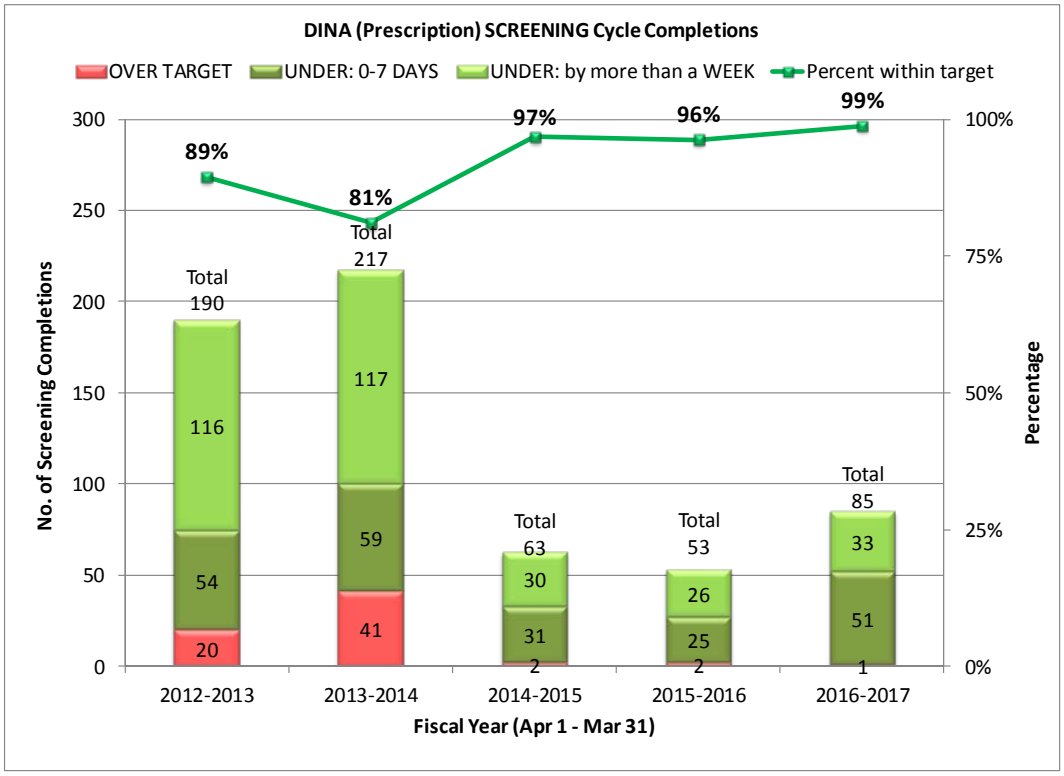
DINA - Reconsideration of Final Decisions by Year Requested							
Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	**12-13**	**13-14**	**14-15**	**15-16**	**16-17**	**Final Decision in Dispute**	**Submission Status (as of May 12 2017)**
Total Received	**0**	**0**	**1**	**0**	**1**		
Total Granted	***0***	***0***	***0***	***0***	***1***	NON-Withdrawal	Cleared
Total Pending	***0***	***0***	***0***	***0***	***0***		
Total Denied	***0***	***0***	***0***	***0***	***0***		
Denied						New Drug Letter	Rejected
Denied						NOD-Withdrawal	Withdrawn
Total Cancelled	***0***	***0***	***1***	***0***	***0***		
Cancelled by Health Canada			1			New Drug Letter	Refused

PERFORMANCE

DINA: Review Cycle Completions

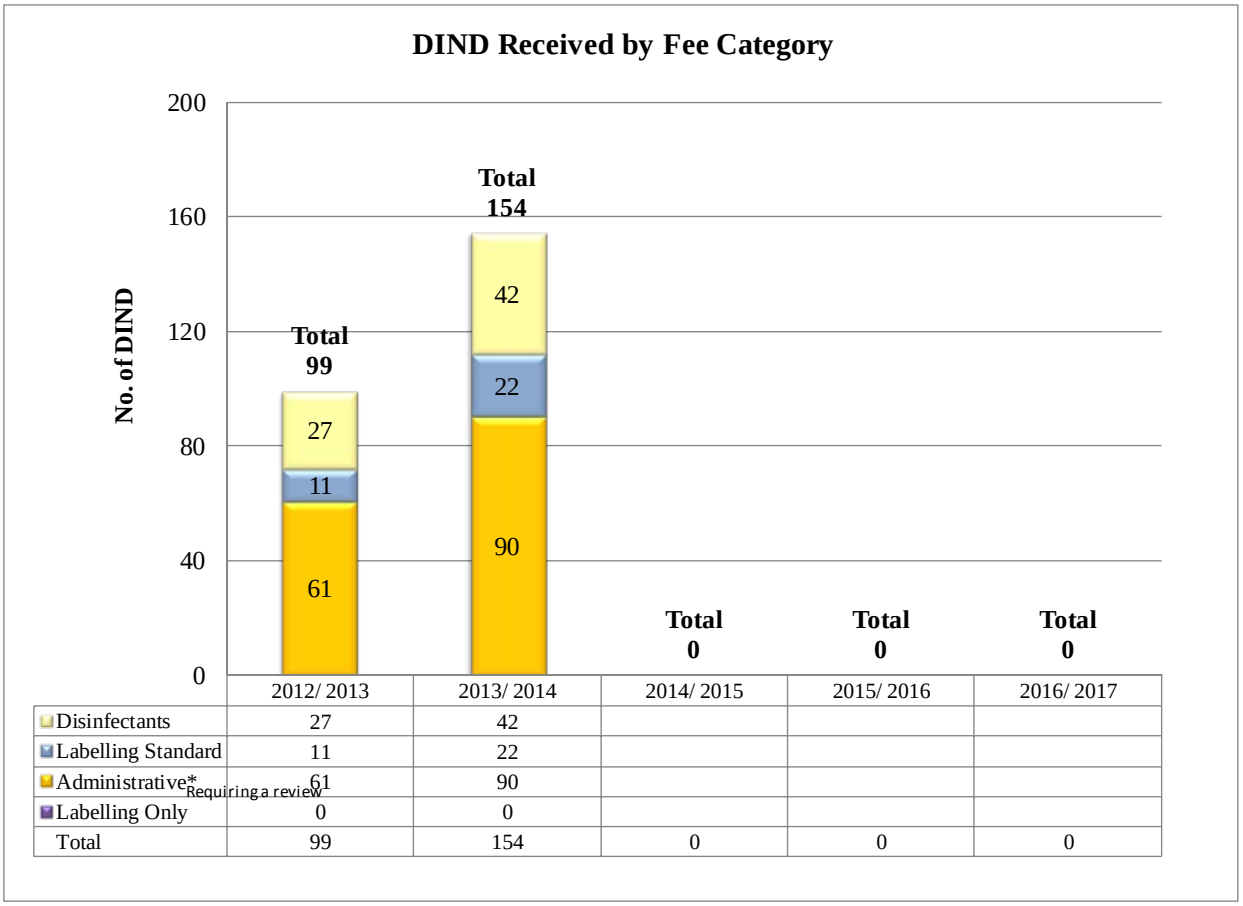


DINA: Screening Cycle Completions



DIND: Application for a Drug Identification Number - DISINFECTANT PRODUCT

DIND: Number Received



	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Disinfectants	27	42			
Labelling Standard	11	22			
Administrative* Requiring a review	61	90			
Labelling Only	0	0			
Total	99	154	0	0	0

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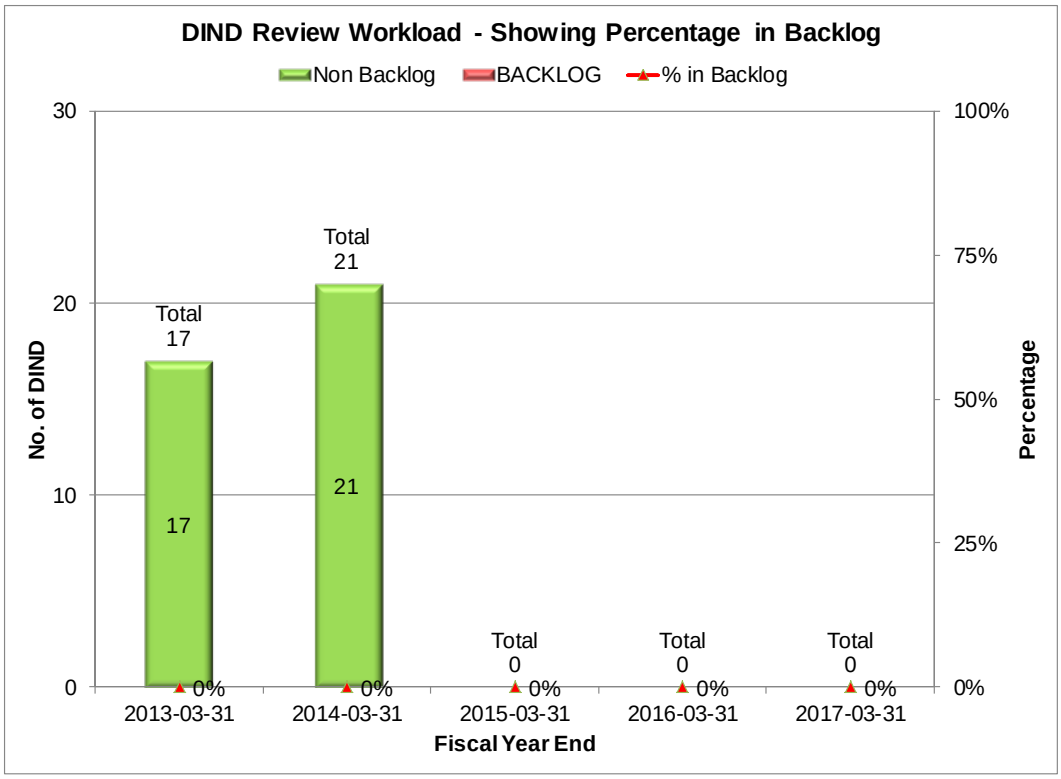
REVIEW WORKLOAD

DIND: Review Workload Showing Percentage in Backlog

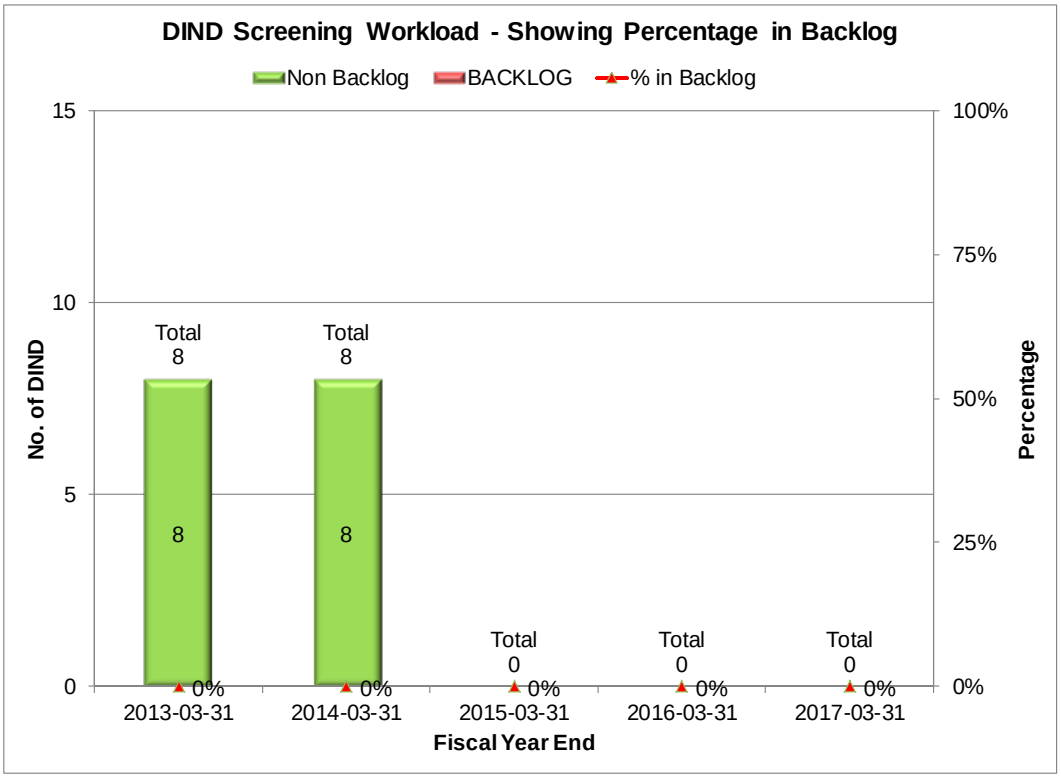


DIND: Review Workload by User Fee Category

TPD DIND All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2013-03-31	2014-03-31	2015-03-31	2016-03-31	2017-03-31
Labelling Only (Form)	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Disinfectant (Form and Supporting Data)	**17**	**21**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**17**	**21**	**0**	**0**	**0**
Non Backlog	**17**	**21**	*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

TPD DIND All SCREENING WORKLOAD BY User Fee Category (excluding administrative) and Fiscal Year End					
CLASS	**2013-03-31**	**2014-03-31**	**2015-03-31**	**2016-03-31**	**2017-03-31**
Labelling Only (Form)	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Disinfectant (Form & Support	**3**	**7**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Standard	**5**	**1**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**8**	**8**	**0**	**0**	**0**
Non Backlog	**8**	**8**	**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	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NOTIFICATION FORM/DIN ISSUED	62	75	-	-	-
NO OBJECTION LETTER	3	1	-	-	-
CANCELLED BY COMPANY			-	-	-
REJECTION LETTER (SCREENING)	1		-	-	-
SCREENING DEFICIENCY NOTICE	21	18	-	-	-

DIND - LABELLING STANDARD					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NOTIFICATION FORM/DIN ISSUED	6	25	-	-	-
REJECTION LETTER (SCREENING)			-	-	-
SCREENING DEFICIENCY NOTICE	5	17	-	-	-
CANCELLED BY COMPANY	1		-	-	-
REJECTION LETTER (SCREENING)			-	-	-
NEW DRUG LETTER SCREEN	1	1	-	-	-

DIND - DIS NONCLIN/CLINICAL					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NOTIFICATION FORM/DIN ISSUED	28	24	-	-	-
DIN INCORR SUBTYPE-CLASS			-	-	-
NO OBJECTION LETTER	3	7	-	-	-
NOTICE OF NON-COMPLIANCE	7	4	-	-	-
REJECTION LETTER (SCREENING)			-	-	-
SCREENING DEFICIENCY NOTICE	9		-	-	-
SPONSOR SUB CHANGE ACCEPT			-	-	-
CANCELLED BY COMPANY	2	1	-	-	-
NON WITHDRAWAL LETTER		1	-	-	-

DIND - DIS NONCLIN/C&M					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
SCREENING DEFICIENCY NOTICE	-	-	-	-	-

DIND - DISINFECT LABEL ONLY					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
SCREENING DEFICIENCY NOTICE	1	2	-	-	-
CANCELLED BY COMPANY	3		-	-	-

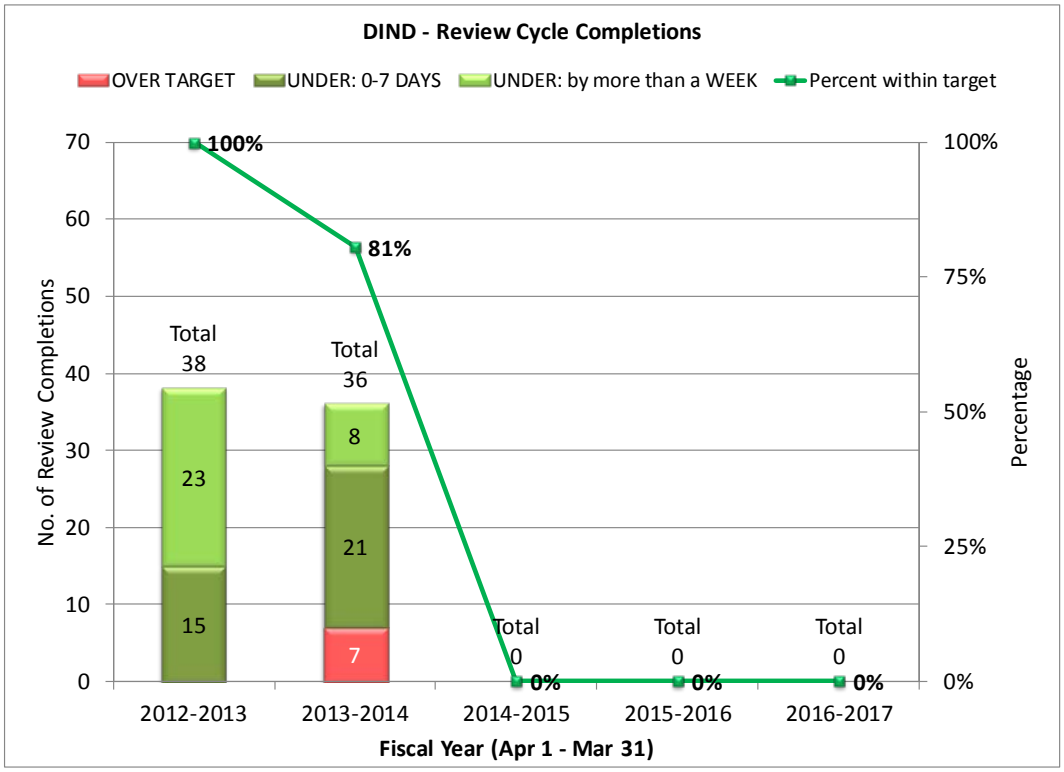
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

DIND: Requests for Reconsideration of Final Decisions

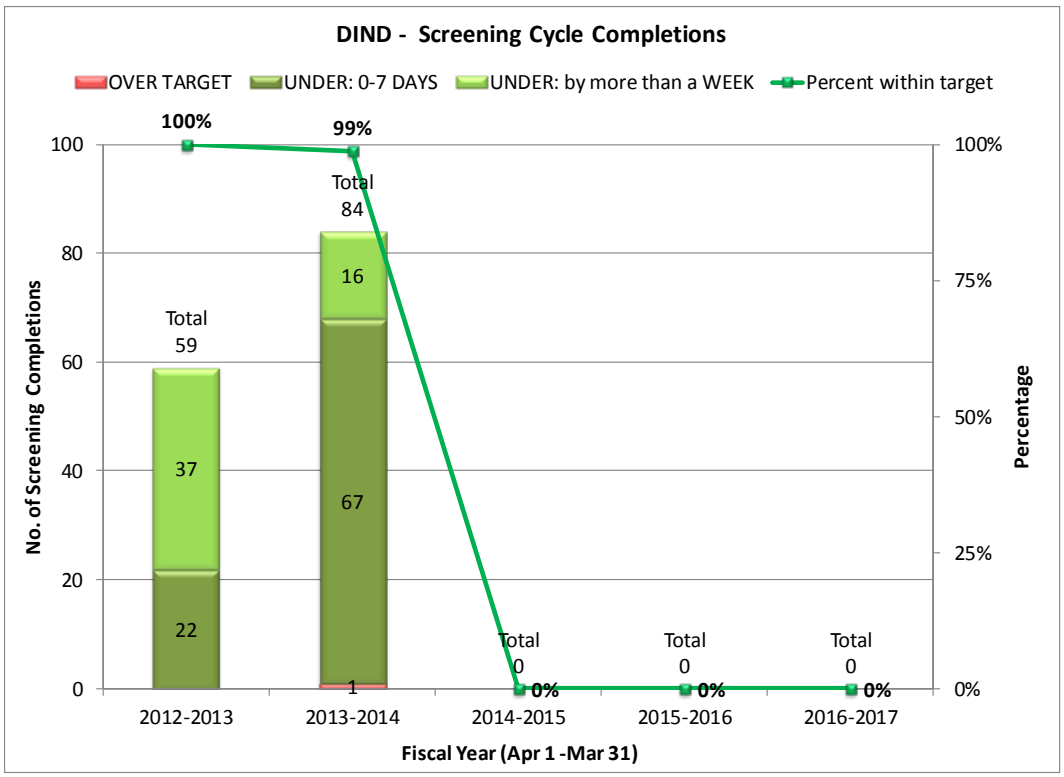
DIND - Reconsideration of Final Decisions by Year Requested Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	**12-13**	**13-14**	**14-15**	**15-16**	**16-17**	**Final Decision in Dispute**	**Submission Status (as of May 12 2017)**
Total Received	**0**	**0**	**0**	**0**	**1**		
Total Denied	***0***	***0***	***0***	***0***	***1***		
Denied					1	NON-Withdrawal	Withdrawn

PERFORMANCE

DIND: Review Cycle Completions

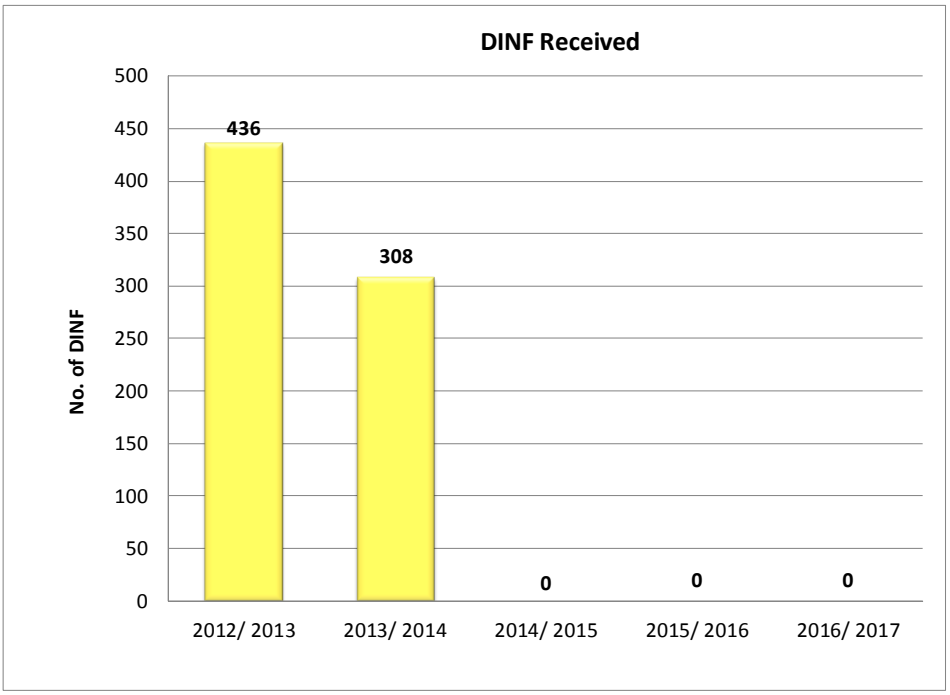


DIND: Screening Cycle Completions

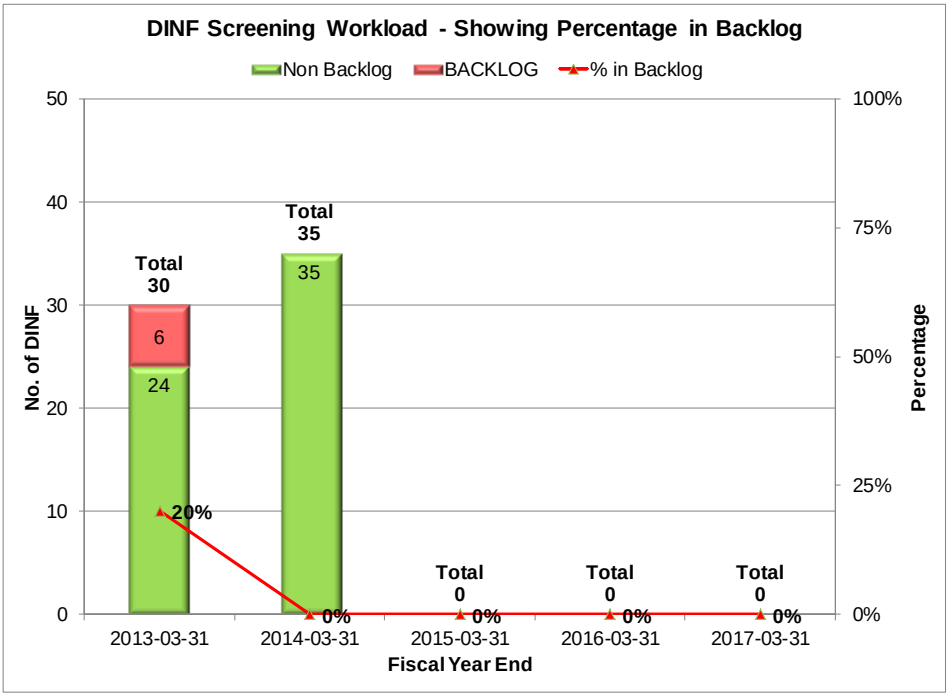


DINF: CATEGORY IV PRODUCT - (LABELLING STANDARD)

DINF: Number Received



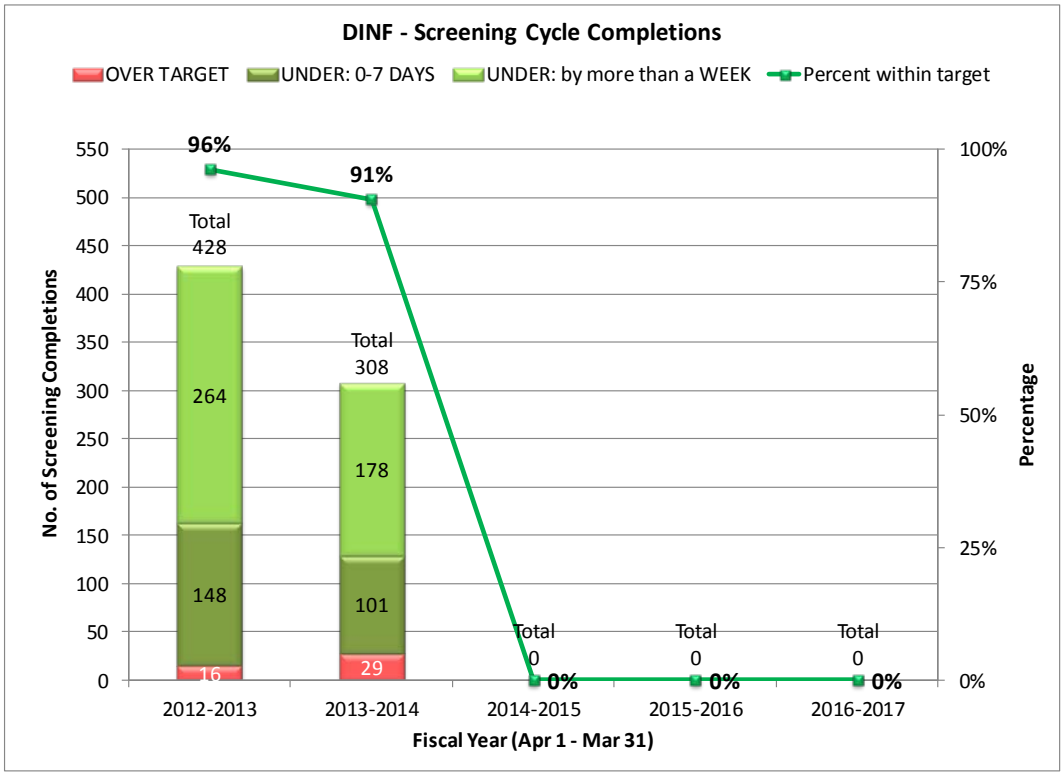
DINF: Screening Workload Showing Percentage in Backlog



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					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NOTIFICATION FORM/DIN ISSUED	325	286	-	-	-
NO OBJECTION LETTER	4	1	-	-	-
CANCELLED BY COMPANY	74	11	-	-	-
DIN INCORR SUBTYPE-CLASS	5	1	-	-	-
NEW DRUG LETTER SCREEN	1		-	-	-
NOT SATISFACTORY NOTICE			-	-	-
REJECTION LETTER (SCREENING)	32	8	-	-	-
SCREENING DEFICIENCY NOTICE	45	12	-	-	-
SPONSOR SUB CHANGE ACCEPT		1	-	-	-

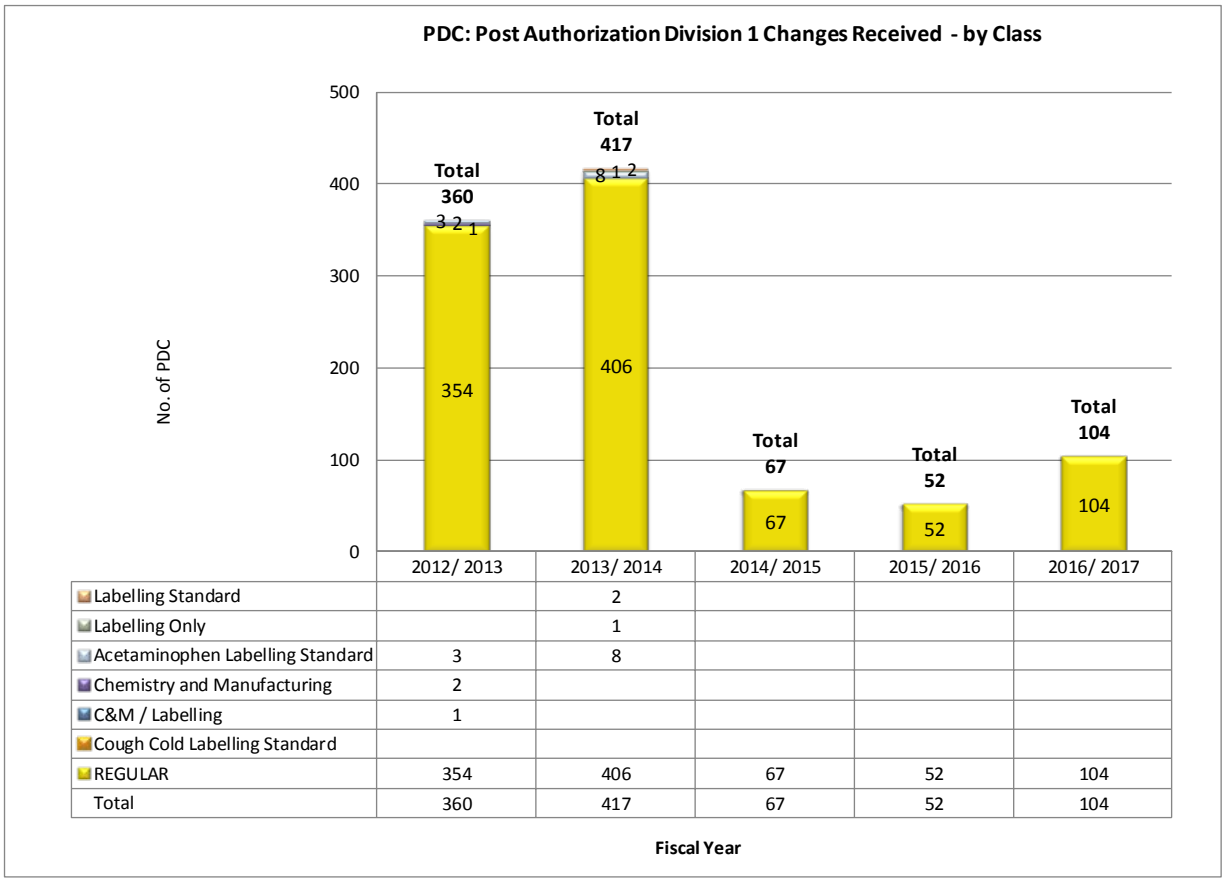
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

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	**12-13**	**13-14**	**14-15**	**15-16**	**16-17**	**Final Decision in Dispute**	**Submission Status (as of May 12 2017)**
Total Received	**2**	**0**	**0**	**0**	**0**		
Total Granted	***0***	***0***	***0***	***0***	***0***		
Total Denied	***1***	***0***	***0***	***0***	***0***	Rejection at Screening	Rejected
Total Cancelled by Company	***1***	***0***	***0***	***0***	***0***	Rejection at Screening	Rejected

PDC: POST-AUTHORIZATION DIVISION 1 CHANGES

Post-Authorization Division 1 Changes (PDC) Received



	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Labelling Standard		2			
Labelling Only		1			
Acetaminophen Labelling Standard	3	8			
Chemistry and Manufacturing	2				
C&M / Labelling	1				
Cough Cold Labelling Standard					
REGULAR	354	406	67	52	104
Total	360	417	67	52	104

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

PDC					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
COUGH COLD LABELLING STANDARD					
NO OBJECTION LETTER					
NOT SATISFACTORY NOTICE					
ACETAMINOPHEN LS					
CANCELLED BY COMPANY					
NO OBJECTION LETTER	1	10			
NOT SATISFACTORY NOTICE					
REGULAR					
CANCELLED BY COMPANY	17	16	7	11	18
NO OBJECTION LETTER	251	362	67	43	80
NOT SATISFACTORY NOTICE	51	15			1
NOTIFICATION FORM/DIN ISSUED					
REJECTION LETTER (SCREENING)					
C&M ONLY					
NO OBJECTION LETTER	5				
CANCELLED BY COMPANY					
C&M LABELLING					
NO OBJECTION LETTER					
CANCELLED BY COMPANY					
NOT SATISFACTORY NOTICE	1				
LABELLING ONLY					
NO OBJECTION LETTER		1			
LABELLING STANDARD					
NO OBJECTION LETTER		2			

REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

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

PDC - **Reconsideration of Final Decisions by Year Requested**

Fiscal Year of Request (April 1 - March 31)

Breakdown by Reconsideration Decision	12-13	13-14	14-15	15-16	16-17	Final Decision in Dispute	Submission Status (as of May 12 2017)
Total Received	**0**	**2**	**0**	**0**	**0**		
Total Cancelled by Company		***2***				Not Satisfactory Notice	Rejected

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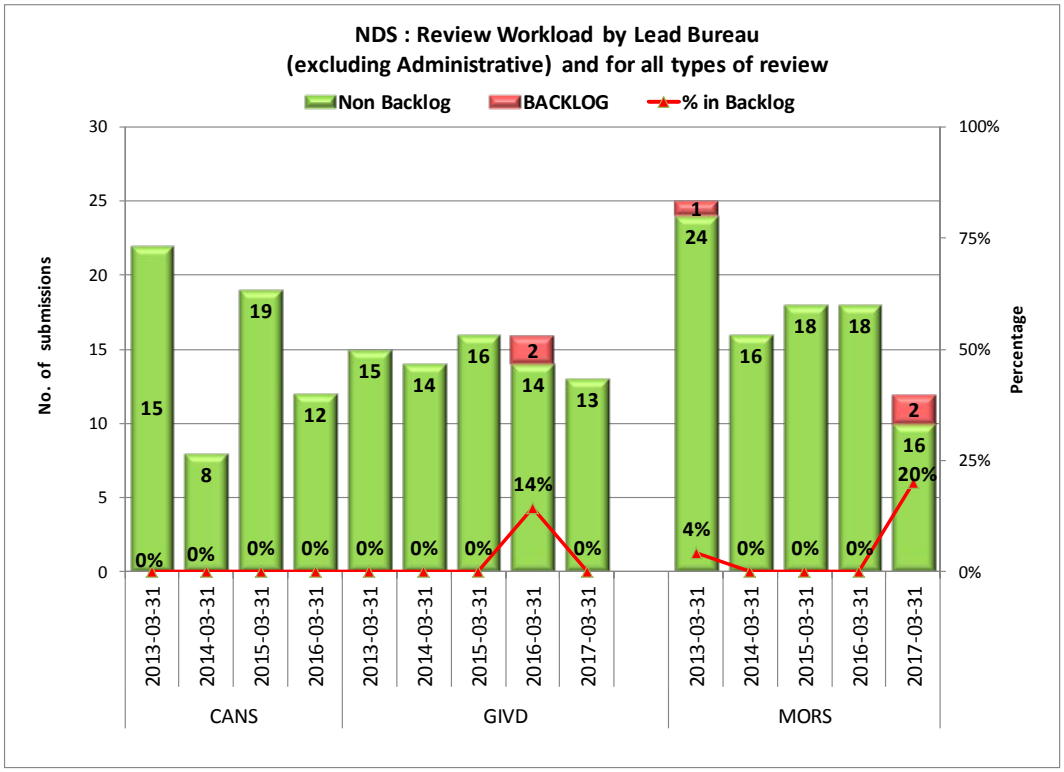
APPENDIX A - Lead Bureau Summaries

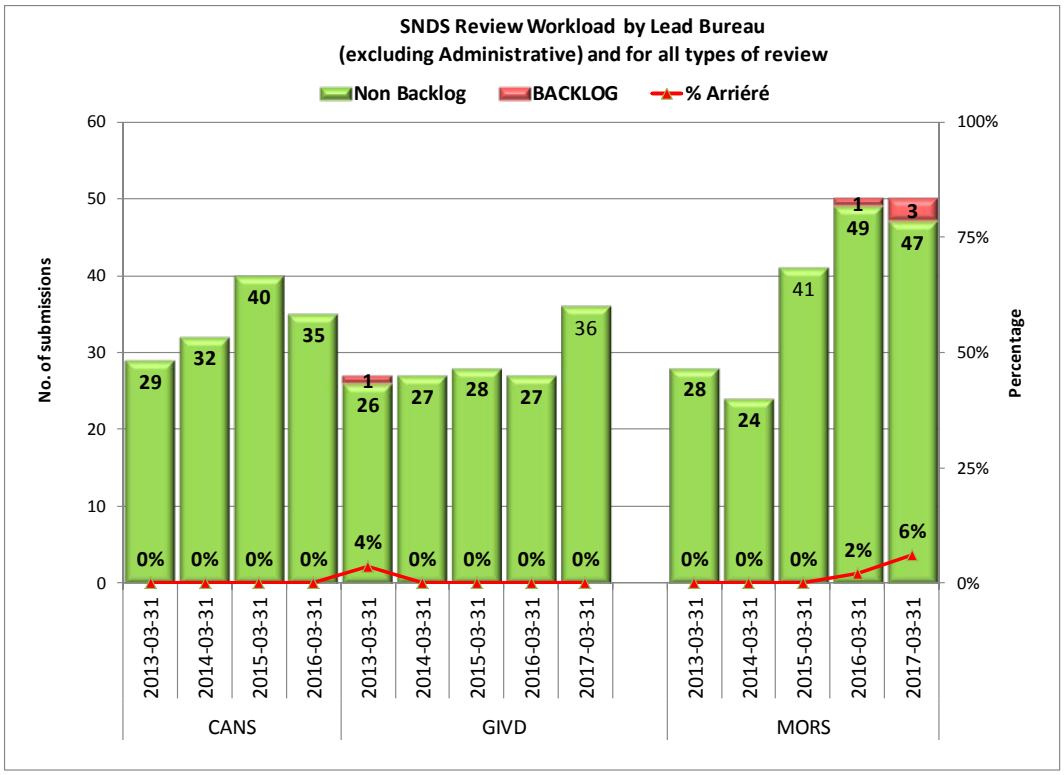
NDS & SNDS

WORKLOAD by Lead Bureau

NDS Review Workload by Lead Bureau

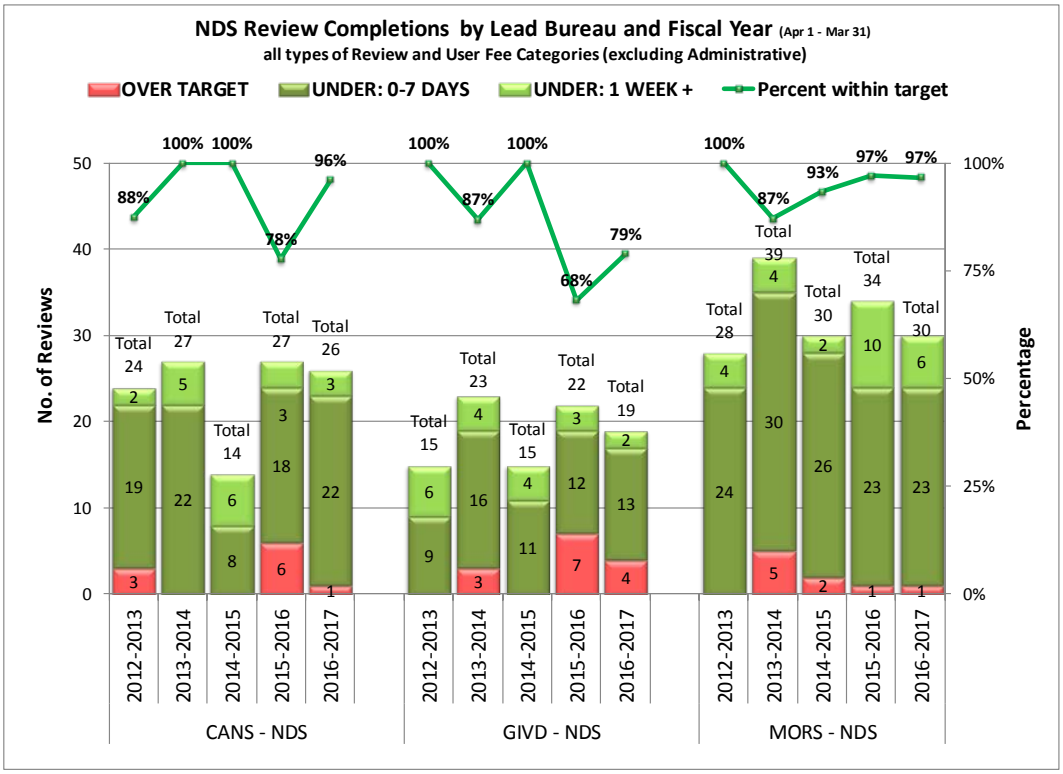


SNDS Review Workload by Lead Bureau

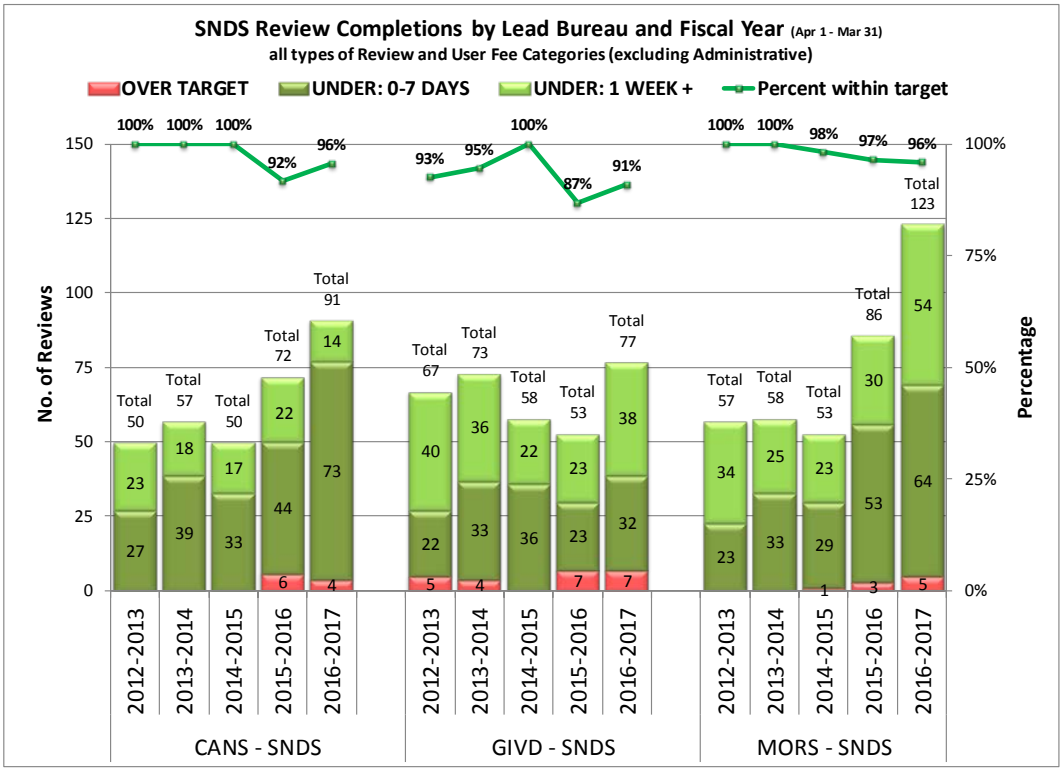


PERFORMANCE by Lead Bureau

NDS Review Performance by Lead Bureau

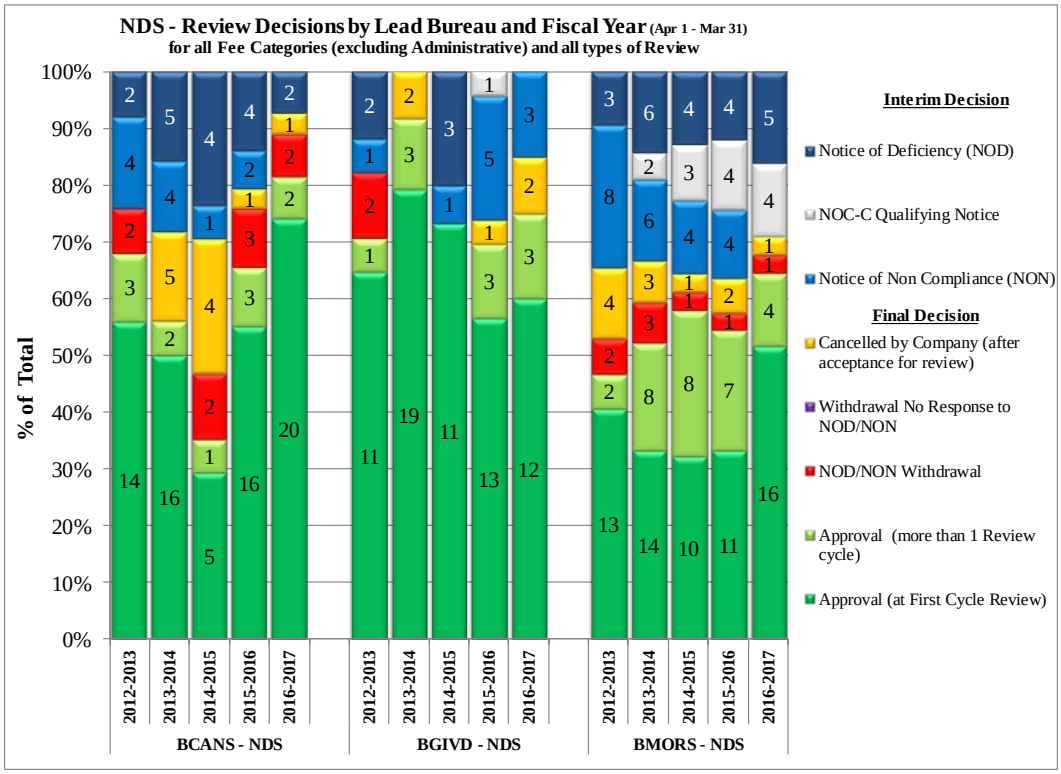


SNDS Review Performance by Lead Bureau

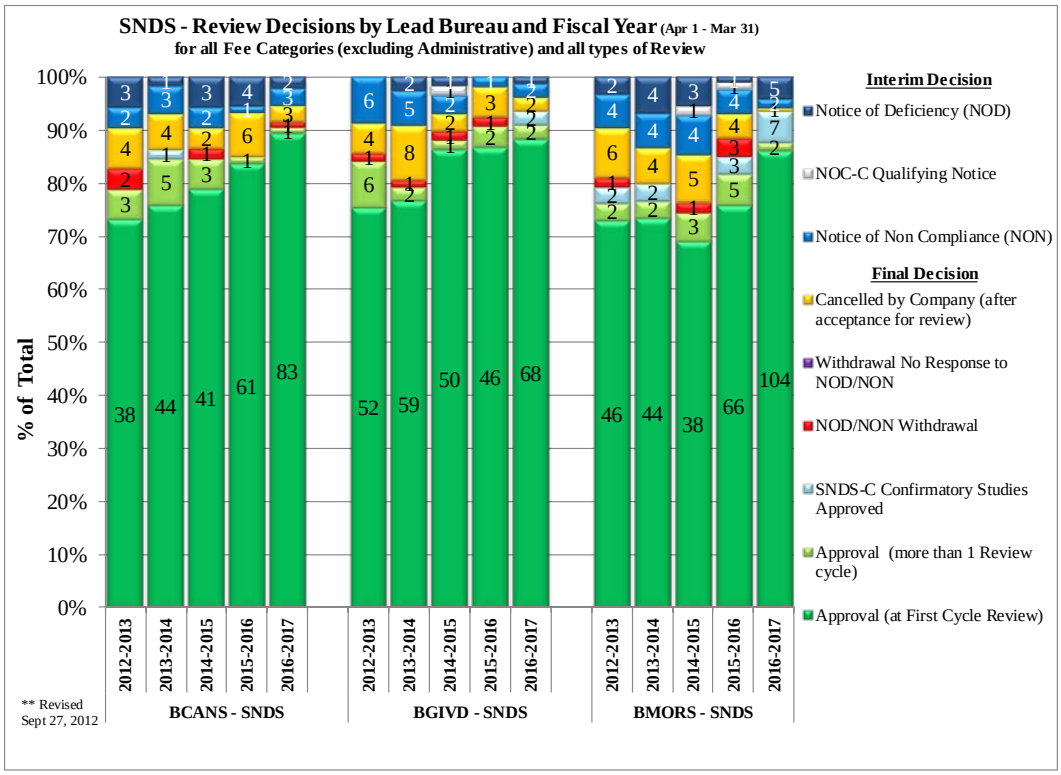


REVIEW DECISIONS by Lead Bureau

NDS Review Decisions by Lead Bureau

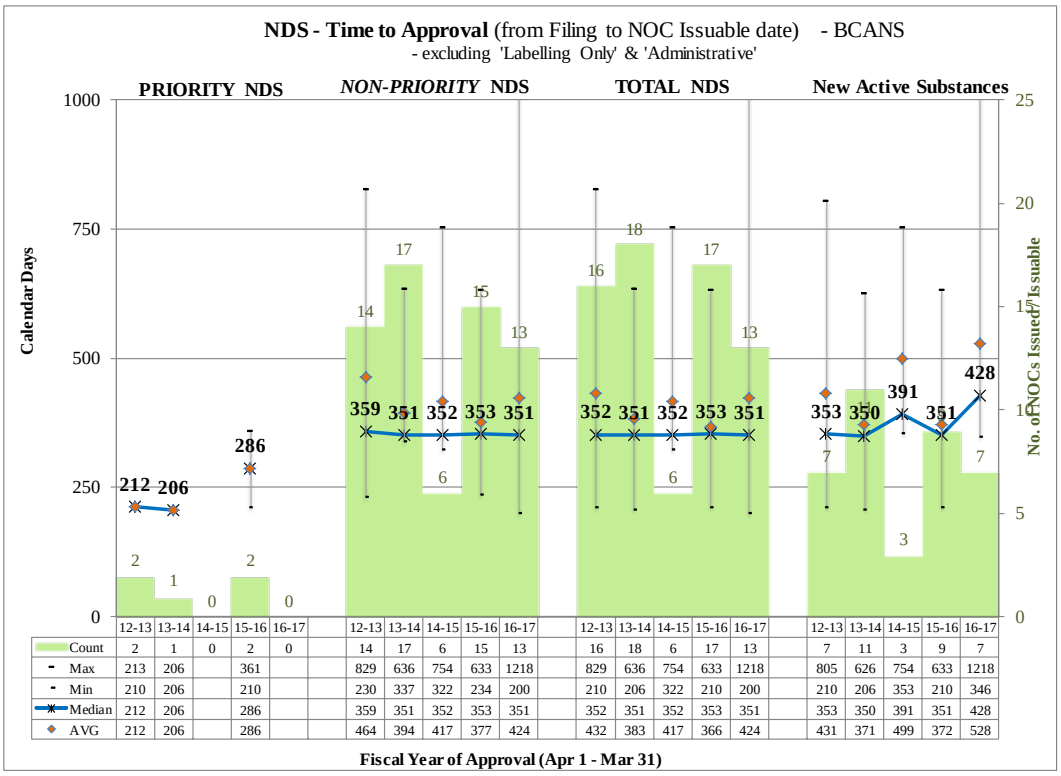


SNDS Review Decisions by Lead Bureau



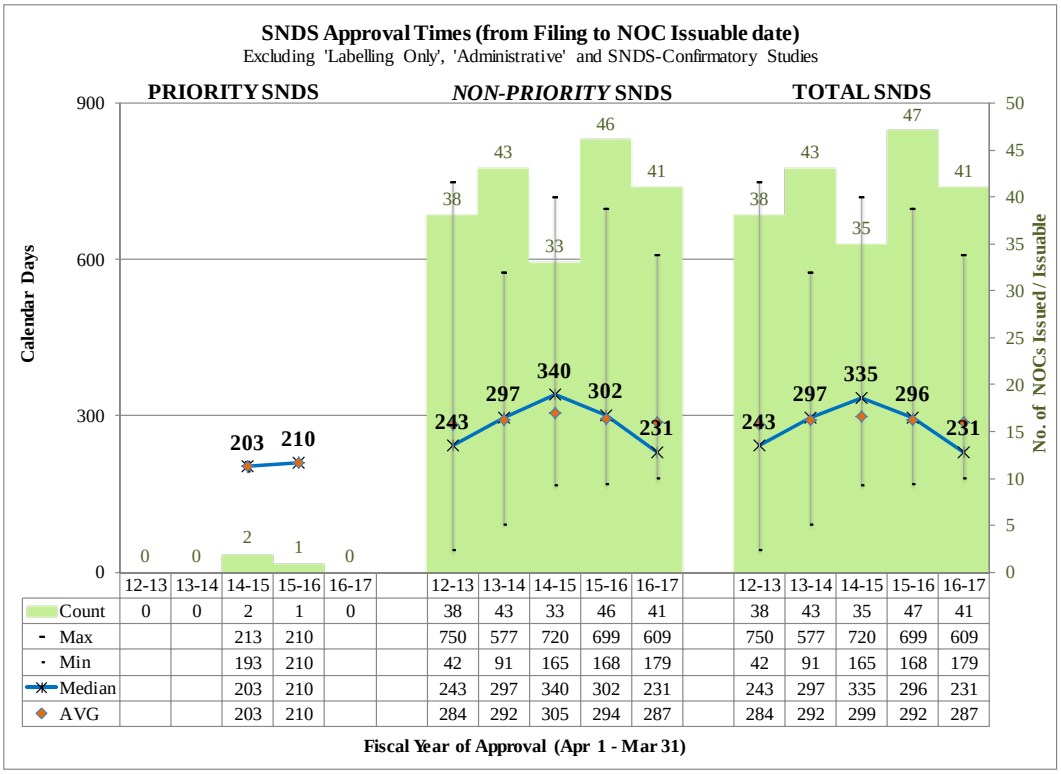
APPROVALS by Lead Bureau

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



	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17
Count	2	1	0	2	0	14	17	6	15	13	16	18	6	17	13	7	11	3	9	7
Max	213	206		361		829	636	754	633	1218	829	636	754	633	1218	805	626	754	633	1218
Min	210	206		210		230	337	322	234	200	210	206	322	210	200	210	206	353	210	346
Median	212	206		286		359	351	352	353	351	352	351	352	353	351	353	350	391	351	428
AVG	212	206		286		464	394	417	377	424	432	383	417	366	424	431	371	499	372	528

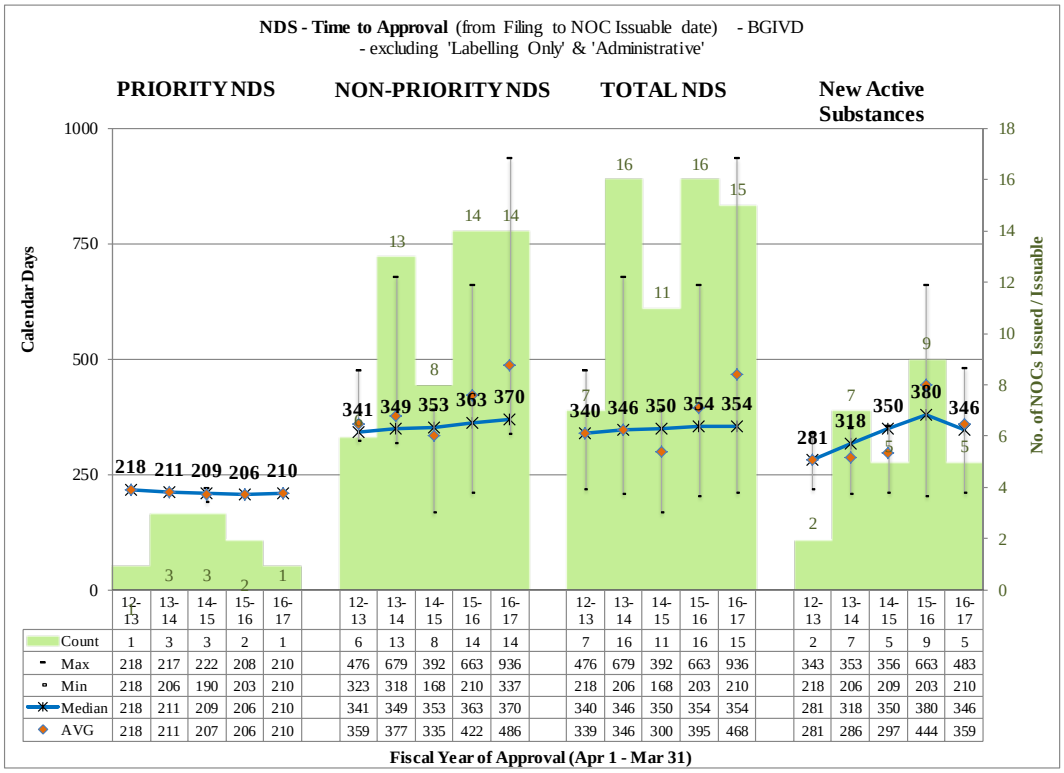
SNDS Approvals – Bureau of Cardiology, Allergy and Neurological Sciences (BCANS)



	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17
Count	0	0	2	1	0	38	43	33	46	41	38	43	35	47	41
Max			213	210		750	577	720	699	609	750	577	720	699	609
Min			193	210		42	91	165	168	179	42	91	165	168	179
Median			203	210		243	297	340	302	231	243	297	335	296	231
AVG			203	210		284	292	305	294	287	284	292	299	292	287

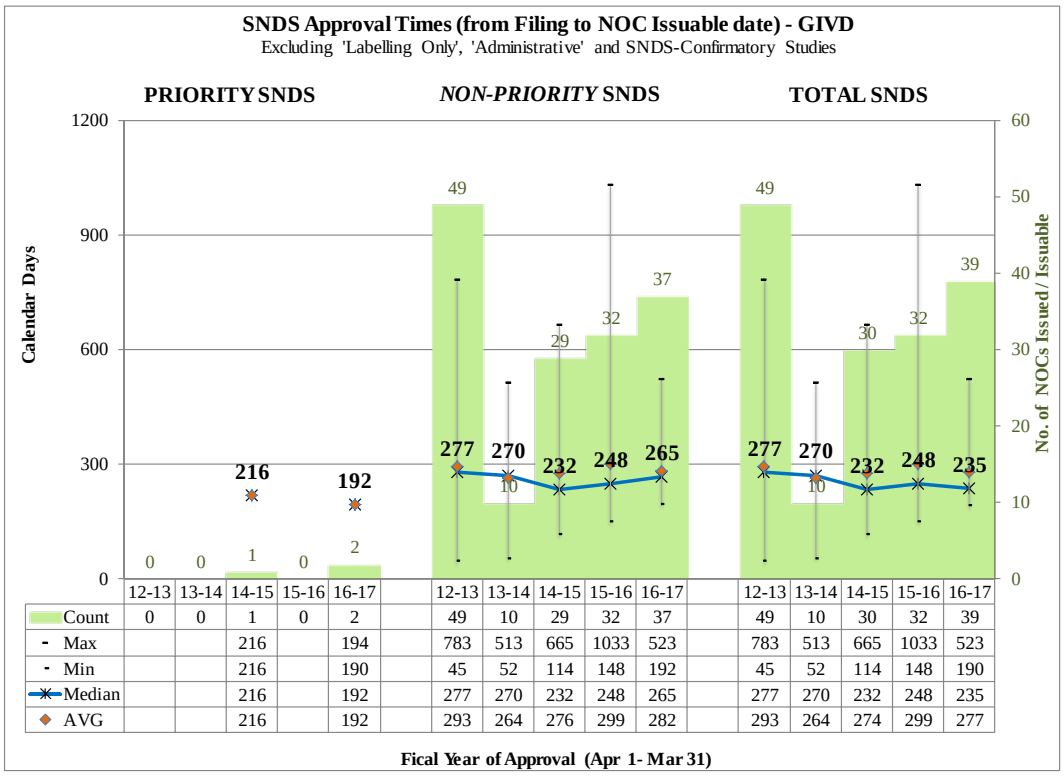
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

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



	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17
Count	1	3	3	2	1	6	13	8	14	14	7	16	11	16	15	2	7	5	9	5
Max	218	217	222	208	210	476	679	392	663	936	476	679	392	663	936	343	353	356	663	483
Min	218	206	190	203	210	323	318	168	210	337	218	206	168	203	210	218	206	209	203	210
Median	218	211	209	206	210	341	349	353	363	370	340	346	350	354	354	281	318	350	380	346
AVG	218	211	207	206	210	359	377	335	422	486	339	346	300	395	468	281	286	297	444	359

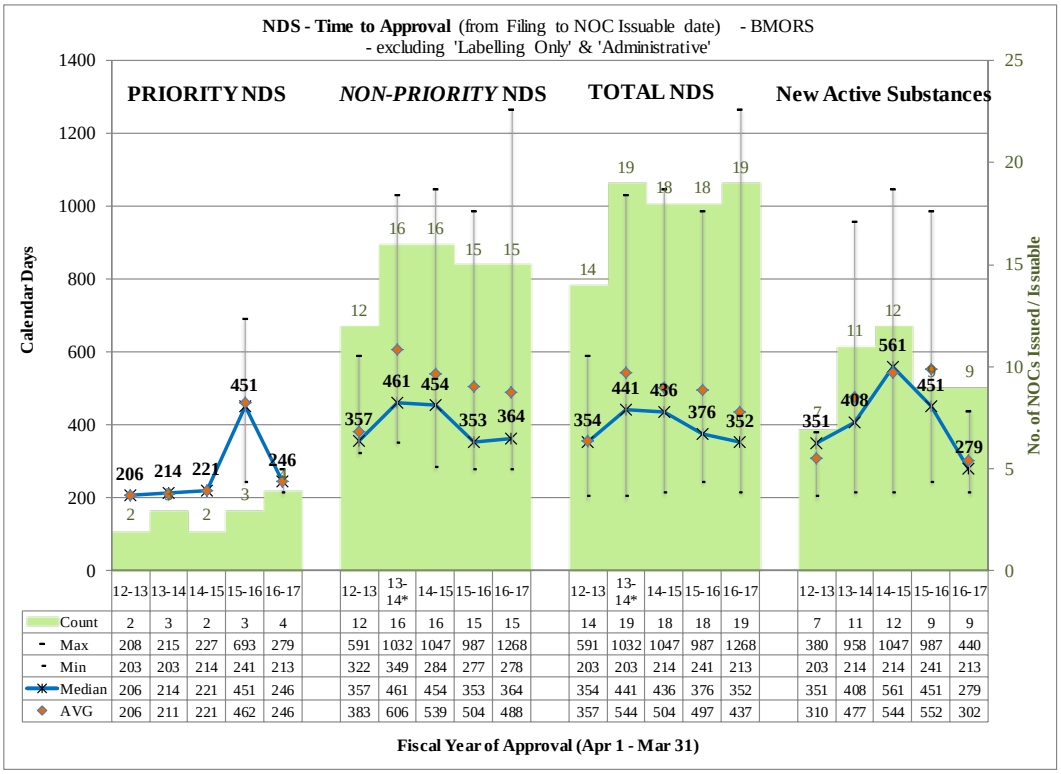
SNDS Approvals – Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD)



	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17
Count	0	0	1	0	2	49	10	29	32	37	49	10	30	32	39
Max			216		194	783	513	665	1033	523	783	513	665	1033	523
Min			216		190	45	52	114	148	192	45	52	114	148	190
Median			216		192	277	270	232	248	265	277	270	232	248	235
AVG			216		192	293	264	276	299	282	293	264	274	299	277

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.

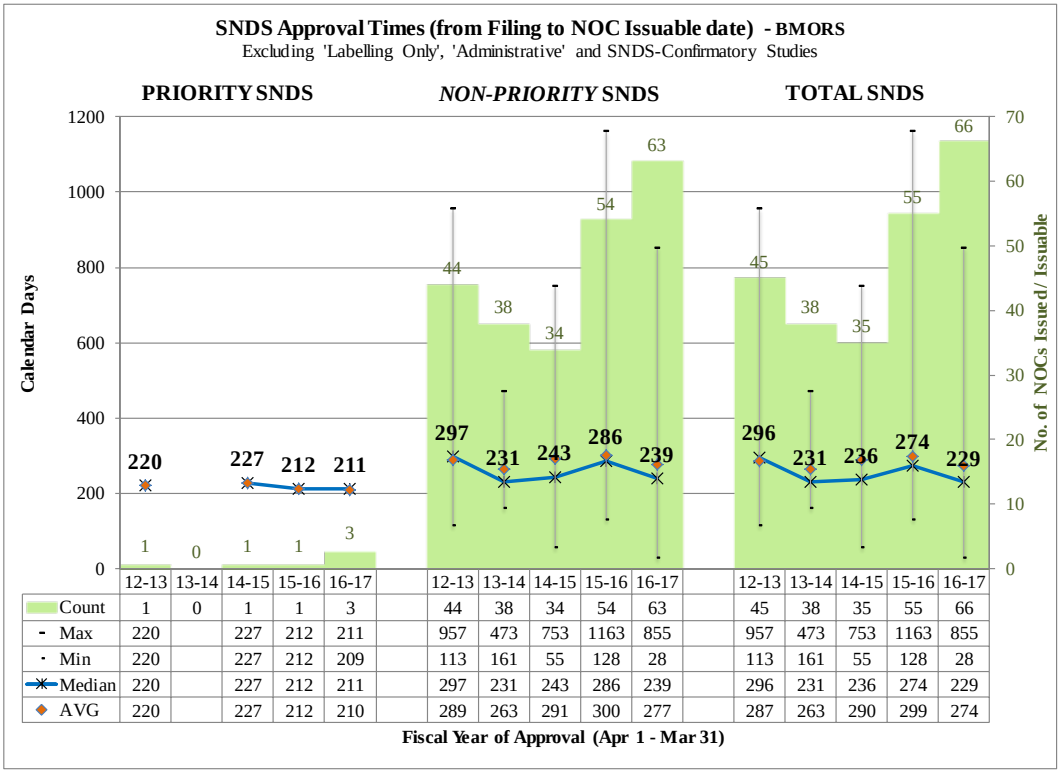
NDS Approvals – Bureau of Metabolism, Oncology & Reproductive Sciences (BMORS)



	12-13	13-14	14-15	15-16	16-17	12-13	13-14*	14-15	15-16	16-17	12-13	13-14*	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17
Count	2	3	2	3	4	12	16	16	15	15	14	19	18	18	19	7	11	12	9	9
Max	208	215	227	693	279	591	1032	1047	987	1268	591	1032	1047	987	1268	380	958	1047	987	440
Min	203	203	214	241	213	322	349	284	277	278	203	203	214	241	213	203	214	214	241	213
Median	206	214	221	451	246	357	461	454	353	364	354	441	436	376	352	351	408	561	451	279
AVG	206	211	221	462	246	383	606	539	504	488	357	544	504	497	437	310	477	544	552	302

*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)



	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17
Count	1	0	1	1	3	44	38	34	54	63	45	38	35	55	66
Max	220		227	212	211	957	473	753	1163	855	957	473	753	1163	855
Min	220		227	212	209	113	161	55	128	28	113	161	55	128	28
Median	220		227	212	211	297	231	243	286	239	296	231	236	274	229
AVG	220		227	212	210	289	263	291	300	277	287	263	290	299	274

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

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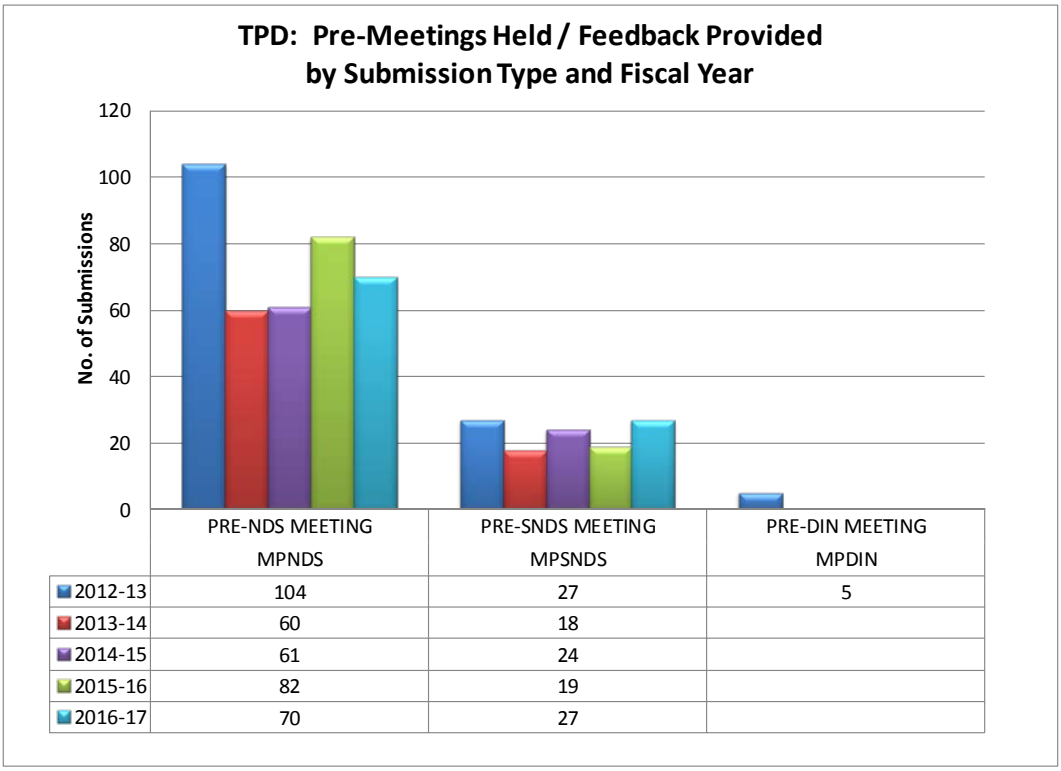
Appendix B: Pre-submission Meetings

6

Pre-submission Meetings Held / Feedback Provided



	PRE-NDS MEETING MPNDS	PRE-SNDS MEETING MPSNDS	PRE-DIN MEETING MPDIN
2012-13	104	27	5
2013-14	60	18	
2014-15	61	24	
2015-16	82	19	
2016-17	70	27	

Pre-CTA Meeting figures were unavailable.

[6] 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

APPENDIX C – Regulatory Activities in eCTD Format

Regulatory Activities in eCTD Format

Overview

This section of the Annual Drug Submission Performance Report for fiscal year 2016-2017 reflects Electronic Common Technical Document (eCTD) regulatory activity data received for the Therapeutic Products Directorate (TPD), the Biologic and Genetic Therapies Directorate (BGTD), the Marketed Health Products Directorate (MHPD) and the Natural and Non-Nonprescription Health Product Directorate (NNHPD-NDED). The time period for which data is displayed in this report ranges from April 1st, 2012 to March 31st, 2017. Any questions about Appendix C should be forwarded to **eReview@hc-sc.gc.ca**.

Electronic Common Technical Document (eCTD) Regulatory Activities

Health Canada strongly recommends sponsors to file their regulatory activities in eCTD format in order to stay aligned with international standards and requirements. Health Canada accepts regulatory activities in eCTD electronic-only filling format that are filed in compliance with the ICH eCTD specification and Health Canada's *"Guidance Document: Preparation of Drug Regulatory Activities in Electronic Common Technical Document (eCTD)".*

As of **January 1st, 2018**, the following regulatory activity types, as well as all additional information and subsequent regulatory activities/transactions (as per section 1.3 of the *Guidance Document: Preparation of Drug Regulatory Activities in eCTD Format*) for human drugs, must be filed in eCTD format: New Drug Submission (NDS), Supplement to a New Drug Submission (SNDS), Abbreviated New Drug Submission (ANDS), and Supplement to an Abbreviated New Drug Submission (SANDS). Sponsors are also encouraged to refer to the *Notice: Mandatory use of the Electronic Common Technical Document (eCTD) format.* Exemption from the mandatory eCTD format requirement will be considered on a case by case basis.

Common Electronic Submission Gateway (CESG)

As of January 1st, 2017, the CESG is mandatory for all regulatory transactions under 10GB in size (including first transactions) prepared in the eCTD format. Sponsors providing files greater than 10 GB should continue to use media. For detailed information on how to file using media, refer to Section 3.2 (ii) of the Guidance Document – Preparation of Regulatory Activities in eCTD Format. Sponsors are also encouraged to refer to the Frequently Asked Questions – Common Electronic Submission Gateway (CESG FAQ) document for future updates.

GLOSSARY OF TERMS

eCTD: Electronic Common Technical Document

Dossier: A collection of all regulatory activities throughout the life cycle of a product.

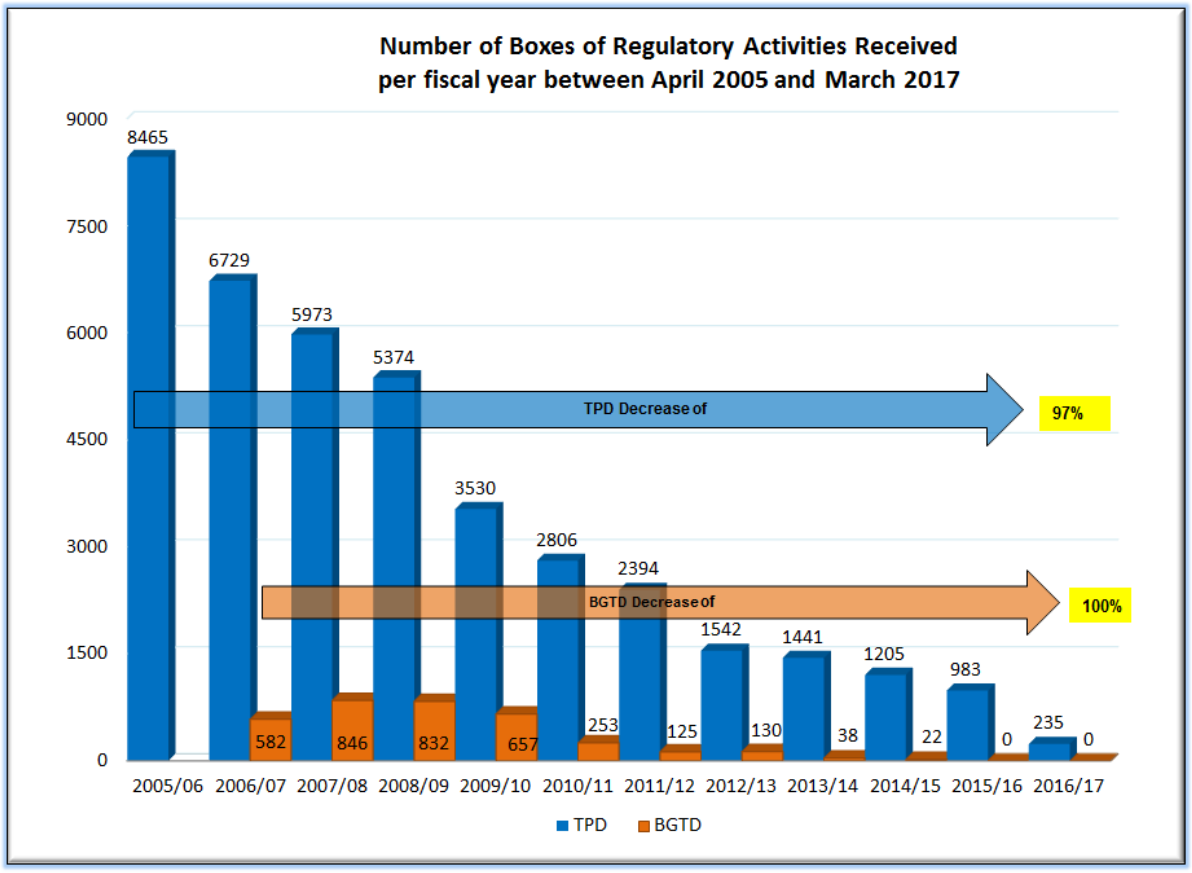
Regulatory Activity: a collection of all regulatory transactions throughout the process of a specific activity which includes, but is not limited to, NDS, ANDS, DIN Application, YBPR.

Regulatory Transaction (Sequence): any information package sent by the sponsor as part of a regulatory activity such as initial data, unsolicited and solicited information (see definition for additional information).

Pharmacovigilance Data (PV Data):

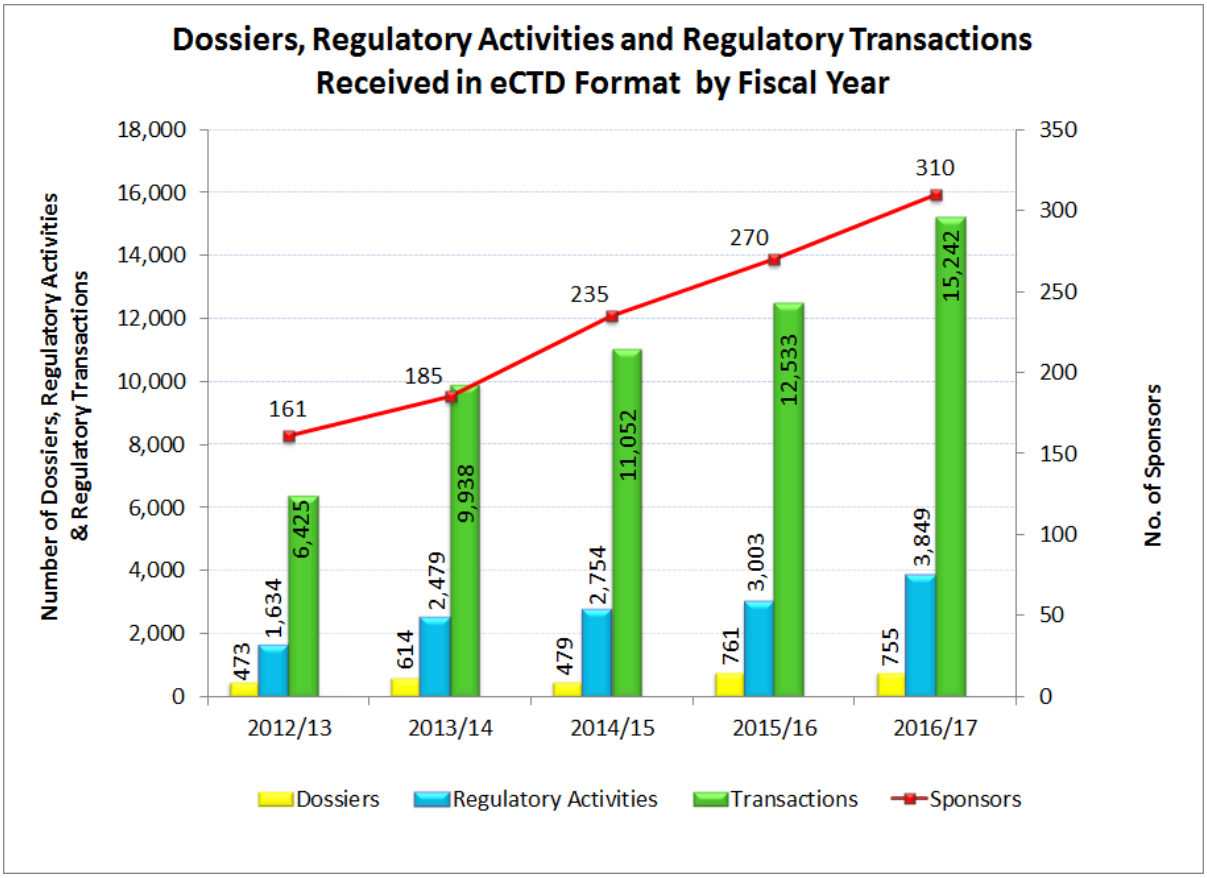
PSUR-C: Periodic Safety Update Reports – Confirmatory
PBRER-C: Periodic Benefit-Risk Evaluation Reports - Confirmatory
PSUR-PV: Periodic Safety Update Reports - Pharmacovigilance
PBRER-PV: Periodic Benefit-Risk Evaluation Reports - Pharmacovigilance
RMP-PV: Risk Management Plan - Pharmacovigilance
UD-PV: Undefined Data – Pharmacovigilance

Number of Boxes of Regulatory Activities Received



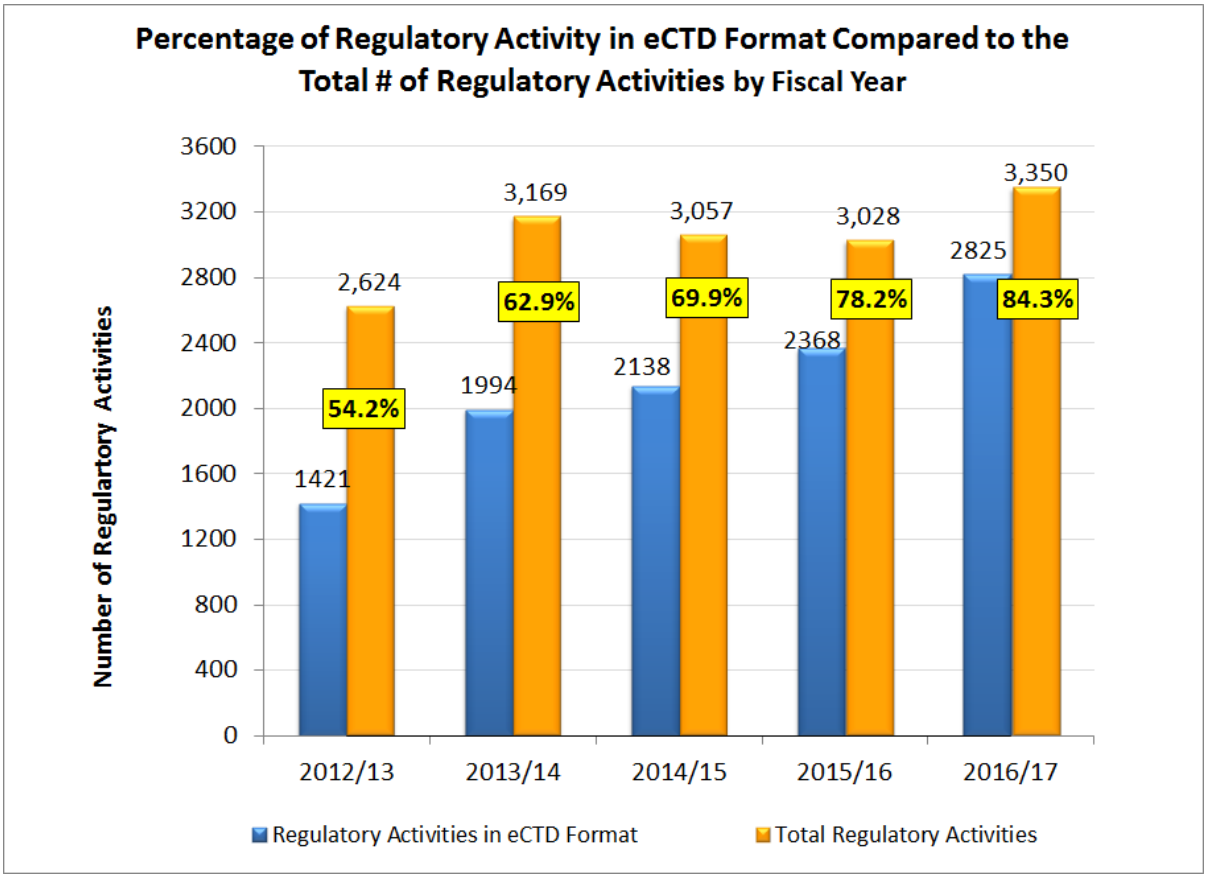
The above chart displays the reduction in boxes of paper Health Canada has received as a result of accepting regulatory activities electronically, both in CTD and eCTD formats.

Dossiers, Regulatory Activities and Regulatory Transactions Received in eCTD Format by Fiscal Year



The above chart reflects data for all regulatory activities that are accepted in eCTD format as per the *Guidance Document: Preparation of Drug Regulatory Activities in Electronic Common Technical Document (eCTD).*

Percentage of Regulatory Activity in eCTD Format Compared to the Total Number of Regulatory Activities



The above chart only reflects data for some of the regulatory activities that are accepted in eCTD format as per the *Guidance Document: Preparation of Drug Regulatory Activities in Electronic Common Technical Document (eCTD).* The regulatory activity types included in this chart are NDS, SNDS, ANDS, SANDS, SNDS-C, NC and PV-Data (submitted to TPD & BGTD & MHPD & NHPD). The reflected data includes all administrative class types with the exception of those processed only by OSIP.

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