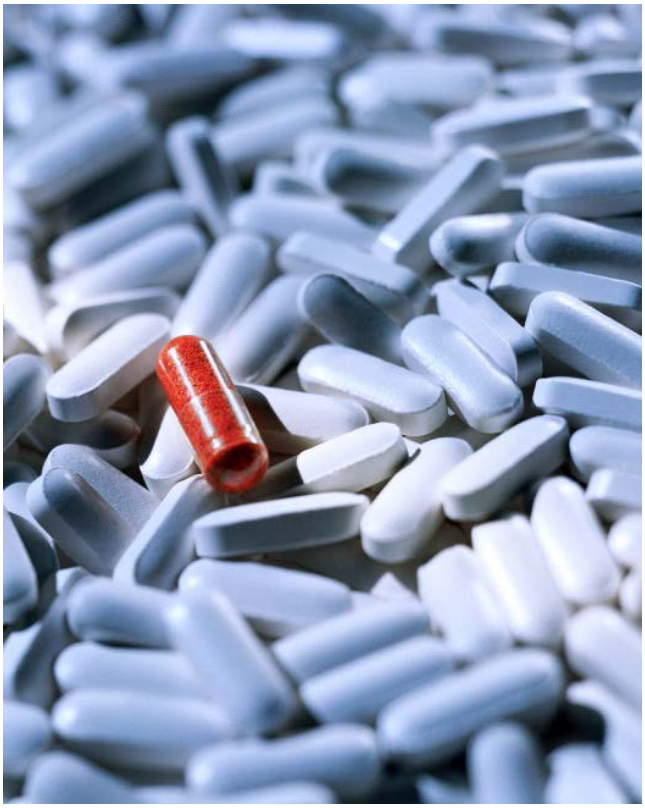
Therapeutic Products Directorate

Drug Submission Performance Annual Report
Fiscal Year
2015 – 2016

Apr 1 2015 – Mar 31 2016



Canada

This page is left blank intentionally.

This page is left blank intentionally.

Table of Contents

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 2011-12 to 2015-16.

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 2015-16 fiscal year (from Apr 1 2015 to March 31 2016).

What's New

- 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.

- The CTA and CTA-A performance graphs now include average and median days.

- A new graph has been added to show the number of Notifiable Changes received by Lead Bureau.

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.

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

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 (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

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"[3] 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.

[3] For further clarification refer to the Guidance for Industry: Management of Drug Submissions http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/mgmt-gest/mands_gespd-eng.php#a5.7

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[4]	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 **http://www.hc-sc.gc.ca/dhp-mps/prodpharma/fees-frais/fee_frais_guide-eng.php#app1**

[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.

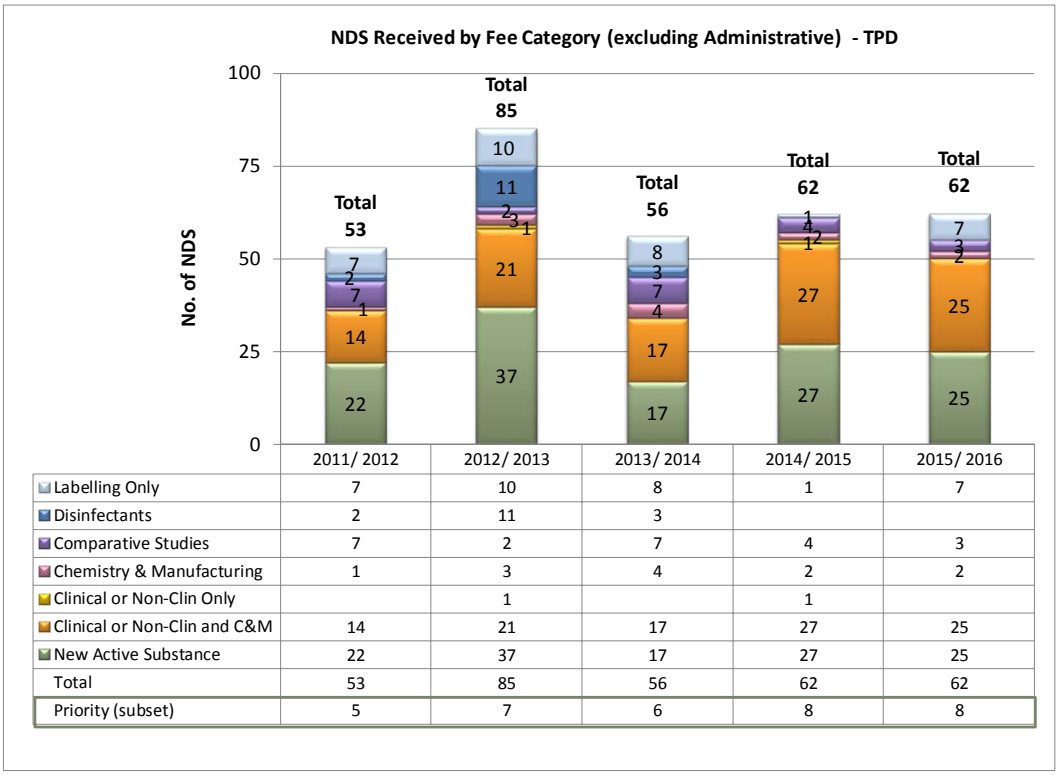
New Drug Submission (NDS)

&

Supplemental New Drug Submission (SNDS)

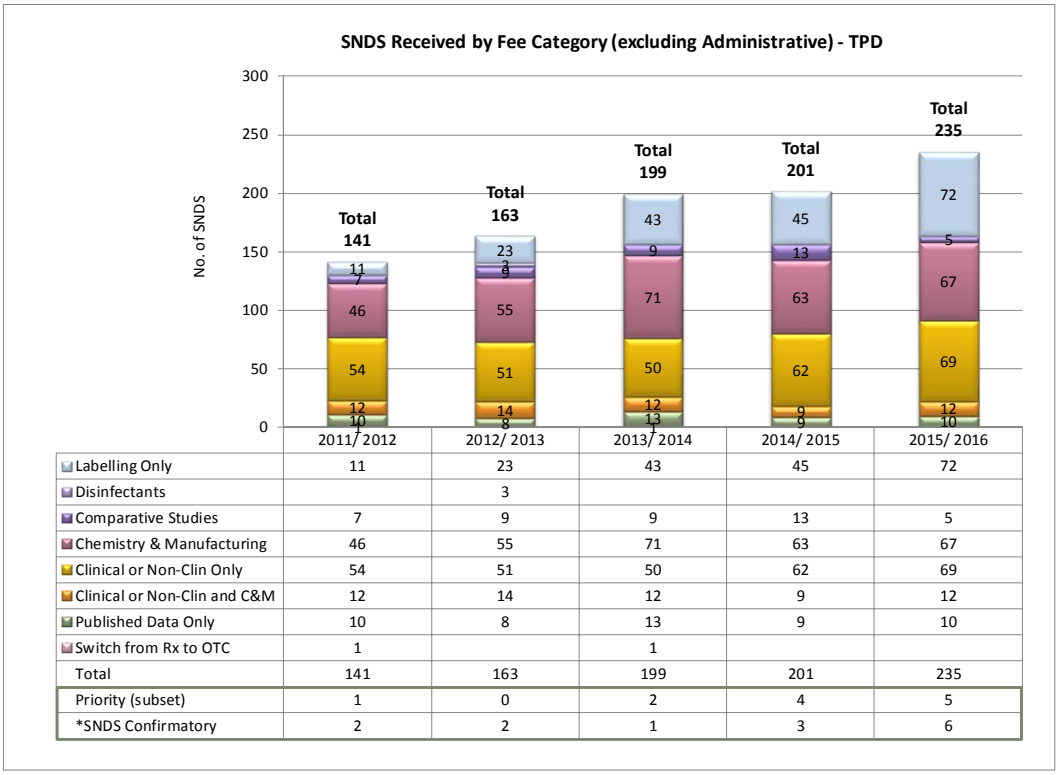
SUBMISSIONS RECEIVED[5]

New Drug Submissions (NDS) Received by Fee Category



	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
Labelling Only	7	10	8	1	7
Disinfectants	2	11	3		
Comparative Studies	7	2	7	4	3
Chemistry & Manufacturing	1	3	4	2	2
Clinical or Non-Clin Only		1		1	
Clinical or Non-Clin and C&M	14	21	17	27	25
New Active Substance	22	37	17	27	25
Total	53	85	56	62	62
Priority (subset)	5	7	6	8	8

Supplemental New Drug Submissions (SNDS) Received by Fee Category

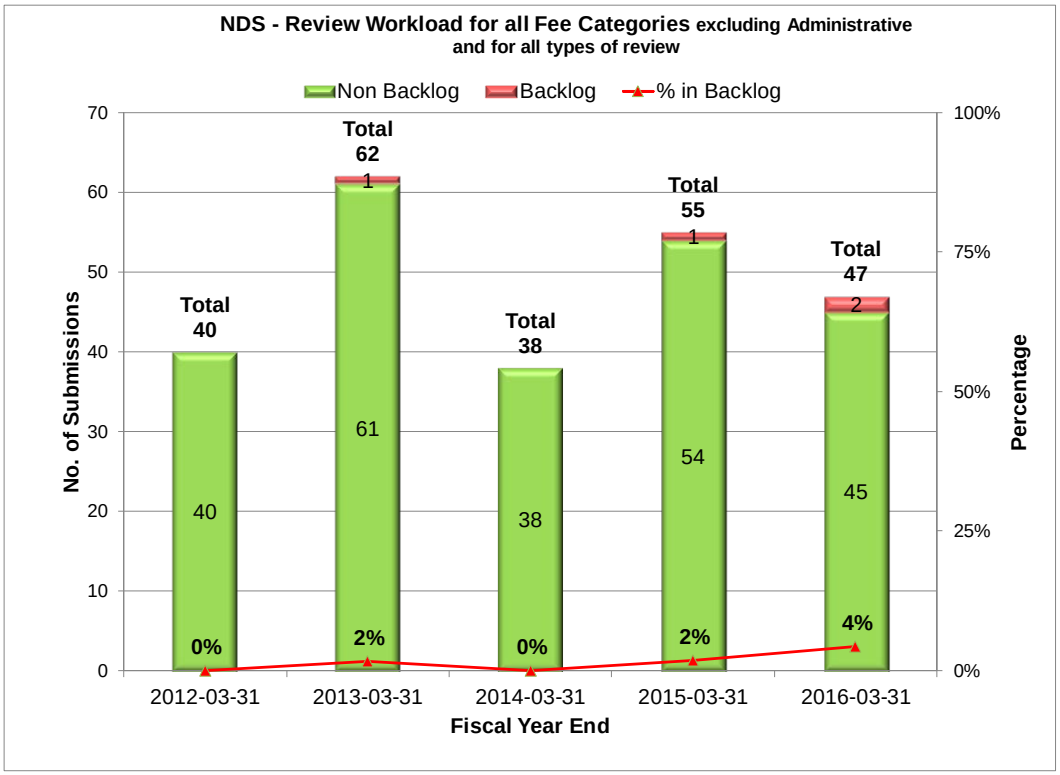


	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
Labelling Only	11	23	43	45	72
Disinfectants		3			
Comparative Studies	7	9	9	13	5
Chemistry & Manufacturing	46	55	71	63	67
Clinical or Non-Clin Only	54	51	50	62	69
Clinical or Non-Clin and C&M	12	14	12	9	12
Published Data Only	10	8	13	9	10
Switch from Rx to OTC	1		1		
Total	141	163	199	201	235
Priority (subset)	1	0	2	4	5
*SNDS Confirmatory	2	2	1	3	6

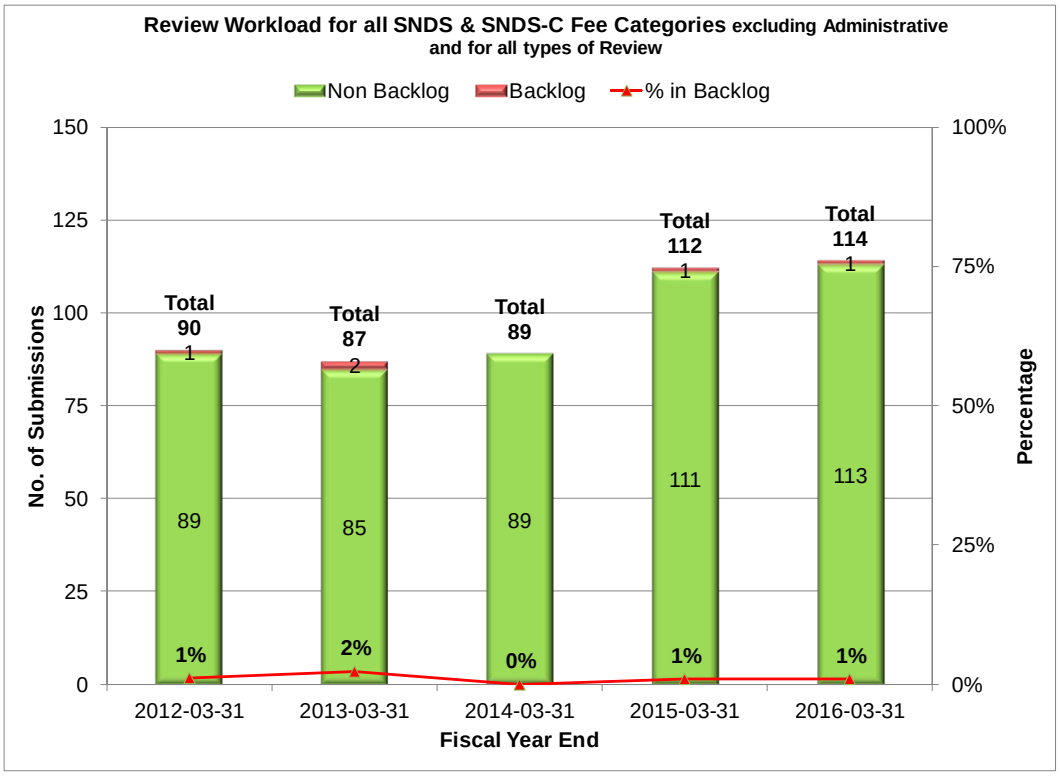
[5] TPD's non-prescription (or over-the-counter) and disinfectant drug review functions were moved to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013 and are now being reported separately in the NNHPD Drug Submission Performance Annual Report.

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

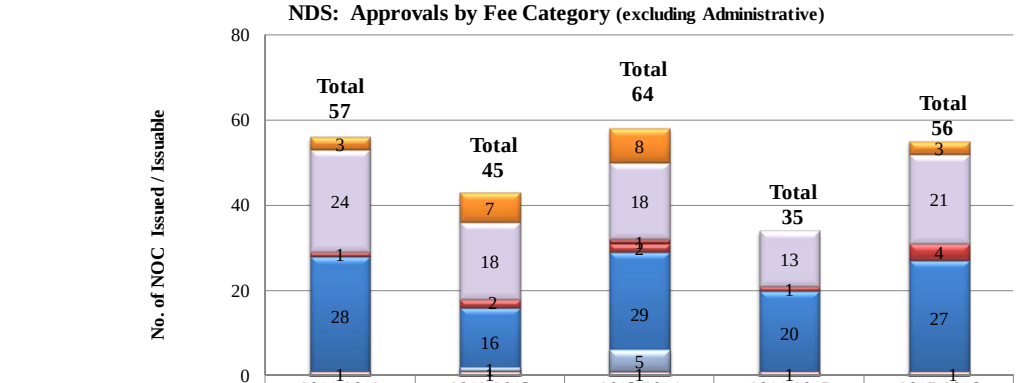
TPD NDS: All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2012-03-31	2013-03-31	2014-03-31	2015-03-31	2016-03-31
Labelling Only	1	1	0	1	3
Backlog	*0*	*0*	*0*	*0*	*0*
Disinfectant	1	4	3	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	2	0	3	2	0
Backlog	*0*	*0*	*0*	*1*	*0*
Chemistry & Manufacturing	0	2	3	2	3
Backlog	*0*	*0*	*0*	*0*	*2*
Clinical or Non-Clin Only	0	0	0	1	0
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	19	20	15	26	24
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	17	35	14	23	17
Backlog	*0*	*1*	*0*	*0*	*0*
Total	**40**	**62**	**38**	**55**	**47**
Non Backlog	**40**	**61**	**38**	**54**	**45**
Backlog	**0**	**1**	**0**	**1**	**2**
% in Backlog	**0%**	**2%**	**0%**	**2%**	**4%**
Priority (subset)	**2**	**5**	**0**	**4**	**4**
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					
	2012-03-31	2013-03-31	2014-03-31	2015-03-31	2016-03-31
Labelling Only	**0**	**1**	**7**	**9**	**13**
Backlog	*0*	*0*	*0*	*0*	*1*
Comparative Studies	**5**	**2**	**4**	**8**	**1**
Backlog	*1*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**21**	**29**	**22**	**29**	**31**
Backlog	*0*	*2*	*0*	*1*	*0*
Clinical or Non-Clin Only	**47**	**39**	**39**	**51**	**50**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**10**	**11**	**10**	**9**	**12**
Backlog	*0*	*0*	*0*	*0*	*0*
Disinfectants	**0**	**1**	**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	**7**	**5**	**7**	**6**	**7**
Backlog	0	0	0	0	0
Total	**90**	**87**	**89**	**112**	**114**
Non Backlog	**89**	**85**	**89**	**111**	**113**
Backlog	**1**	**2**	**0**	**1**	**1**
% in Backlog	**1%**	**2%**	**0%**	**1%**	**1%**
Priority (subset)	1	0	1	2	5
Backlog	0	0	0	0	0
***SNDS-C (Confirmatory)**	3	1	0	3	6
Backlog	0	0	0	0	0

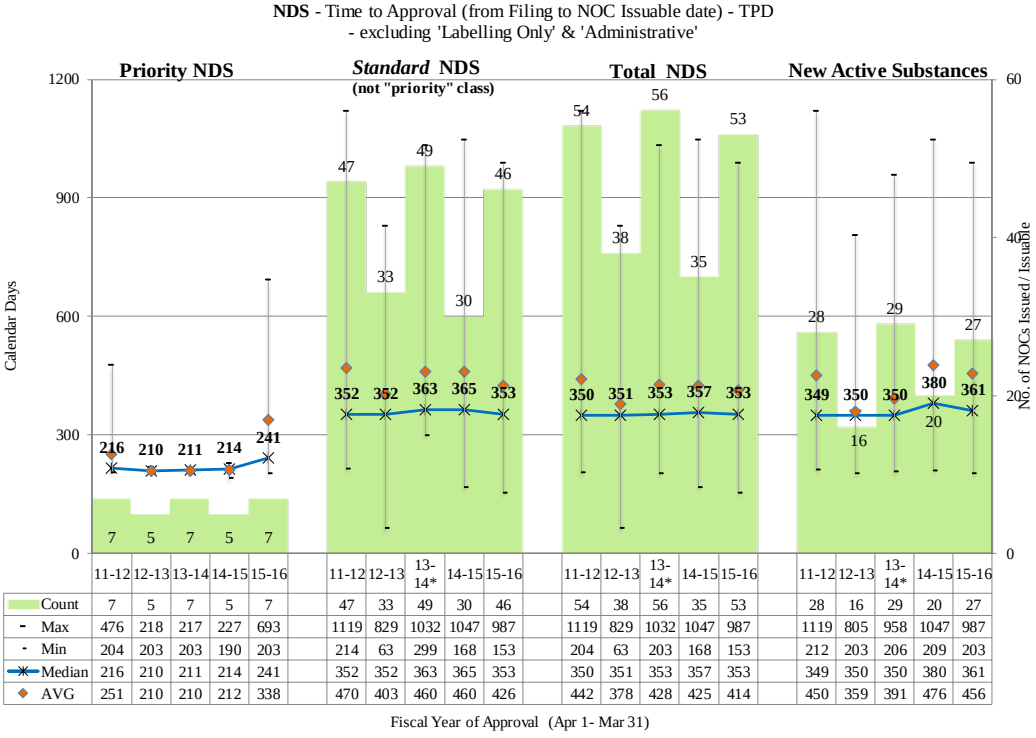
APPROVALS

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



	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
Labelling Only	3	7	8		3
Clinical or Non-Clin and C&M	24	18	18	13	21
Clinical or Non-Clin Only			1		
Comparative Studies	1	2	2	1	4
New Active Substance	28	16	29	20	27
Disinfectants		1	5		
Chemistry & Manufacturing	1	1	1	1	1
Total	57	45	64	35	56
Notice of Compliance	56	43	61	32	49
NOC on Hold (Patent)	1		1	1	1
NOC on Hold (Switch)		1			1
NOC with Conditions		1	2	2	5
Priority (subset)	7	5	7	5	7

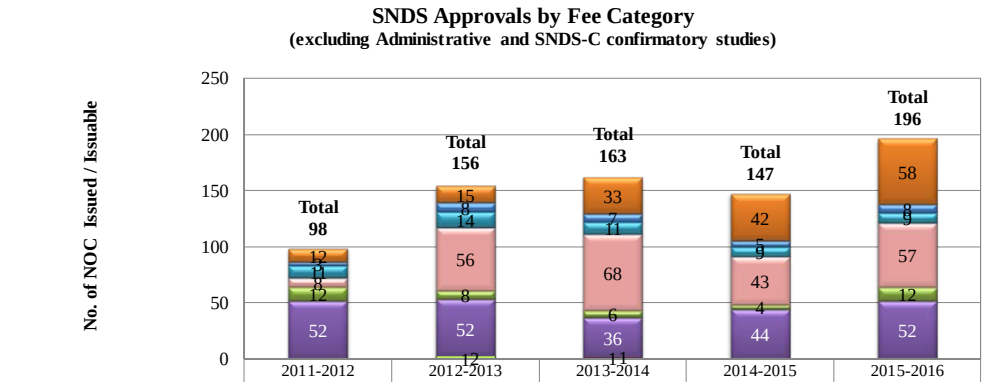
NDS Approval Times



	Priority NDS					Standard NDS (not "priority" class)					Total NDS					New Active Substances				
	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14*	14-15	15-16	11-12	12-13	13-14*	14-15	15-16	11-12	12-13	13-14*	14-15	15-16
Count	7	5	7	5	7	47	33	49	30	46	54	38	56	35	53	28	16	29	20	27
Max	476	218	217	227	693	1119	829	1032	1047	987	1119	829	1032	1047	987	1119	805	958	1047	987
Min	204	203	203	190	203	214	63	299	168	153	204	63	203	168	153	212	203	206	209	203
Median	216	210	211	214	241	352	352	363	365	353	350	351	353	357	353	349	350	350	380	361
AVG	251	210	210	212	338	470	403	460	460	426	442	378	428	425	414	450	359	391	476	456

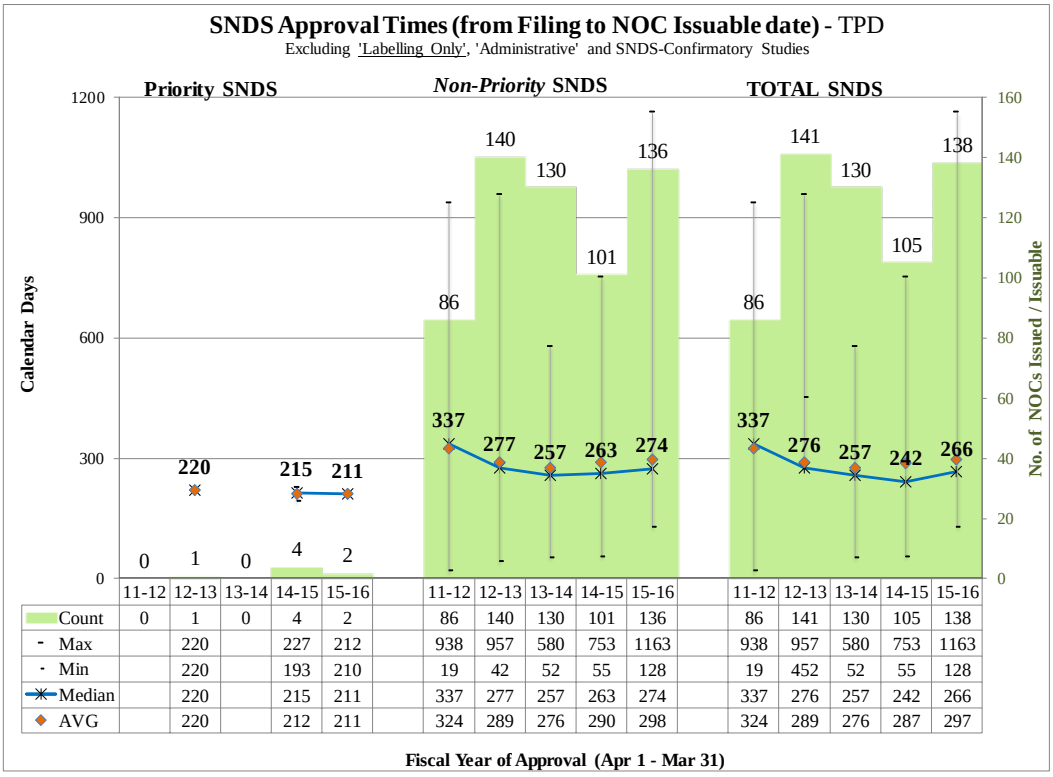
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor. *One outlier is included for fiscal year 2013-14. The NDS was in rejected status for over 4 years but following a judicial 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



	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
Labelling Only	12	15	33	42	58
Published Data Only	3	8	7	5	8
Clinical or Non-Clin and C&M	11	14	11	9	9
Chemistry & Manufacturing	8	56	68	43	57
Comparative Studies	12	8	6	4	12
Clinical or Non-Clin Only	52	52	36	44	52
Switch from Rx to OTC	0	1	1		
Disinfectants	0	2	1		
Total	98	156	163	147	196
Notice of Compliance	95	152	156	141	190
NOC on Hold (Patent)			1	1	1
NOC on Hold (Switch)		3	4		
NOC with Conditions	3	1	2	5	5
Priority (subset)	0	1	0	4	

SNDS Approval Times



	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16
Count	0	1	0	4	2	86	140	130	101	136	86	141	130	105	138
Max		220		227	212	938	957	580	753	1163	938	957	580	753	1163
Min		220		193	210	19	42	52	55	128	19	452	52	55	128
Median		220		215	211	337	277	257	263	274	337	276	257	242	266
AVG		220		212	211	324	289	276	290	298	324	289	276	287	297

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 2015-2016

New Active Substance Approvals – TPD Fiscal Year 2015-2016 (April 1 2015 – March 31 2016)				
Brand Name (Active Ingredient(s) - Indication(s))	**Class**	**Company**	**Filing (CR[6]) Date**	**Approval Date (dd-mon-yy)**
AMITIZA (Lubiprostone) - is indicated for the treatment of chronic idiopathic constipation (CIC) in adults. The efficacy of AMITIZA® has been established in double-blinded, placebo-controlled clinical studies of 4 weeks duration. Efficacy of AMITIZA® beyond 4 weeks has not been established.	NAS	Sucampo Pharma Americas LLC	31-Oct-14	14-Oct-15
BRIDION (Sugammadex) - is indicated for reversal of moderate to deep neuromuscular blockade induced by rocuronium or vecuronium in adults undergoing surgery.	NAS	Merck Canada Inc.	23-Dec-14	5-Feb-16
BRIVLERA (Brivaracetam) - is indicated as adjunctive therapy in the management of partial-onset seizures in adult patients with epilepsy who are not satisfactorily controlled with conventional therapy.	NAS	UCB Canada Inc.	30-Mar-15	9-Mar-16
CARBAGLU (Carglumic Acid) - Acute hyperammonemia in patients with NAGS deficiency: Carbaglu is indicated as an adjunctive therapy in pediatric and adult patients for the treatment of acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS). During acute hyperammonemic episodes, concomitant administration of Carbaglu with other ammonia lowering therapies such as alternate pathway medications, hemodialysis, and dietary protein restriction are recommended. **Maintenance therapy for chronic hyperammonemia in patients with NAGS deficiency:** Carbaglu is indicated for maintenance therapy in pediatric and adult patients for chronic hyperammonemia due to the deficiency of the hepatic enzyme N-aceytlglutamate synthase (NAGS). During maintenance therapy, the concomitant use of other ammonia lowering therapies and protein restriction may be reduced or discontinued based on plasma ammonia levels.	Priority -NAS	Orphan Europe Sarl	14-Jan-14	10-Apr-15
COTELLIC (Cobimetinib Fumarate) - is indicated for use in combination with vemurafenib for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600 mutation.	NAS	Hoffmann La Roche Limited	12-Mar-15	22-Feb-16

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

New Active Substance Approvals – TPD Fiscal Year 2015-2016 (April 1 2015 – March 31 2016)				
Brand Name (Active Ingredient(s) - Indication(s))	**Class**	**Company**	**Filing (CR[6]) Date**	**Approval Date (dd-mon-yy)**
DAKLINZA (Daclatasvir as Daclatasvir Dihydrochloride) - is indicated 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 and compensated liver disease, including cirrhosis.	NOC-C NAS	Bristol-Myers Squibb Canada	16-May-14	13-Aug-15 NOC-C
ENTRESTO (Sacubitril, Valsartan) - is indicated for the treatment of heart failure with reduced ejection fraction (HFrEF) in patients with NYHA Class II or III, to reduce the incidence of cardiovascular death and heart failure hospitalisation.	Priority -NAS	Novartis Pharmaceuticals Canada Inc.	6-Mar-15	2-Oct-15
FETZIMA (Levomilnacipran Hydrochloride) - is indicated for the short-term symptomatic relief of major depressive disorder (MDD).	NAS	Actavis Specialty Pharmaceuticals Co.	13-Aug-13	8-May-15
GENVOYA (Elvitegravir, Cobicistat, Emtricitabine, Tenofovir Alafenamide Hemifumarate) - is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients 12 years of age and older (and weighing ≥ 35 kg) and with no known mutations associated with resistance to the individual components of GENVOYA.	NAS	Gilead Sciences Canada Inc.	19-Jan-15	27-Nov-15
IBRANCE (Palbociclib) - is indicated: in combination with letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease.	NAS	Pfizer Canada Inc.	12-Feb-15	16-Mar-16 NOC-C
ICLUSIG (Ponatinib Hydrochloride) - is indicated for the treatment of adult patients with chronic phase (CP), accelerated phase (AP), or blast phase (BP) chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom other tyrosine kinase inhibitor (TKI) therapy is not appropriate, including CML or Ph+ ALL that is T315I mutation positive or where there is prior TKI resistance or intolerance.	NOC-C NAS	Ariad Pharmaceuticals Inc.	23-May-13	2-Apr-15 NOC-C

New Active Substance Approvals – TPD
Fiscal Year 2015-2016
(April 1 2015 – March 31 2016)

Brand Name (Active Ingredient(s) - Indication(s))	Class	Company	Filing (CR[6]) Date	Approval Date (dd-mon-yy)
JARDIANCE (Empagliflozin) - Monotherapy: is indicated for use as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus for whom metformin is inappropriate due to contraindications or intolerance. **Add-on combination**: is indicated in adult patients with type 2 diabetes mellitus to improve glycemic control, when metformin used alone does not provide adequate glycemic control, in combination with: metformin, metformin and a sulfonylurea, pioglitazone (alone or with metformin) and basal or prandial insulin (alone or with metformin), when the existing therapy, along with diet and exercise, does not provide adequate glycemic control.	NAS	Boehringer Ingelheim (Canada) Ltd Ltee	17-Apr-13	23-Jul-15
KYPROLIS (Carfilzomib) - in combination with lenalidomide and dexamethasone is indicated for the treatment of patients with relapsed multiple myeloma who have received 1 to 3 prior lines of therapy.	Priority -NAS	Amgen Canada Inc.	19-May-15	15-Jan-16
LENVIMA (Lenvatinib Mesylate) - is indicated for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer.	NAS	Eisai Limited	8-Jan-15	22-Dec-15
MIFEGYMISO (Mifepristone and Misoprostol) - is indicated for medical termination of a developing intra-uterine pregnancy with a gestational age up to 49 days as measured from the first day of the Last Menstrual Period (LMP) in a presumed 28-day cycle.	NAS	Linepharma International Limited	14-Nov-12	29-Jul-15
MOVANTIK (Naloxegol Oxalate) - is indicated for the treatment of opioid-induced constipation (OIC) in adult patients with non-cancer pain who have had an inadequate response to laxative(s).	NAS	AstraZeneca Canada Inc.	30-Aug-13	2-Jun-15
OFEV (Nintedanib Esilate) - is indicated for the treatment of Idiopathic Pulmonary Fibrosis (IPF).	NAS	Boehringer Ingelheim (Canada) Ltd Ltee	9-Jul-14	25-Jun-15
ORKAMBI (Ivacaftor, Lumacaftor) - is indicated for the treatment of cystic fibrosis (CF) in patients age 12 years and older who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.	Priority -NAS	Vertex Pharmaceuticals (Canada) Incorporated	30-Jan-15	26-Jan-16

New Active Substance Approvals – TPD
Fiscal Year 2015-2016
(April 1 2015 – March 31 2016)

Brand Name (Active Ingredient(s) - Indication(s))	Class	Company	Filing (CR[6]) Date	Approval Date (dd-mon-yy)
RAVICTI (Glycerol Phenylbutyrate) - is indicated for: Use as a nitrogen-binding agent for chronic management of adult and pediatric patients ≥2 years of age with UCDs who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. RAVICTI should be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, and protein-free calorie supplements).	Priority -NAS	Horizon Pharma Ireland Ltd.	25-Apr-14	18-Mar-16
ROSIVER (Ivermectin) - cream, 1% is indicated for the topical treatment of inflammatory lesions (papules and pustules) of rosacea in adults 18 years of age or older.	NAS	Galderma Canada inc.	6-May-14	22-Apr-15
SUNVEPRA (Asunaprevir) - is indicated in combination with other agents for the treatment of chronic hepatitis C (CHC) in adult patients with hepatitis C virus (HCV) genotypes 1 or 4 and compensated liver disease, including cirrhosis.	NAS	Bristol-Myers Squibb Canada	16-May-14	9-Mar-16
UPTRAVI (Selexipag) - is indicated for the long-term treatment of idiopathic pulmonary arterial hypertension (iPAH), heritable pulmonary arterial hypertension (HPAH), PAH associated with connective tissue disorders and PAH associated with congenital heart disease, in adult patients with WHO functional class (FC) II–III to delay disease progression. Disease progression included: hospitalization for PAH, initiation of intravenous or subcutaneous prostanoids, or other disease progression events (decrease of 6-minute walk distance [6MWD] associated with either worsened PAH symptoms or need for additional PAH-specific treatment).	NAS	Actelion Pharmaceuticals Ltd.	13-Feb-15	20-Jan-16
VARITHENA (Polidocanol) - is indicated for the treatment of incompetent great saphenous veins, accessory saphenous veins, and visible varicosities of the great saphenous vein (GSV) system, above and below the knee. Varithena™ is intended for use in adults with clinically significant venous reflux as diagnosed by duplex ultrasound.	NAS	Provensis Ltd.	20-Aug-14	4-Aug-15
VIIBRYD (Vilazodone Hydrochloride) - is indicated for the symptomatic relief of Major Depressive Disorder (MDD) in adults.	NAS	Forest Laboratories Canada Inc.	29-Jul-14	16-Jul-15

New Active Substance Approvals – TPD Fiscal Year 2015-2016 (April 1 2015 – March 31 2016)				
Brand Name (Active Ingredient(s) - Indication(s))	**Class**	**Company**	**Filing (CR[6]) Date**	**Approval Date (dd-mon-yy)**
XTORO (Finafloxacin) - is indicated for the treatment of acute otitis externa (AOE) caused by susceptible strains of Pseudomonas aeruginosa and Staphylococcus aureus, with or without an otowick, in patients age 1 year and older.	NAS	Alcon Canada Inc.	5-Jun-14	11-Mar-16
ZEPATIER (Elbasvir, Grazoprevir) - is indicated for the treatment of chronic hepatitis C (CHC) genotypes 1, 3, or 4 infection in adults as follows: Without ribavirin: in genotype (GT) 1 or 4 treatment-naïve (TN) and peginterferon alfa + ribavirin (PR) treatment-experienced (TE) relapsers (12 weeks); in GT1 protease inhibitor (PI)/PR-TE relapsers (12 weeks); in GT1b TN, non-cirrhotic patients (8 weeks); in GT1b PR- or PI/PR-TE on-treatment virologic failures (12 weeks) With ribavirin: in GT1a PR- or PI/PR-TE on-treatment virologic failures (16 weeks); in GT4 PR-TE on-treatment virologic failures (16 weeks) With sofosbuvir: in GT3 TN patients (12 weeks)	Priority -NAS	Merck Canada Inc.	30-Jun-15	19-Jan-16
ZERBAXA (Ceftolozane Sulfate and Tazobactam Sodium) - is indicated for the treatment of patients 18 years of age or older with the following infections when caused by ZERBAXA™ susceptible strains of the designated microorganisms: **Complicated Intra-abdominal Infections:** ZERBAXA™ is indicated for the treatment of complicated intra-abdominal infections (cIAI) caused by the following Gram-negative and Gram-positive microorganisms: Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Bacteroides fragilis, Streptococcus anginosus, Streptococcus constellatus, and Streptococcus salivarius. **Note:** In the treatment of cIAI, ZERBAXA™ should be used in combination with metronidazole in order to provide adequate anaerobic coverage. **Complicated Urinary Tract Infections, including Pyelonephritis:** ZERBAXA™ is indicated for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis caused by the following Gram-negative microorganisms: Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, and Pseudomonas aeruginosa.	NAS	Merck Canada Inc.	15-Sep-14	30-Sep-15

Priority Submission Approvals - TPD - Fiscal Year 2015-2016

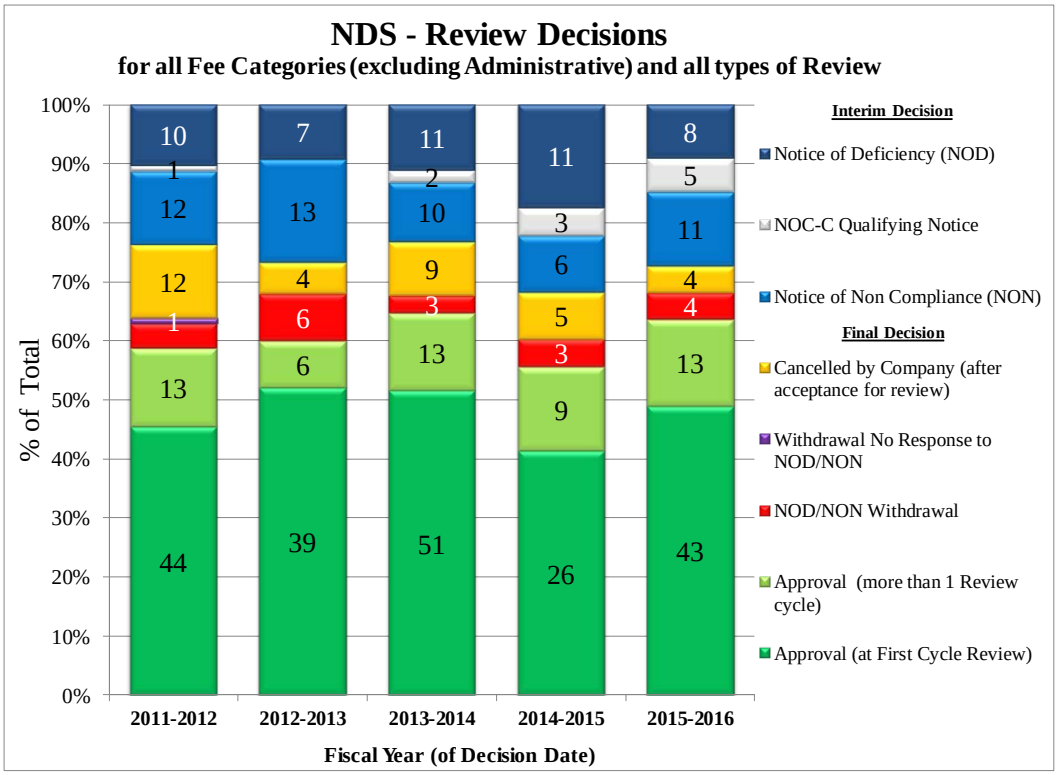
Priority Submission Approvals – TPD Fiscal Year 2015-2016 (April 1 2015 – March 31 2016)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR) Date**	**Approval Date**
CARBAGLU (Carglumic Acid) - Acute hyperammonemia in patients with NAGS deficiency: Carbaglu is indicated as an adjunctive therapy in pediatric and adult patients for the treatment of acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS). During acute hyperammonemic episodes, concomitant administration of Carbaglu with other ammonia lowering therapies such as alternate pathway medications, hemodialysis, and dietary protein restriction are recommended. **Maintenance therapy for chronic hyperammonemia in patients with NAGS deficiency:** Carbaglu is indicated for maintenance therapy in pediatric and adult patients for chronic hyperammonemia due to the deficiency of the hepatic enzyme N-aceytlglutamate synthase (NAGS). During maintenance therapy, the concomitant use of other ammonia lowering therapies and protein restriction may be reduced or discontinued based on plasma ammonia levels.	Priority-NAS	Orphan Europe Sarl	14-Jan-14	10-Apr-15
ENTRESTO (Sacubitril, Valsartan) - is indicated for the treatment of heart failure with reduced ejection fraction (HFrEF) in patients with NYHA Class II or III, to reduce the incidence of cardiovascular death and heart failure hospitalisation.	Priority-NAS	Novartis Pharmaceuticals Canada Inc.	6-Mar-15	2-Oct-15
KALYDECO (Ivacaftor) - is indicated for the treatment of cystic fibrosis (CF): in patients age 2 years and older who have one of the following mutations in the Cystic Fibrosis Transmembrane conductance Regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or G970R and in patients age 18 years and older with an R117H mutation in the CFTR gene.	Priority-CLIN/ C&M	Vertex Pharmaceuticals (Canada) incorporated	14-Nov-14	12-Jun-15
KYPROLIS (Carfilzomib) - in combination with lenalidomide and dexamethasone is indicated for the treatment of patients with relapsed multiple myeloma who have received 1 to 3 prior lines of therapy.	Priority-NAS	Amgen Canada Inc.	19-May-15	15-Jan-16

Priority Submission Approvals – TPD
Fiscal Year 2015-2016
(April 1 2015 – March 31 2016)

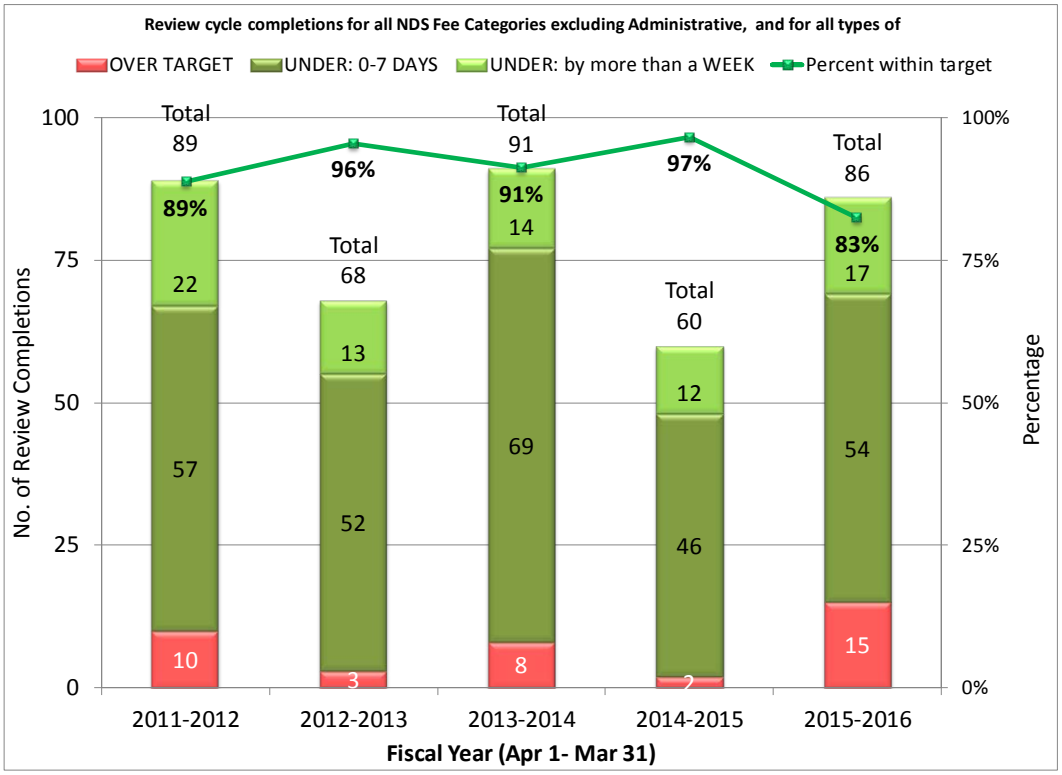
Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR) Date	Approval Date
ORKAMBI (Ivacaftor, Lumacaftor) - is indicated for the treatment of cystic fibrosis (CF) in patients age 12 years and older who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.	Priority-NAS	Vertex Pharmaceuticals (Canada) Incorporated	30-Jan-15	26-Jan-16
RAVICTI (Glycerol Phenylbutyrate) - is indicated for: Use as a nitrogen-binding agent for chronic management of adult and pediatric patients ≥2 years of age with UCDs who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. RAVICTI should be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, and protein-free calorie supplements).	Priority-NAS	Horizon Pharma Ireland Ltd.	25-Apr-14	18-Mar-16
TECHNIVIE (Ombitasvir, Ritonavir, Paritaprevir) - tablets with ribavirin is indicated for the treatment of adults with genotype 4 chronic hepatitis C virus infection without cirrhosis who are either treatment naïve or previously treated with peginterferon and ribavirin.	Priority-CLIN/ C&M	Abbvie Corporation	26-Mar-15	20-Oct-15
XTANDI (Enzalutamide) - is indicated in the setting of medical or surgical castration for the treatment of metastatic castration-resistant prostate cancer (CRPC) in patients who are chemotherapy-naïve with asymptomatic or mildly symptomatic disease after failure of androgen deprivation therapy and/or who have received docetaxel therapy.	Priority-CLIN Only	Astellas Pharma Canada Inc.	15-Sep-14	15-Apr-15
ZEPATIER (Elbasvir, Grazoprevir) - is indicated for the treatment of chronic hepatitis C (CHC) genotypes 1, 3, or 4 infection in adults as follows: Without ribavirin: in genotype (GT) 1 or 4 treatment-naïve (TN) and peginterferon alfa + ribavirin (PR) treatment-experienced (TE) relapsers (12 weeks); in GT1 protease inhibitor (PI)/PR-TE relapsers (12 weeks); in GT1b TN, non-cirrhotic patients (8 weeks); in GT1b PR- or PI/PR-TE on-treatment virologic failures (12 weeks) With ribavirin: in GT1a PR- or PI/PR-TE on-treatment virologic failures (16 weeks); in GT4 PR-TE on-treatment virologic failures (16 weeks) With sofosbuvir: in GT3 TN patients (12 weeks)	Priority-NAS	Merck Canada Inc.	30-Jun-15	19-Jan-16

REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

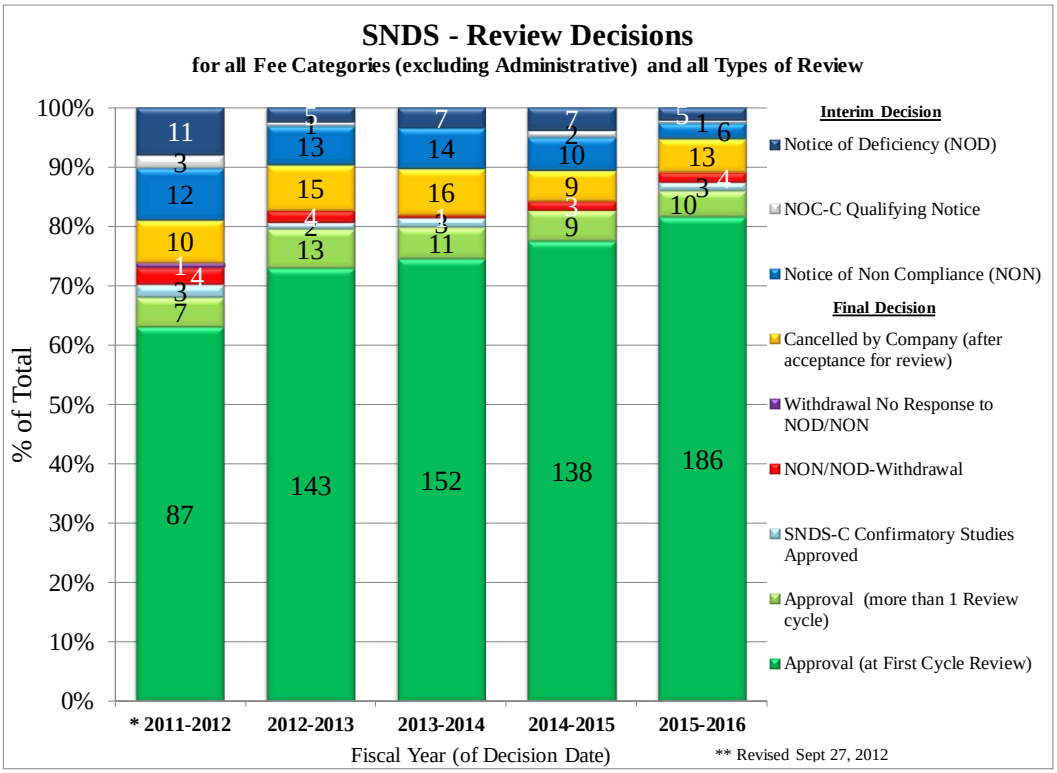


NDS - Review Cycle Completions Showing Percentage Within Target

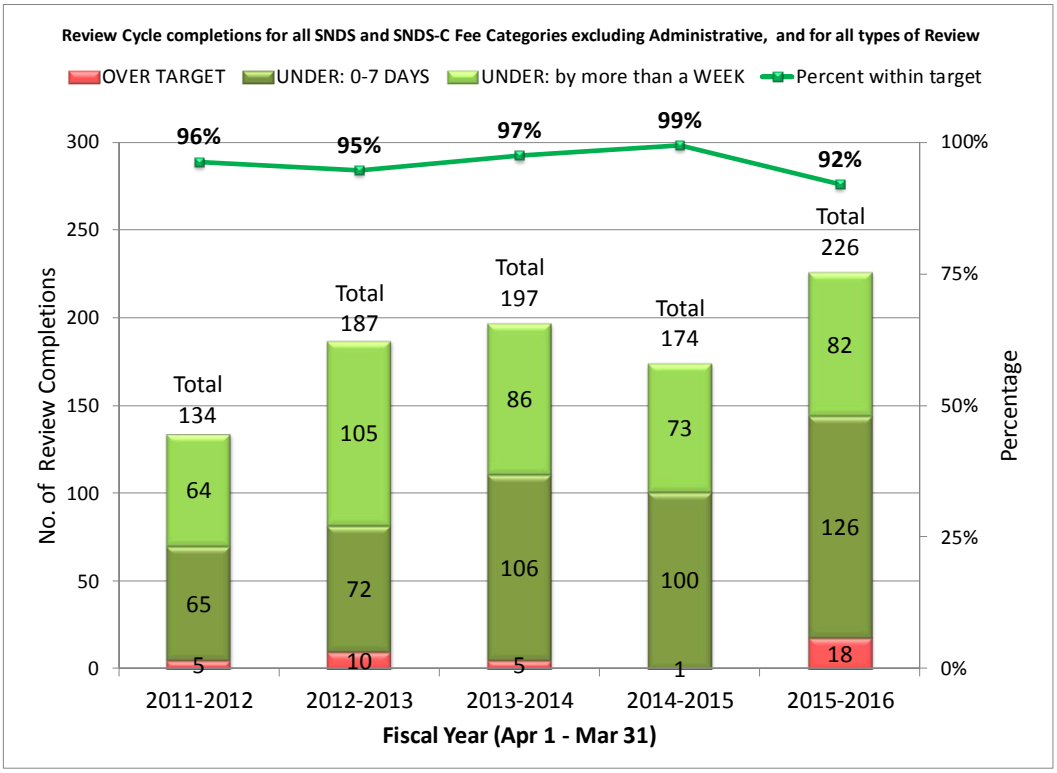


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

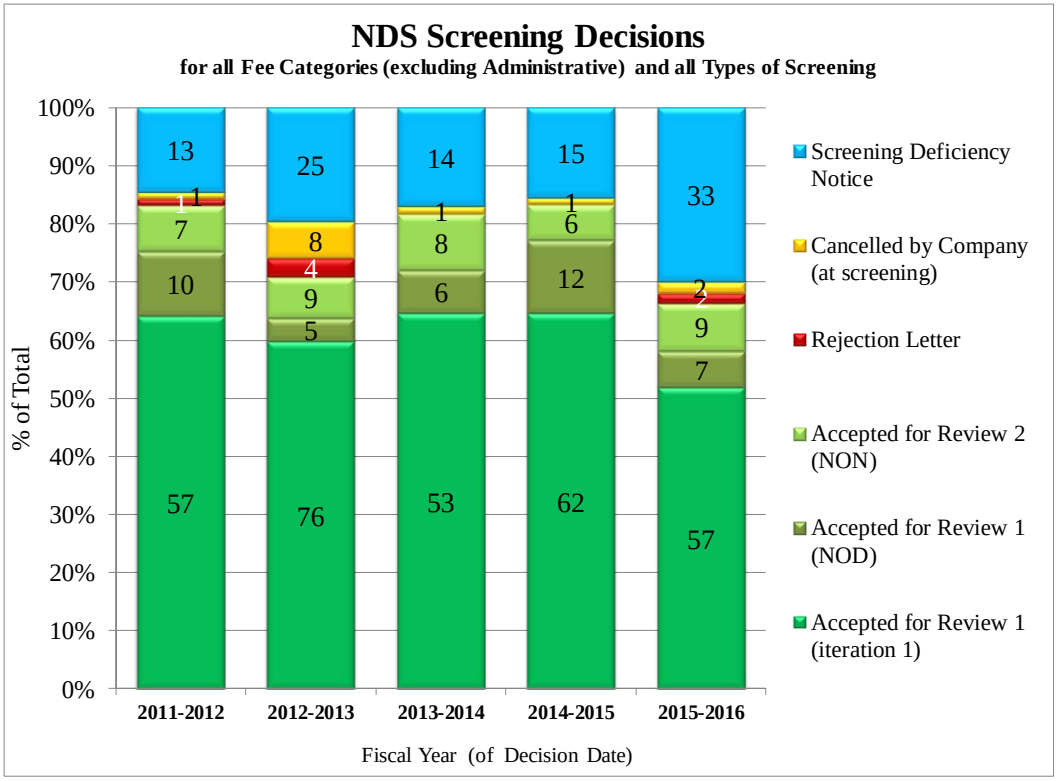


SNDS - Review Cycle Completions Showing Percentage Within Target

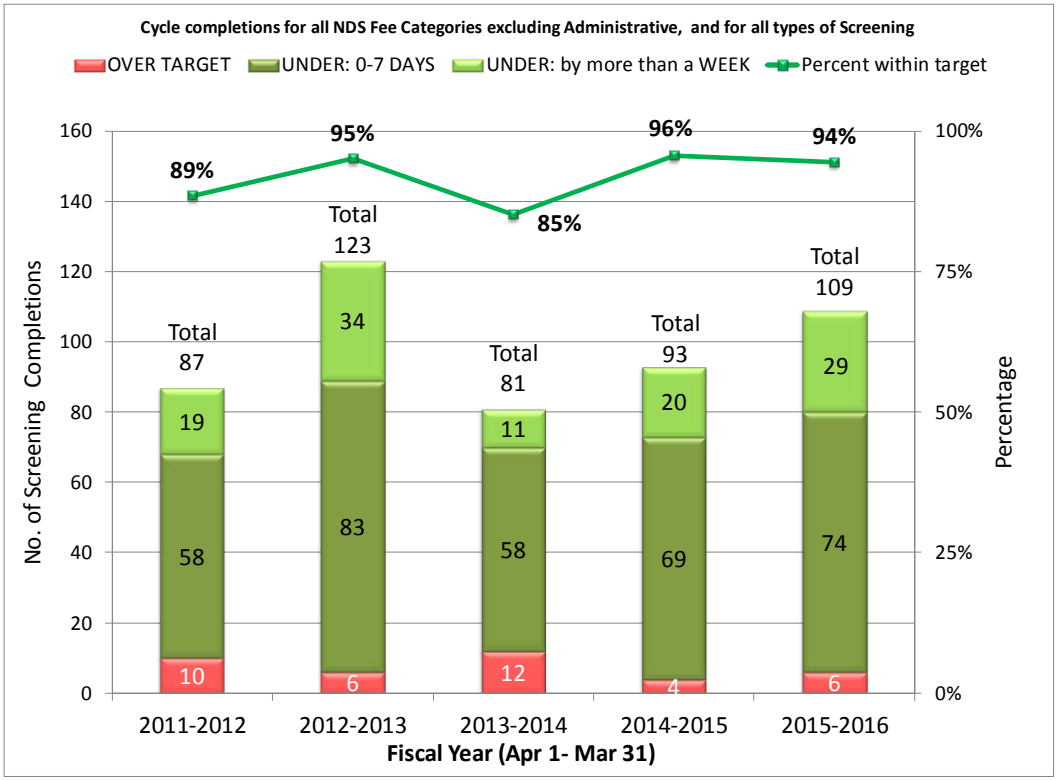


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

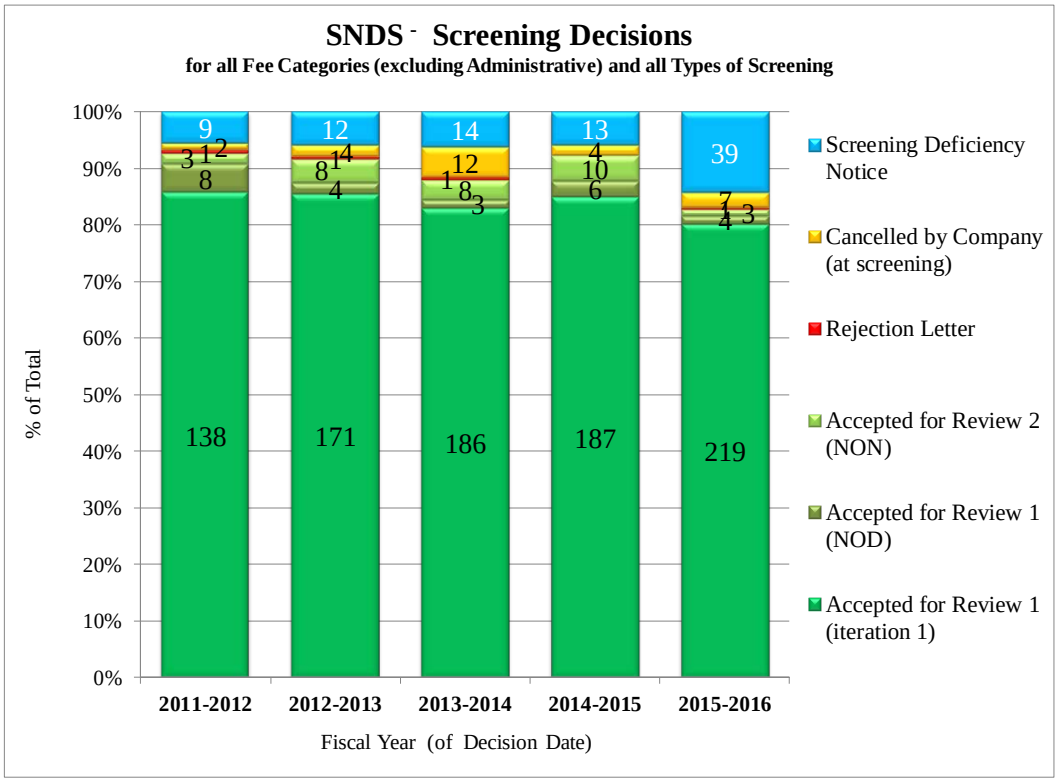


NDS - Screening Cycle Completions Showing Percentage Within Target

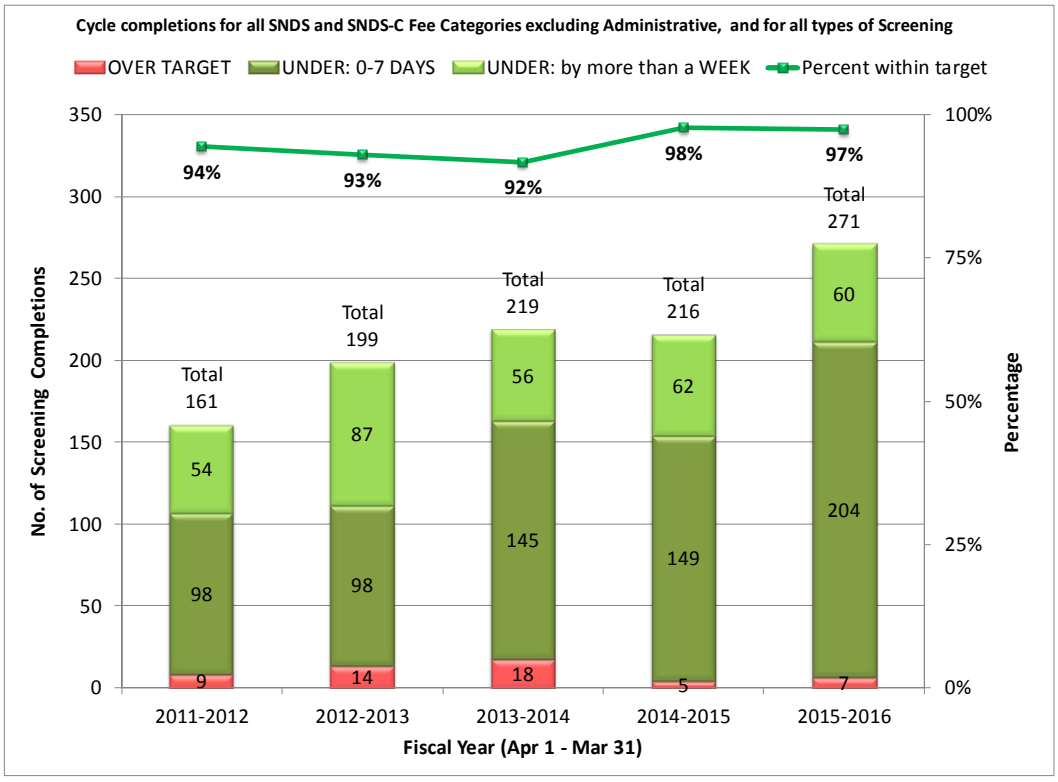


SCREENING CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Screening Decisions



SNDS - Screening Cycle Completions Showing Percentage Within Target



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	11-12	12-13* revised	13-14	14-15	15-16	Final Decision in Dispute	NDS Status (as of Apr 18 2016)
Total Received	**1**	**2**	**1**	**0**	**2**		
Total Pending	***0***	***0***	***0***	***0***	***1***		
PENDING						NOD-Withdrawal	Under Reconsideration
Total Granted	***0***	***1***	***1***	***0***	***0***		
GRANTED			*1*			NON-Withdrawal	Cleared
GRANTED		1				NON-Withdrawal	Cleared
Total Denied	***1***	***1***	***0***	***0***	***1***		
DENIED					1	NOD-Withdrawal	Withdrawn
DENIED		1				Screening Rejection Letter	Rejected
DENIED	1					NON-Withdrawal	Withdrawn

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

SNDS - Reconsideration of Final Decisions Requests Received

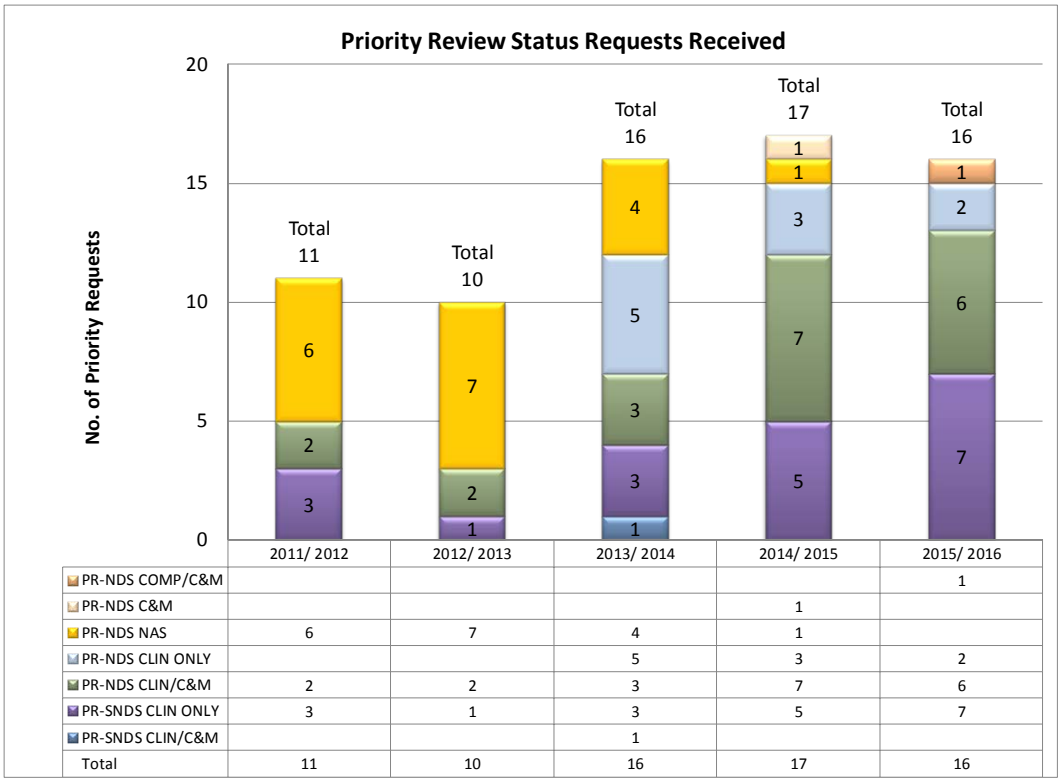
Fiscal Year of Request (April 1 - March 31)

Breakdown by Reconsideration Decision	11-12	12-13	13-14	14-15	15-16	Final Decision in Dispute	SNDS Status (as of Apr 18 2016)
Total Received	**0**	**0**	**0**	**1**	**2**		
Total Pending					**1**	NOD-Withdrawal	Under Reconsideration
Total Granted				**1**		NOD-Withdrawal	Withdrawn
Total Denied	**0**	**0**	**0**	**0**	**1**	NOD-Withdrawal	Withdrawn

This page is left blank intentionally.

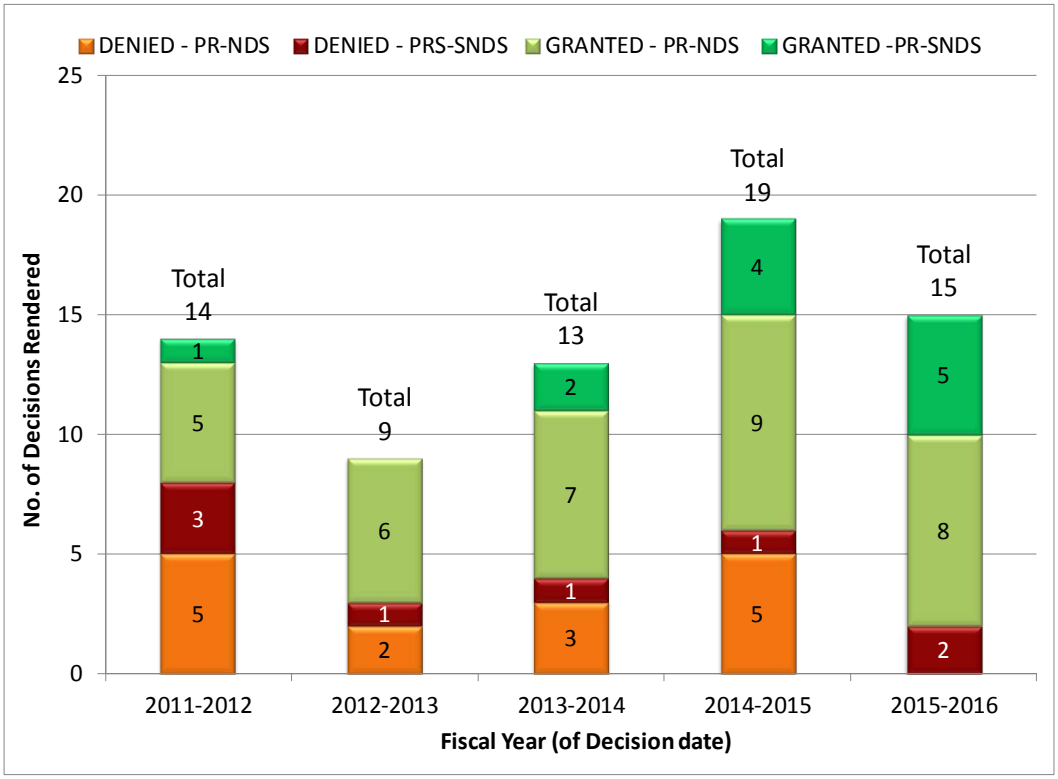
PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests Received



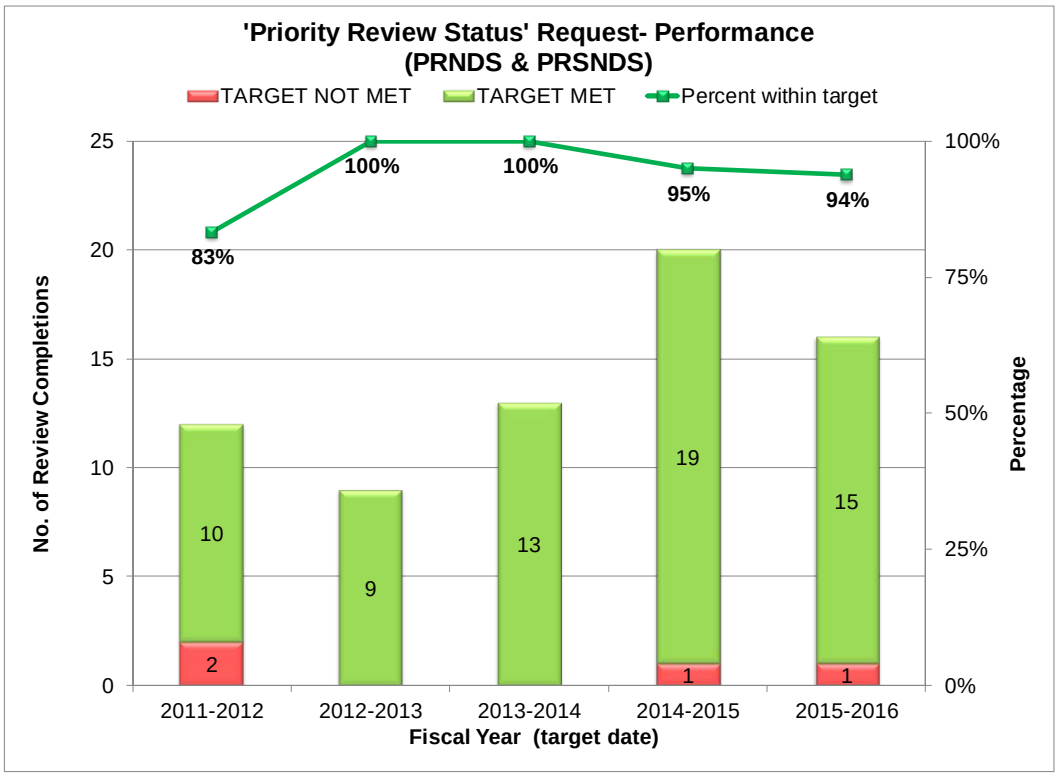
	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
PR-NDS COMP/C&M					1
PR-NDS C&M				1	
PR-NDS NAS	6	7	4	1	
PR-NDS CLIN ONLY			5	3	2
PR-NDS CLIN/C&M	2	2	3	7	6
PR-SNDS CLIN ONLY	3	1	3	5	7
PR-SNDS CLIN/C&M			1		
Total	11	10	16	17	16

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 (Apr - Mar)

Breakdown by Reconsideration Decision	11-12 * revised	12-13	13-14	14-15	15-16	Final Decision in Dispute	Submission Status (as of Apr 18 2016)
Total Received	**1**	**0**	**0**	**0**	**0**		
DENIED	1	0	0	0	0	Priority Review Request (for SNDS) Denied	Refused

Abbreviated New Drug Submissions (ANDS)

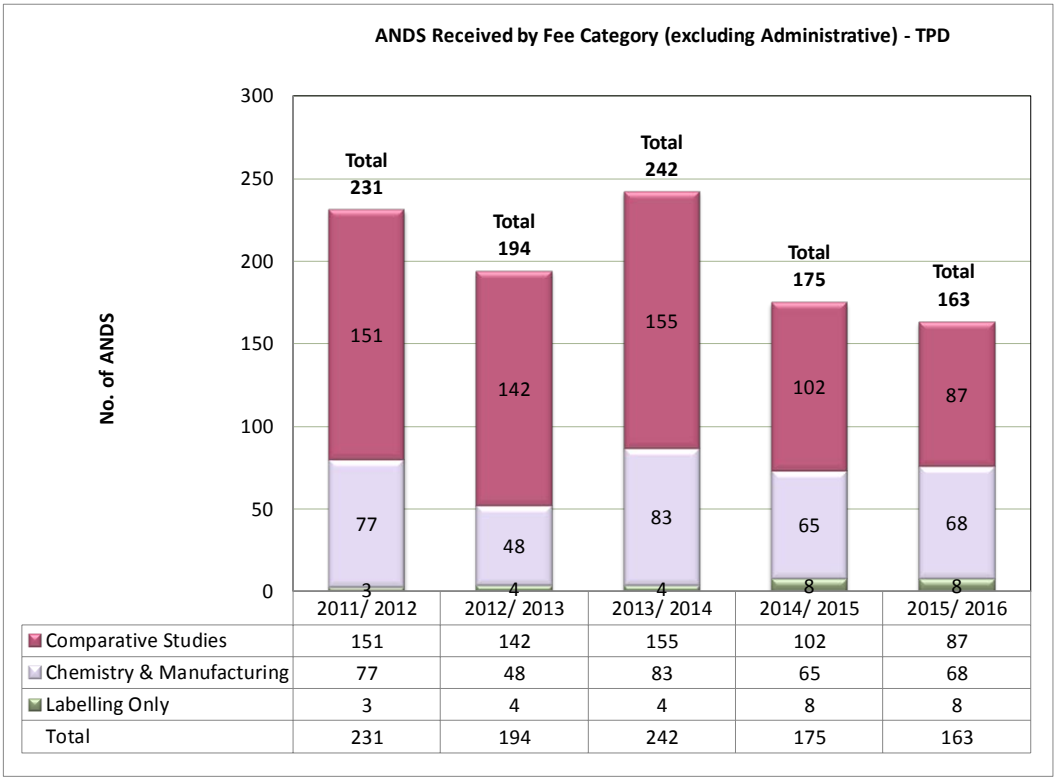
&

Supplemental Abbreviated New Drug Submissions

(SANDS)

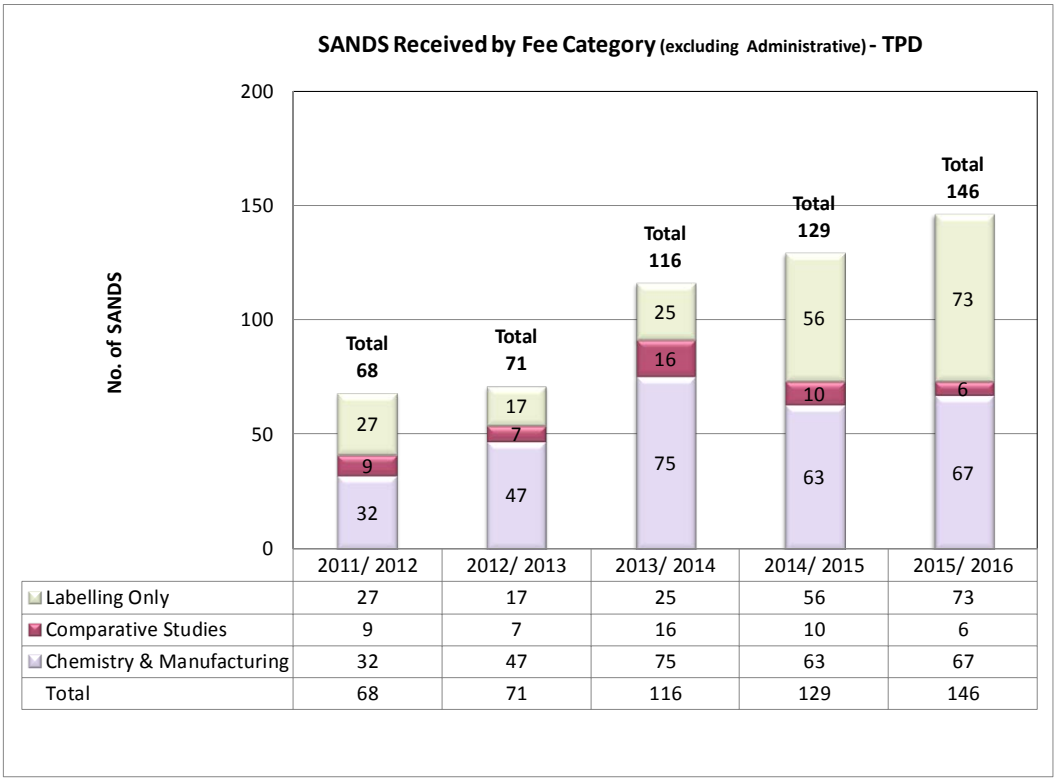
SUBMISSIONS RECEIVED

Abbreviated New Drug Submissions (ANDS) Received by Fee Category



	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
Comparative Studies	151	142	155	102	87
Chemistry & Manufacturing	77	48	83	65	68
Labelling Only	3	4	4	8	8
Total	231	194	242	175	163

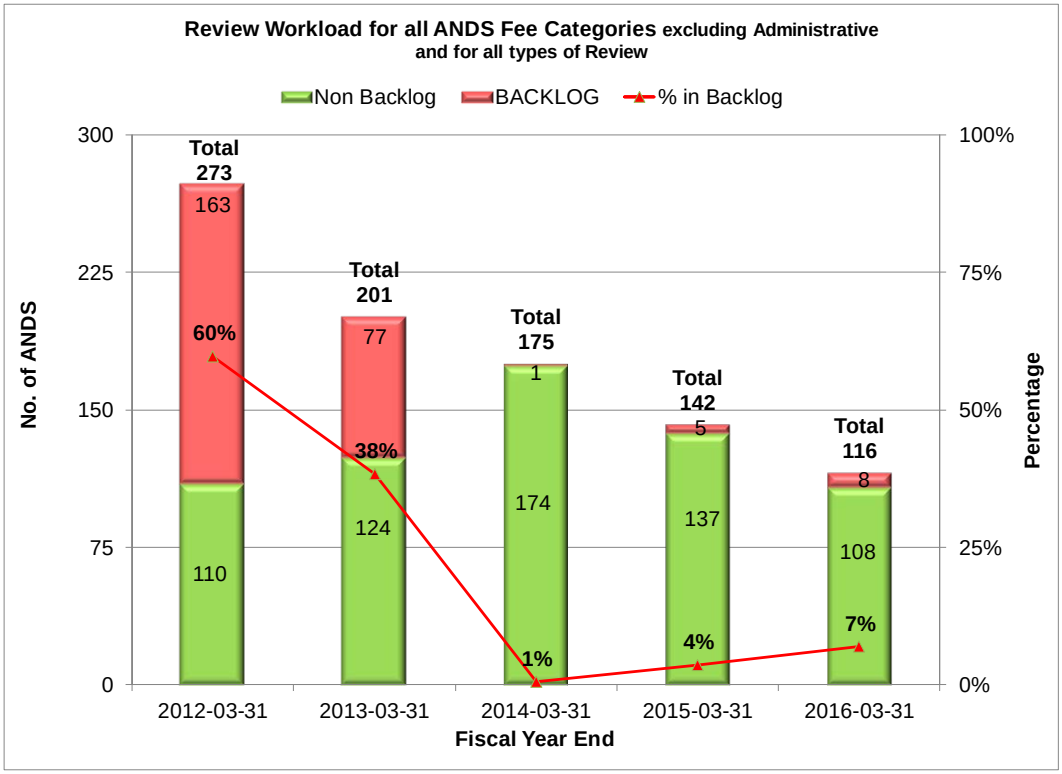
Supplemental Abbreviated New Drug Submission (SANDS) Received by Fee Category



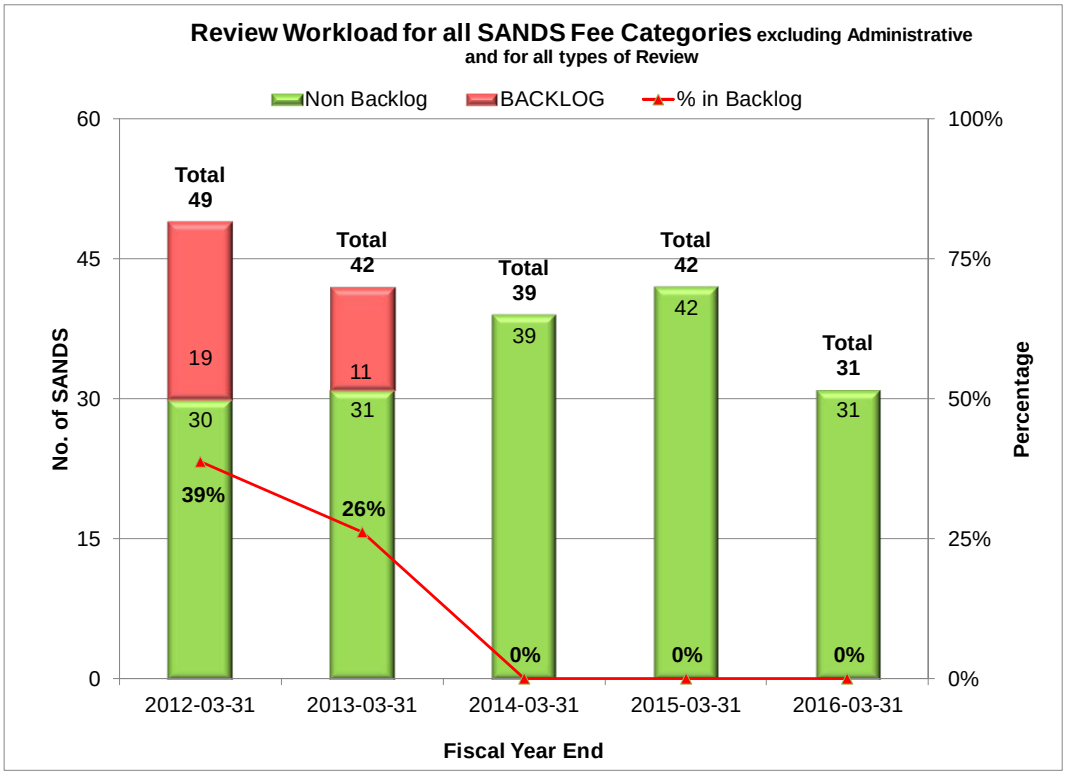
	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
Labelling Only	27	17	25	56	73
Comparative Studies	9	7	16	10	6
Chemistry & Manufacturing	32	47	75	63	67
Total	68	71	116	129	146

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

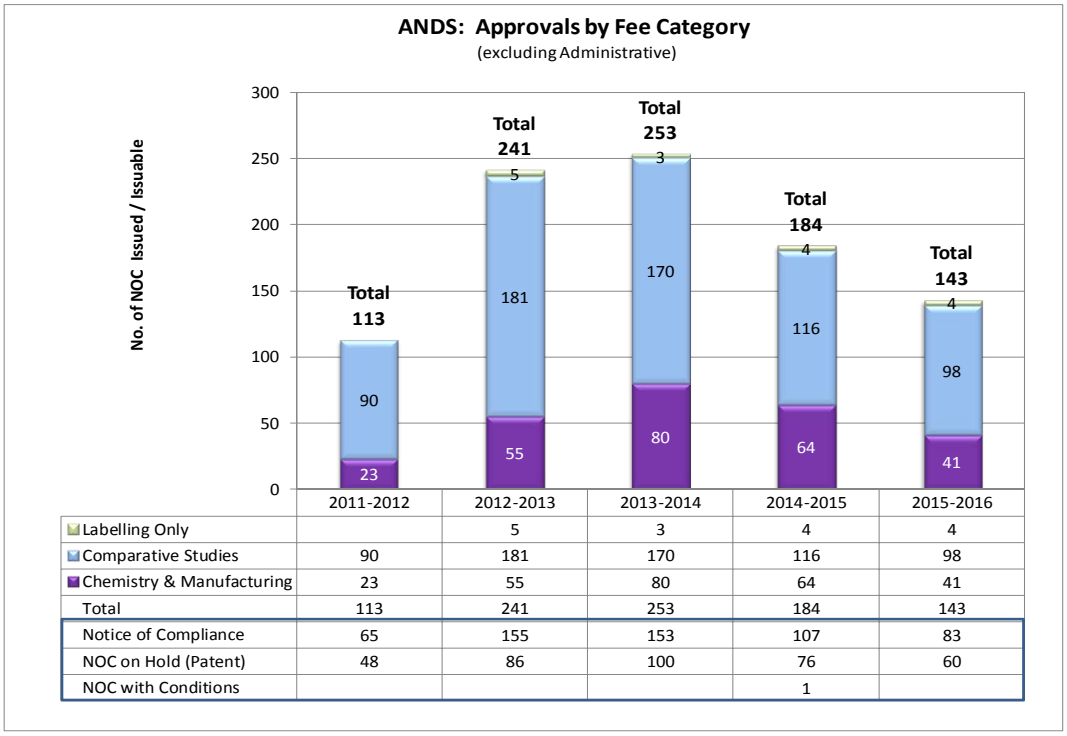
TPD ANDS All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2012-03-31	2013-03-31	2014-03-31	2015-03-31	2016-03-31
Chemistry & Manufacturing	**84**	**79**	**58**	**59**	**49**
Backlog	*46*	*44*	*1*	*1*	*1*
Comparative Studies	**186**	**122**	**117**	**83**	**65**
Backlog	*117*	*33*	*0*	*4*	*7*
Labelling Only	**3**	**0**	**0**	**0**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**273**	**201**	**175**	**142**	**116**
Non Backlog	**110**	**124**	**174**	**137**	**108**
BACKLOG	**163**	**77**	**1**	**5**	**8**
% in Backlog	**60%**	**38%**	**1%**	**4%**	**7%**

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					
	2012-03-31	2013-03-31	2014-03-31	2015-03-31	2016-03-31
Chemistry & Manufacturing	**32**	**33**	**27**	**27**	**24**
Backlog	*11*	*9*	*0*	*0*	*0*
Clinical or Non-Clin Only	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**13**	**6**	**10**	**7**	**2**
Backlog	*8*	*2*	*0*	*0*	*0*
Labelling Only	**4**	**3**	**2**	**8**	**5**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**49**	**42**	**39**	**42**	**31**
Non Backlog	**30**	**31**	**39**	**42**	**31**
BACKLOG	**19**	**11**	**0**	**0**	**0**
% in Backlog	**39%**	**26%**	**0%**	**0%**	**0%**

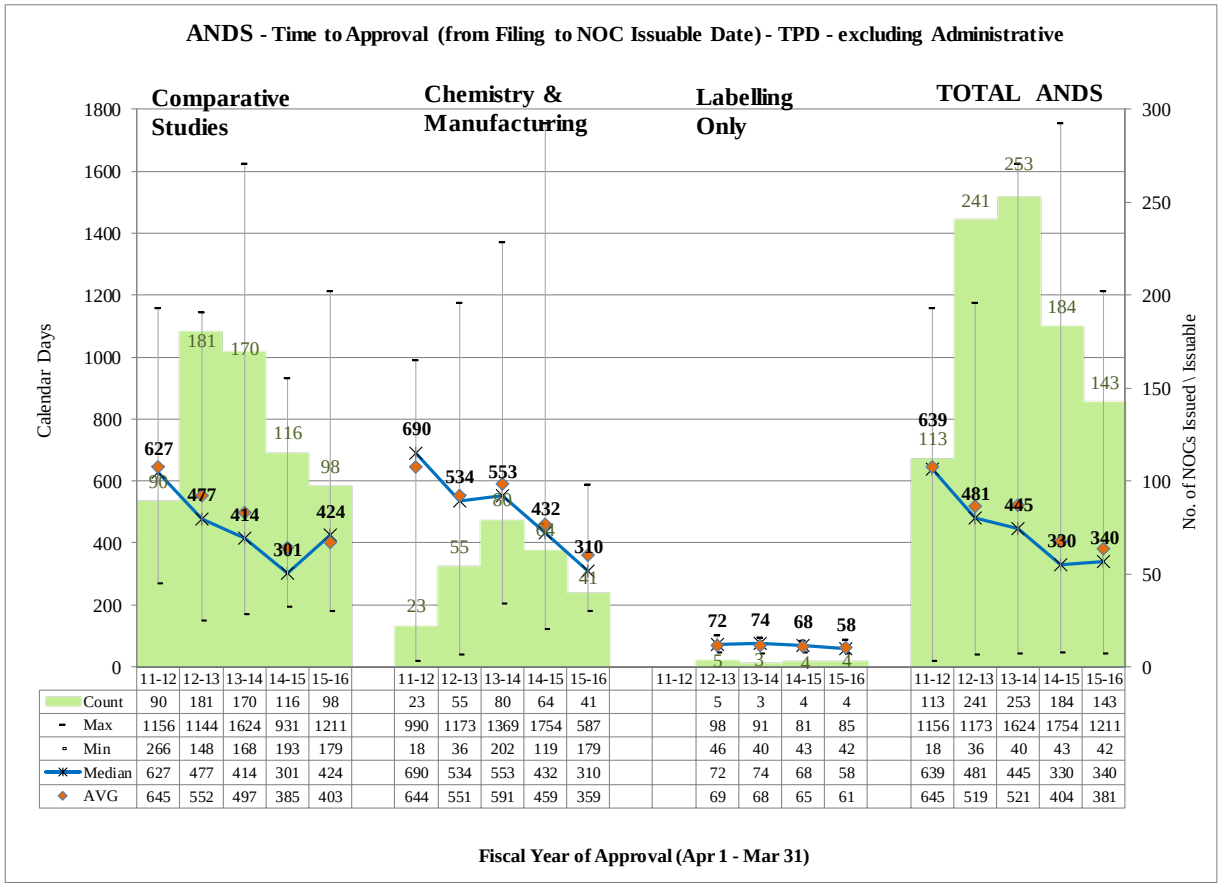
APPROVALS

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



	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
Labelling Only		5	3	4	4
Comparative Studies	90	181	170	116	98
Chemistry & Manufacturing	23	55	80	64	41
Total	113	241	253	184	143
Notice of Compliance	65	155	153	107	83
NOC on Hold (Patent)	48	86	100	76	60
NOC with Conditions				1	

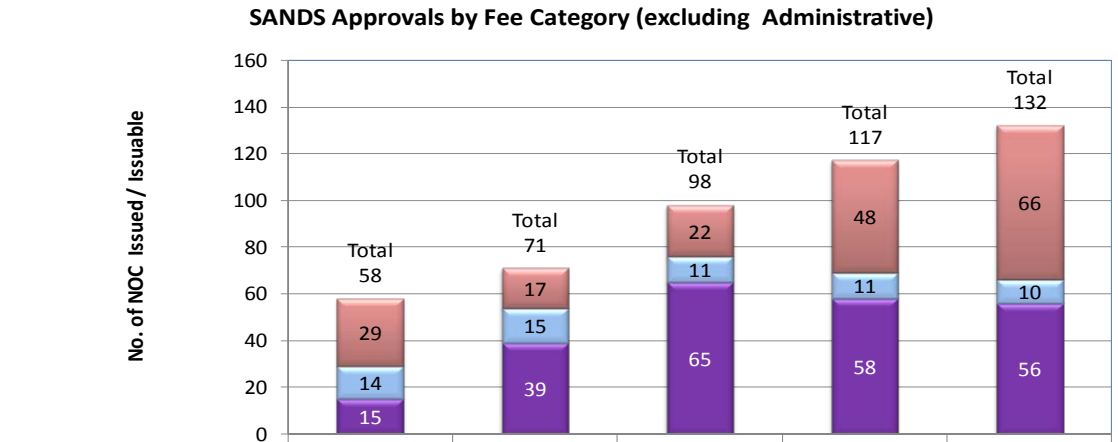
ANDS Approval Times



	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16
Count	90	181	170	116	98	23	55	80	64	41		5	3	4	4	113	241	253	184	143
Max	1156	1144	1624	931	1211	990	1173	1369	1754	587		98	91	81	85	1156	1173	1624	1754	1211
Min	266	148	168	193	179	18	36	202	119	179		46	40	43	42	18	36	40	43	42
Median	627	477	414	301	424	690	534	553	432	310		72	74	68	58	639	481	445	330	340
AVG	645	552	497	385	403	644	551	591	459	359		69	68	65	61	645	519	521	404	381

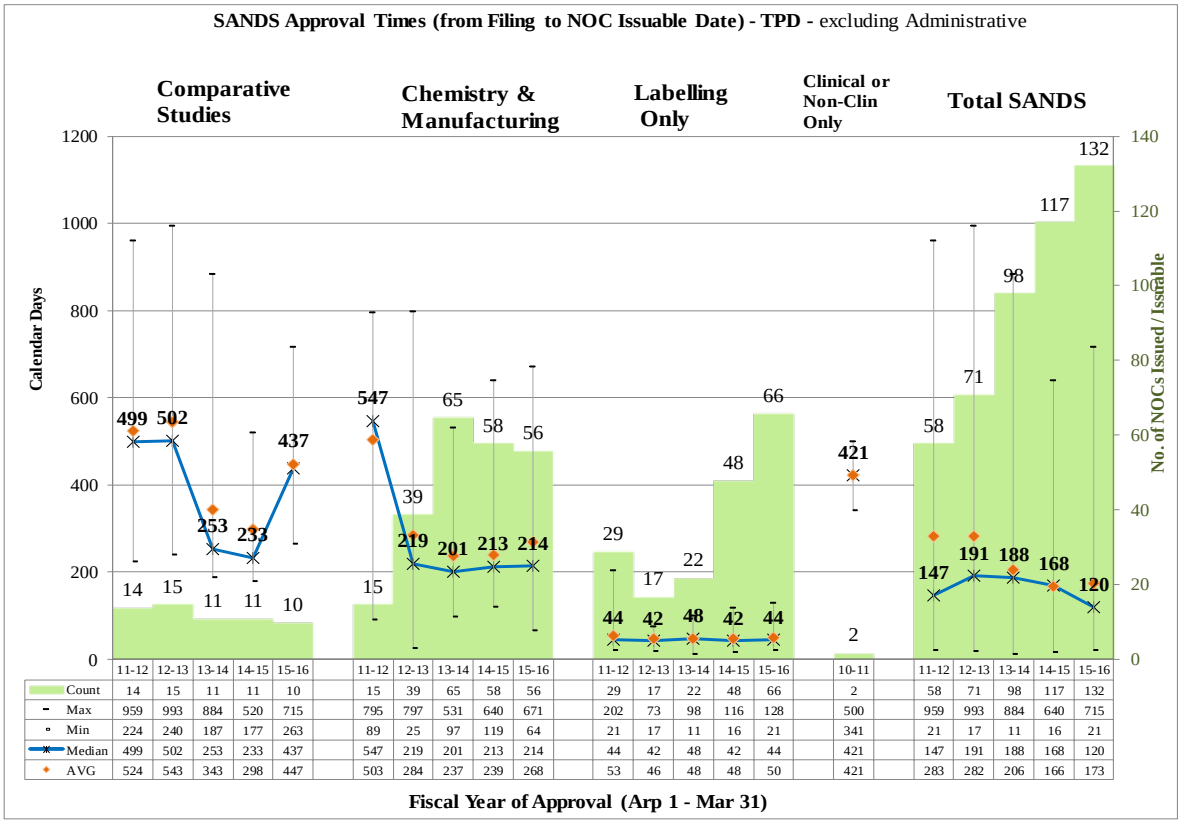
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

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



	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
Labelling Only	29	17	22	48	66
Comparative Studies	14	15	11	11	10
Chemistry & Manufacturing	15	39	65	58	56
Total	58	71	98	117	132
Notice of Compliance	50	49	78	100	111
NOC on Hold (Patent)	8	22	20	17	21
NOC on Hold (Switch)					
NOC with Conditions					

SANDS Approval Times

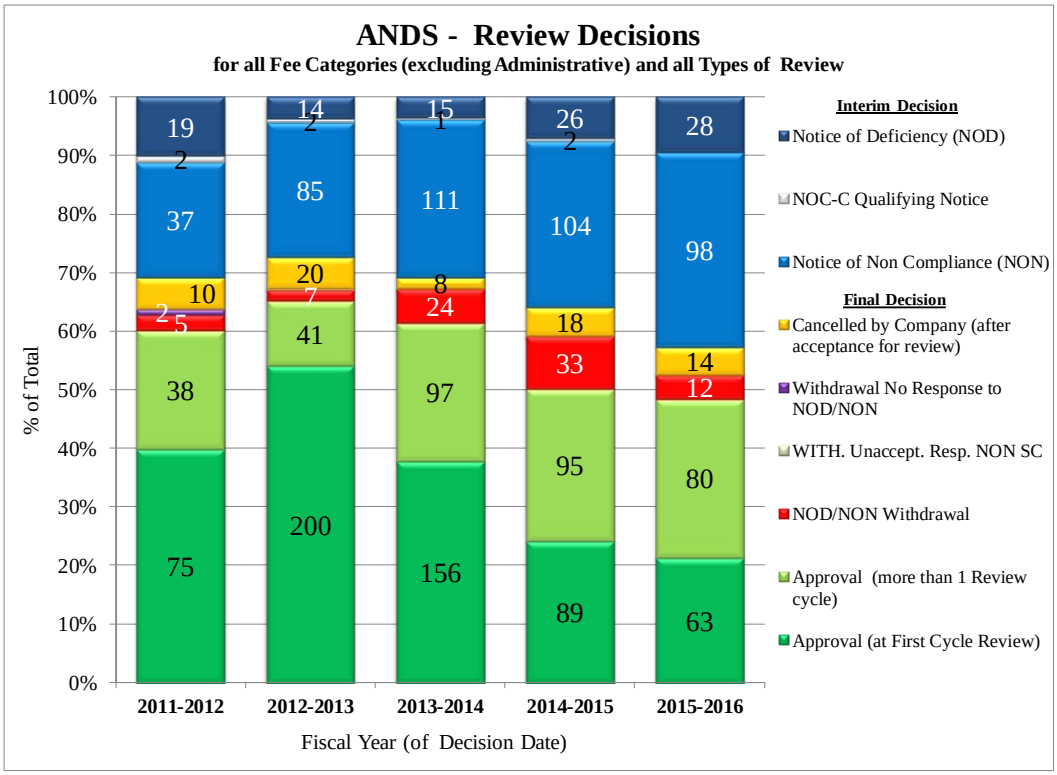


	Comparative Studies					Chemistry & Manufacturing					Labelling Only					Clinical or Non-Clin Only	Total SANDS				
	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16	10-11	11-12	12-13	13-14	14-15	15-16
Count	14	15	11	11	10	15	39	65	58	56	29	17	22	48	66	2	58	71	98	117	132
Max	959	993	884	520	715	795	797	531	640	671	202	73	98	116	128	500	959	993	884	640	715
Min	224	240	187	177	263	89	25	97	119	64	21	17	11	16	21	341	21	17	11	16	21
Median	499	502	253	233	437	547	219	201	213	214	44	42	48	42	44	421	147	191	188	168	120
AVG	524	543	343	298	447	503	284	237	239	268	53	46	48	48	50	421	283	282	206	166	173

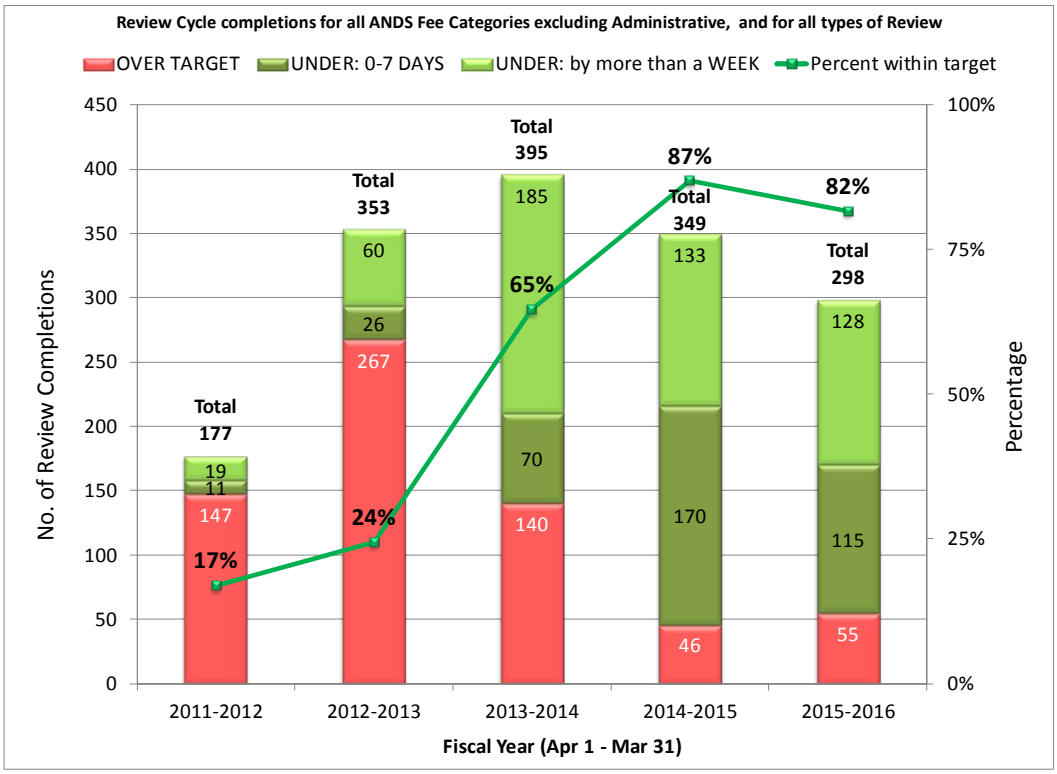
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

REVIEW CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Review Decisions

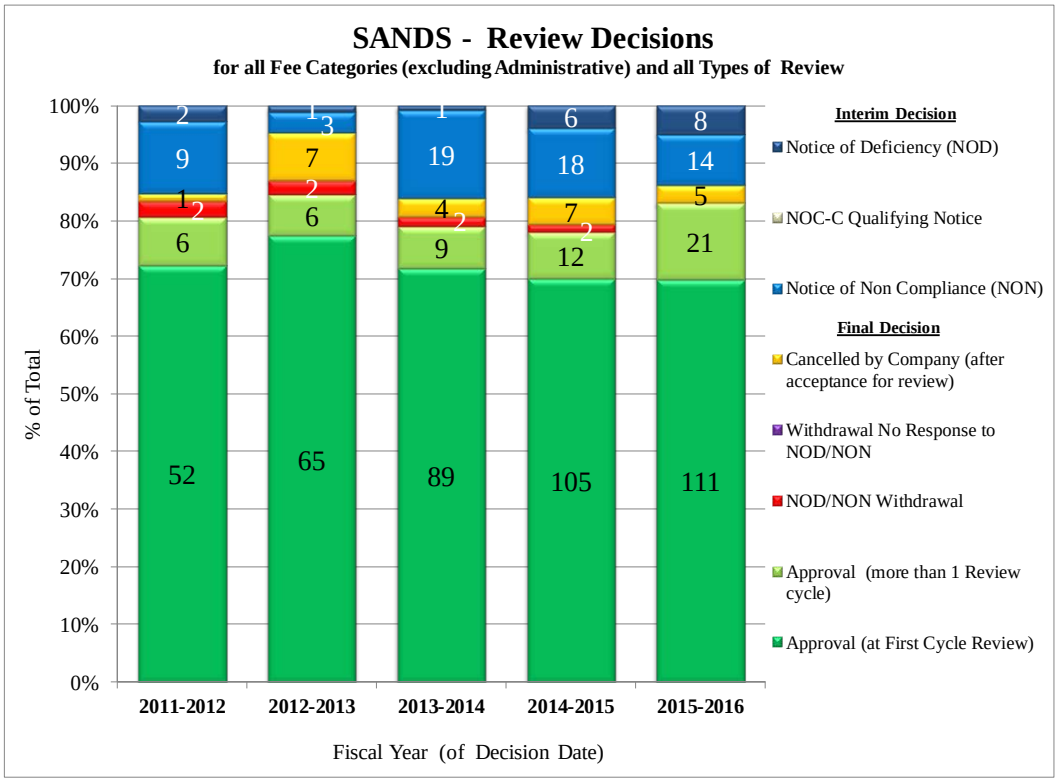


ANDS - Review Cycle Completions Showing Percentage Within Target

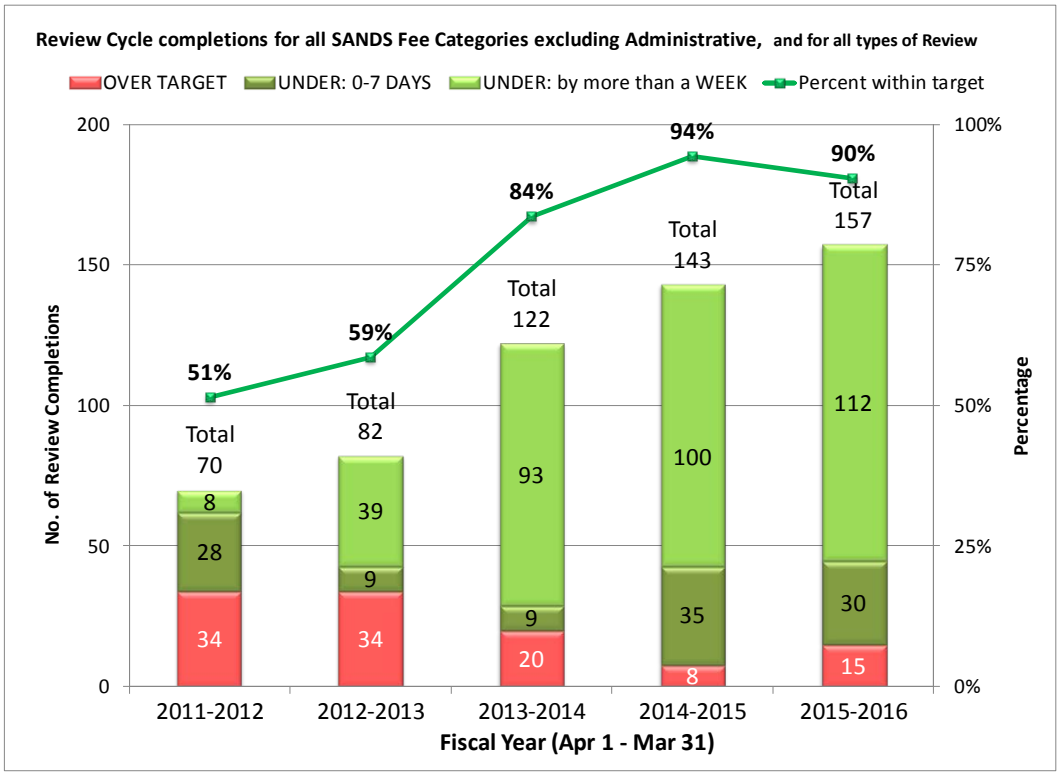


REVIEW CYCLE DECISIONS

Supplemental Abbreviated New Drug Submission (SANDS) Review Decisions

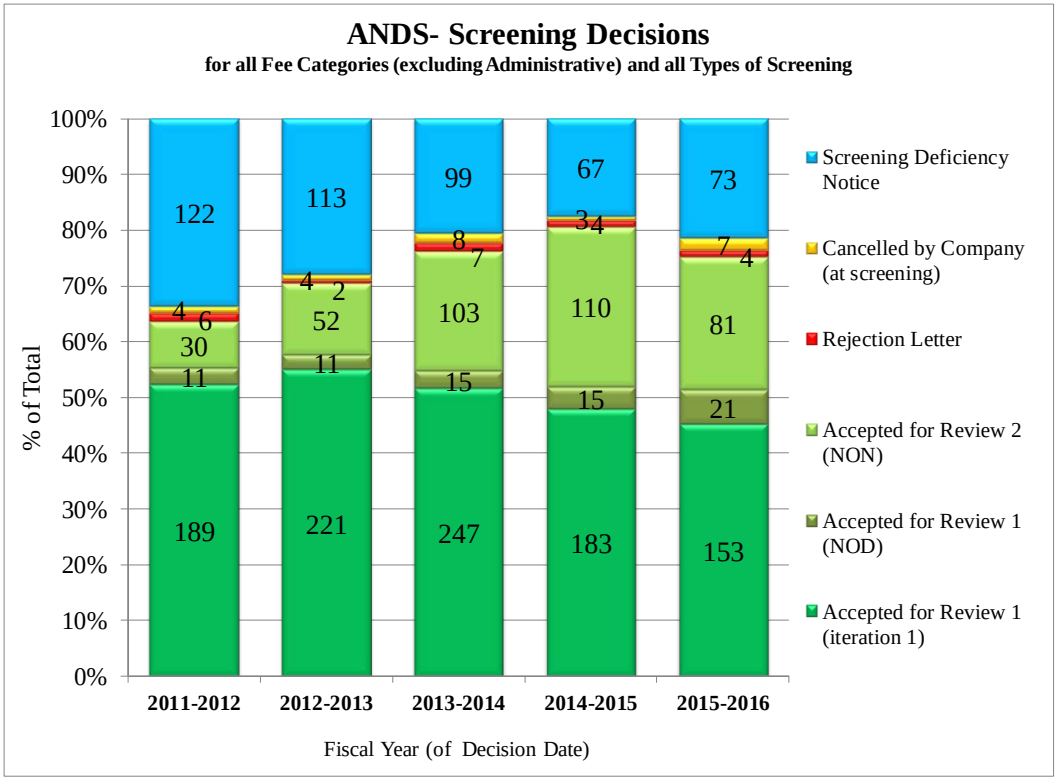


SANDS - Review Cycle Completions Showing Percentage Within Target

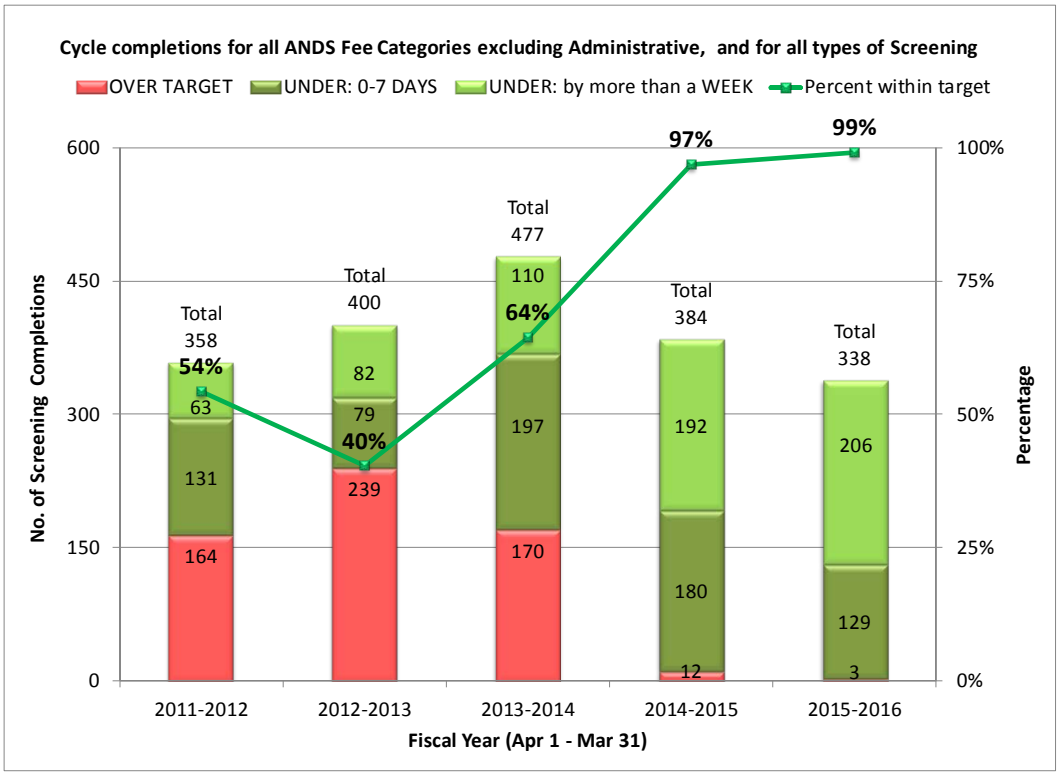


SCREENING CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Screening Decisions

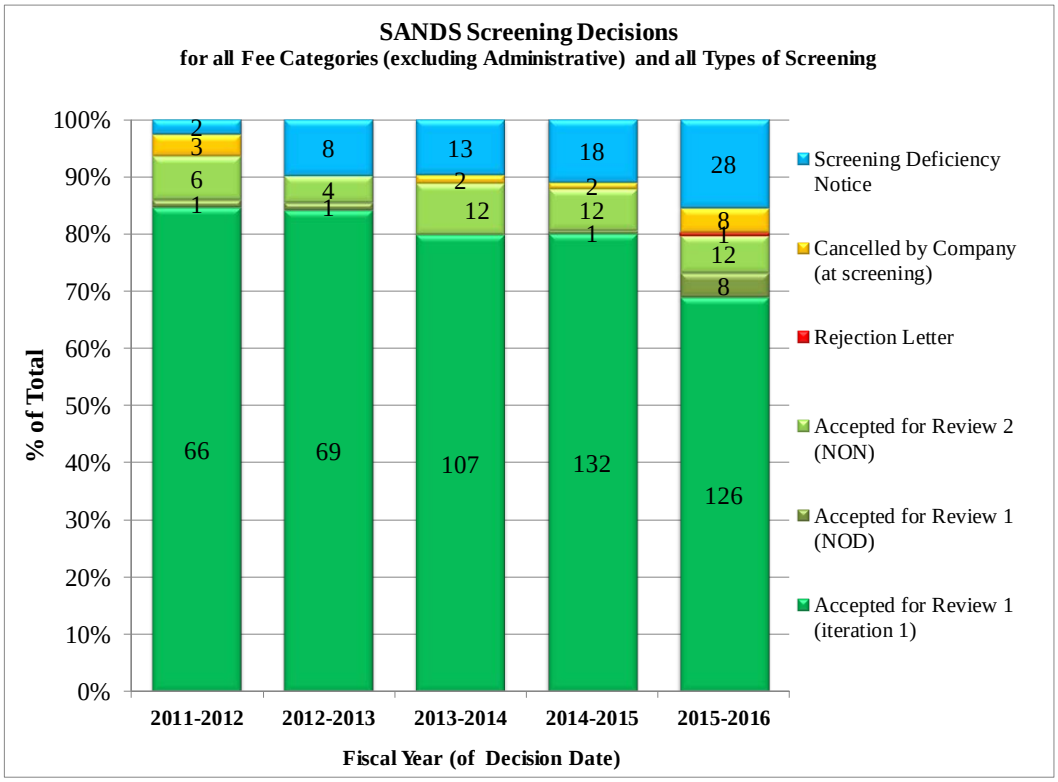


ANDS - Screening Cycle Completions Showing Percentage Within Target

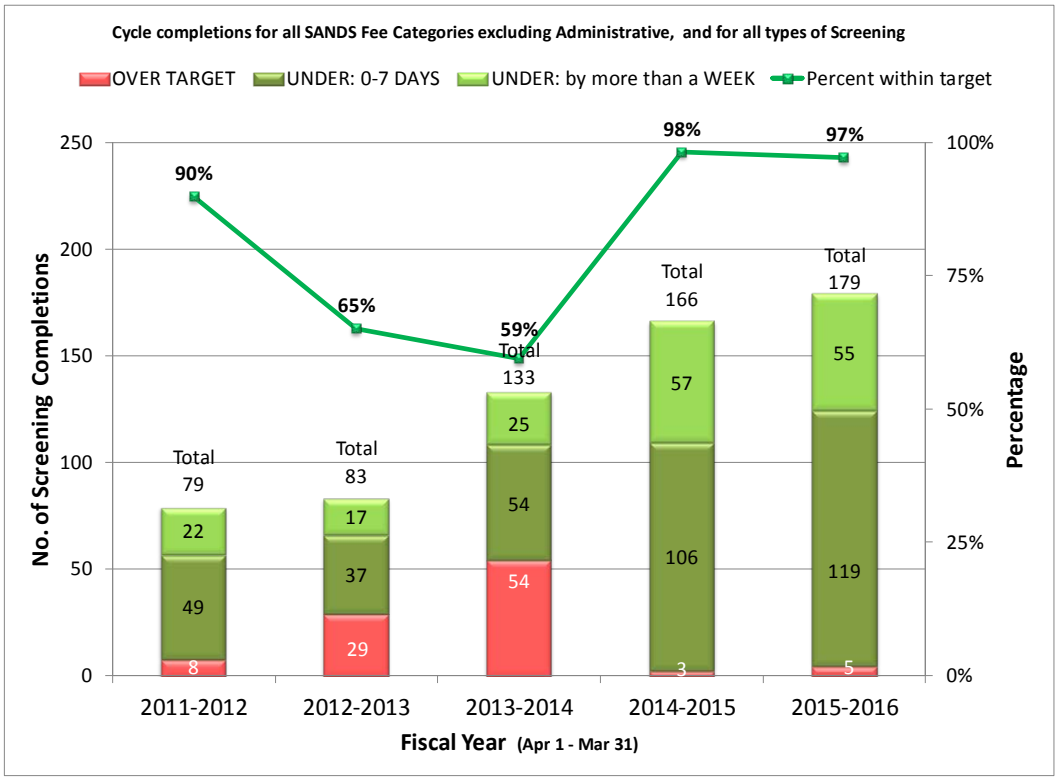


SCREENING CYCLE DECISIONS

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	11-12	12-13	13-14	14-15 * revised	15-16	Final Decision in Dispute	ANDS Status (as of Apr 18 2016)
TOTAL Received	**1**	**0**	**8**	**8**	**3**		
Total Pending	***0***	***0***	***0***	***1***	***1***		
Pending				1	1	NON-Withdrawal	Under Reconsideration
Total Granted	***0***	***0***	***1***	***3***	***1***		
Granted			1	3		NON-Withdrawal	Cleared
Granted					1	NON-Withdrawal	Review Reconsideration
Total Denied	***1***	***0***	***3***	***0***	***1***		
Denied	1					Rejection at Screening	Cancelled by Company
Denied			2			NOD-Withdrawal	Withdrawn
Denied			1		1	NON-Withdrawal	Withdrawn
Total Cancelled	***0***	***0***	***4***	***4***	***0***		
Cancelled by Health Canada			1			NOD-Withdrawal	Review 2
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	Review 2
Cancelled by Company			1	*		NON-Withdrawal	Withdrawn

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

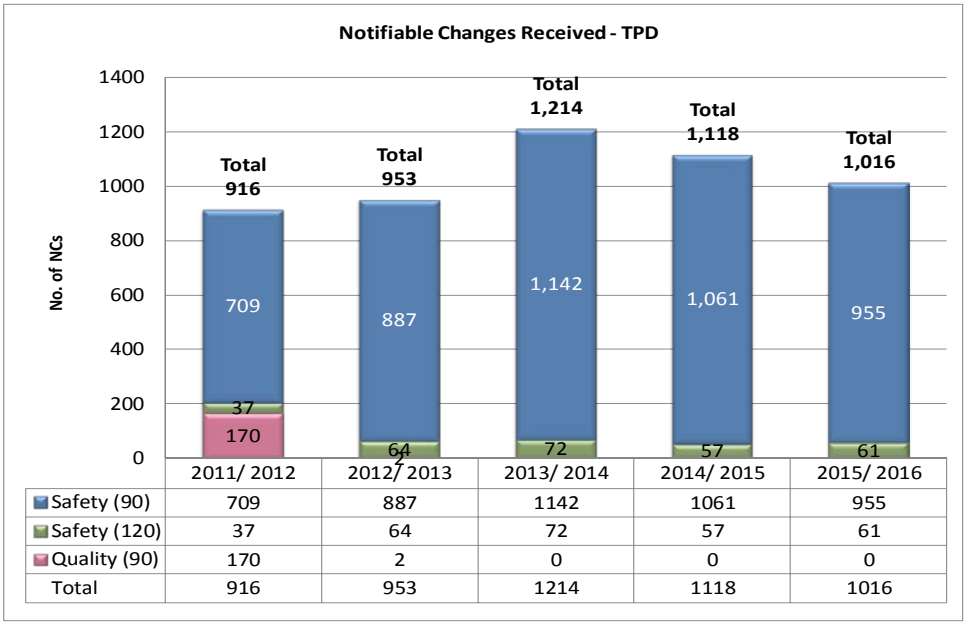
SANDS - Reconsideration of Final Decisions Requests Received

Fiscal Year of Request (Apr - Mar)

Breakdown by Reconsideration Decision	11-12 * revised	12-13	13-14	14-15	15-16	Final Decision in Dispute	SANDS Status (as of Apr 18 2016)
Total Received	**1**	**0**	**0**	**0**	**1**		
Total Granted	1	0	0	0	1		
	1					NON-Withdrawal	Cleared
					1	NOD-Withdrawal	Review Reconsideration

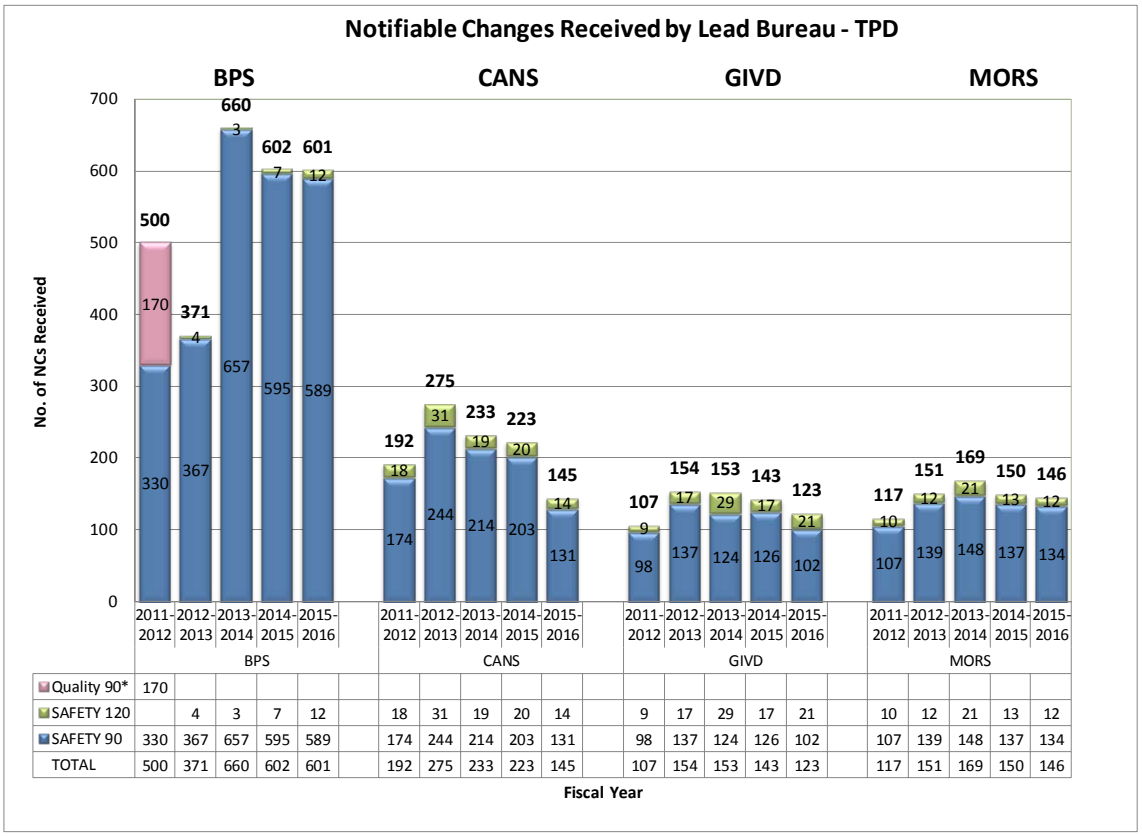
NOTIFIABLE CHANGES (NC)[7,8,9]

Number Received - Notifiable Changes (NC)



	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
Safety (90)	709	887	1142	1061	955
Safety (120)	37	64	72	57	61
Quality (90)	170	2	0	0	0
Total	916	953	1214	1118	1016

Number Received by Lead Bureau- Notifiable Changes (NC)



	BPS					CANS					GIVD					MORS				
Quality 90*	170																			
SAFETY 120		4	3	7	12	18	31	19	20	14	9	17	29	17	21	10	12	21	13	12
SAFETY 90	330	367	657	595	589	174	244	214	203	131	98	137	124	126	102	107	139	148	137	134
TOTAL	500	371	660	602	601	192	275	233	223	145	107	154	153	143	123	117	151	169	150	146

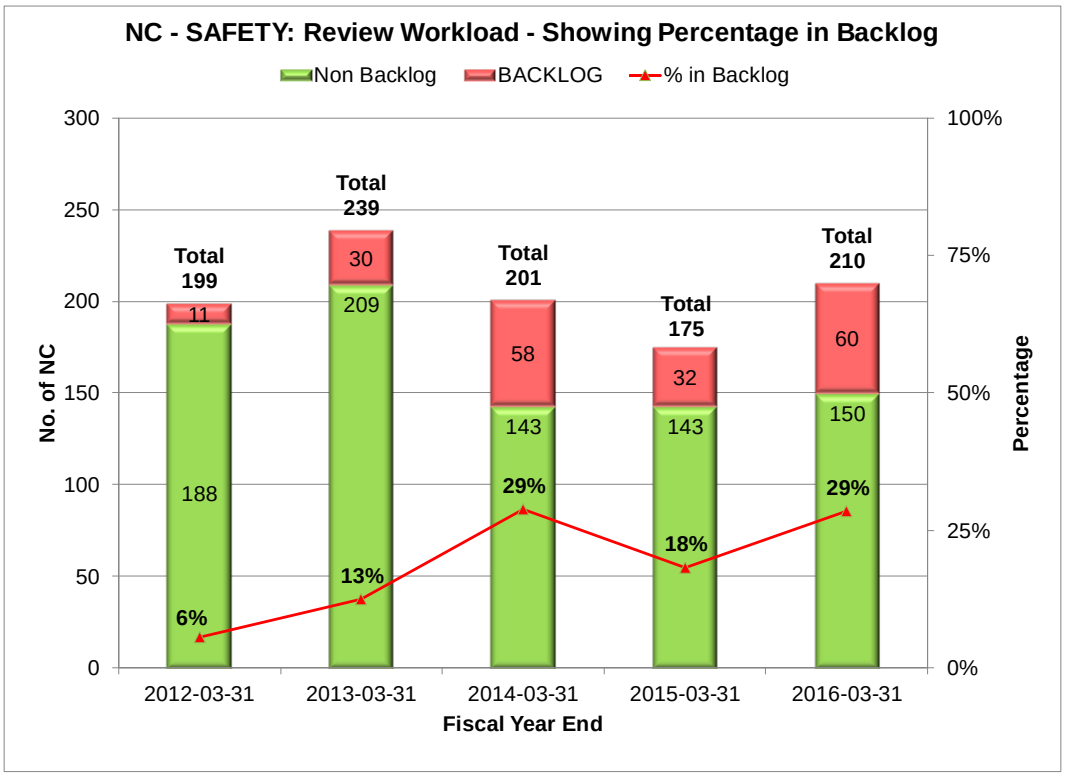
[7] Post-Notice of Compliance (NOC) Changes Guidance Documents became effective as of September 30, 2009. http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/postnoc_change_apresac/noc_postnotice_ac_apresavis_change-eng.php

[8] Post-Notice of Compliance (NOC) Changes - Quality Guidance Appendix 1 for Human Pharmaceuticals became effective October 17, 2011 and resulted in the elimination of Quality NCs for human pharmaceuticals.

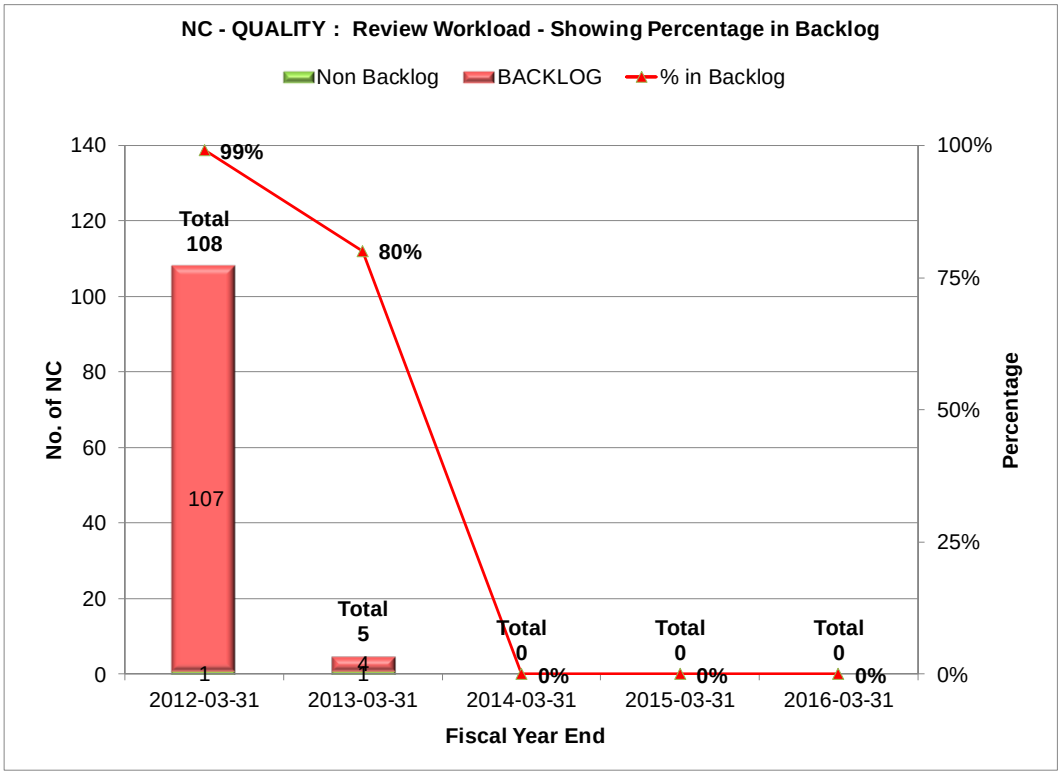
[9] In February 2013 the Safety Labelling Changes to the Product Monographs of Brand Name Pharmaceutical Drug Products process was introduced to inform generic drug manufacturers about new safety information for pharmaceutical drug products so that they can update their PMs for health care professionals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

WORKLOAD

Notifiable Change (NC) SAFETY: Review Workload / Backlog



Notifiable Change (NC) QUALITY: Review Workload / Backlog



Post-Notice of Compliance (NOC) Changes Guidance Documents became effective as of September 30, 2009. Post-Notice of Compliance (NOC) Changes - Quality Guidance Appendix 1 for Human Pharmaceuticals became effective October 17, 2011 and resulted in the elimination of Quality NCs for human pharmaceuticals. . 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 by Class

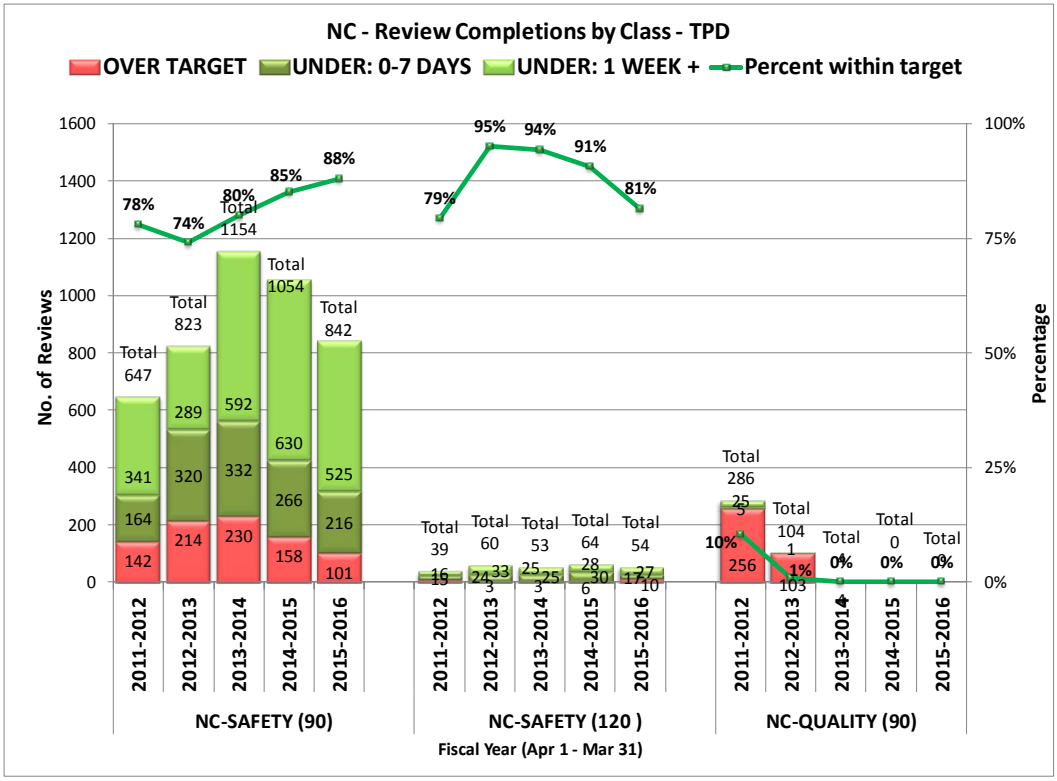
TPD NC- SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2012-03-31	2013-03-31	2014-03-31	2015-03-31	2016-03-31
SAFETY - 90 day	188	227	177	156	194
Backlog	*11*	*29*	*57*	*32*	*60*
SAFETY - 120 day	11	12	24	19	16
Backlog	*0*	*1*	*1*	*0*	*0*
Total	199	239	201	175	210
Non Backlog	188	209	143	143	150
BACKLOG	11	30	58	32	60
% in Backlog	6%	13%	29%	18%	29%

Notifiable Change (NC) QUALITY: Review Workload by Class

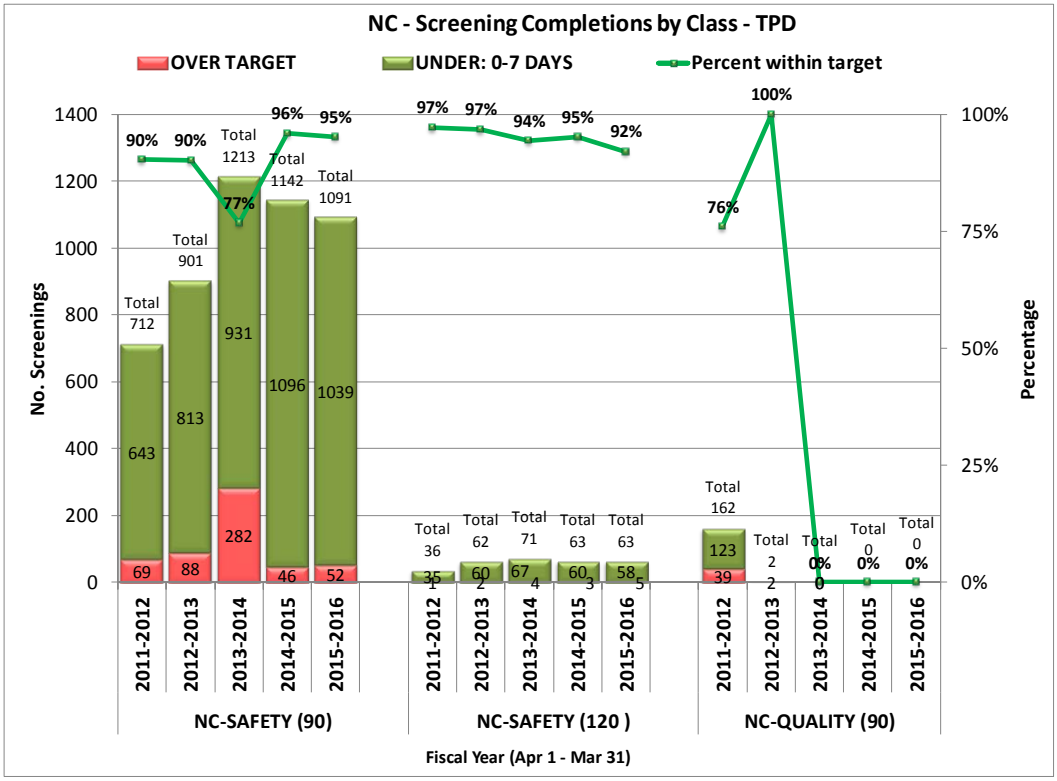
TPD NC- QUALITY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2012-03-31	2013-03-31	2014-03-31	2015-03-31	2016-03-31
QUALITY - 90 day	108	5	0	0	0
Backlog	*107*	*4*	*0*	*0*	*0*
Total	108	5	0	0	0
Non Backlog	1	1	0	0	0
BACKLOG	107	4	0	0	0
% in Backlog	99%	80%	0%	0%	0%

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	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER	638	797	1098	1065	834
CANCELLED BY COMPANY	27	34	42	49	62
NC - HOLD (PATENT)	34	45	72	34	45
SCREEN. DEFICIENCY NOTICE	16	27	91	85	197
REJECTION LETTER (SCR)	2	1	5	6	3
NOT SATISFACTORY NOTICE	1	7	2	5	1
SPONSOR SUB CHANGE ACCEPT					1

NC - SAFETY (120)					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER	38	60	49	63	54
NOT SATISFACTORY NOTICE			1	1	
SCREENING DEFICIENCY NOTICE	2		1	3	6
CANCELLED BY COMPANY	3	1	7	1	6
REJECTION LETTER (SCR)			1		1

Decision Documents by Class - Notifiable Change (NC) Quality

NC - QUALITY (90)					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER	284	105	8	6	
SCREEN. DEFICIENCY NOTICE	17				
CANCELLED BY COMPANY	87	6			
REJECTION LETTER (SCR)	5				
NC - HOLD (PATENT)	12				
NOT SATISFACTORY NOTICE	2	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 (Apr - Mar)

Breakdown by Reconsideration Decision	11-12	12-13	13-14	14-15	15-16	Final Decision in Dispute	NC's Status (as of Apr 18 2016)
Total Received	**0**	**0**	**0**	**0**	**0**		
Total Granted	***0***	***0***	***0***	***0***	***0***		
Total Denied	***0***	***0***	***0***	***0***	***0***		

Post-Notice of Compliance (NOC) Changes Guidance Documents became effective as of September 30, 2009.

Post-Notice of Compliance (NOC) Changes - Quality Guidance Appendix 1 for Human Pharmaceuticals became effective October 17, 2011 and resulted in the elimination of Quality NCs for human pharmaceuticals. .

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.

This page is left blank intentionally.

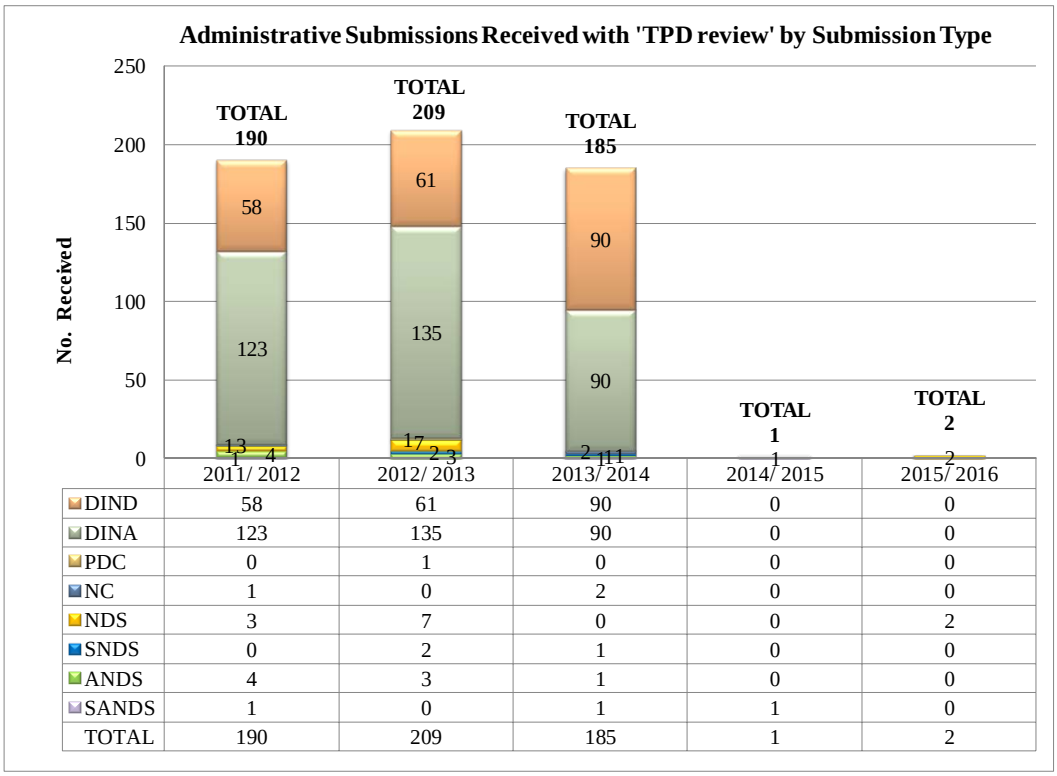
Administrative Submissions

Submissions in support of a manufacturer or product name change.

ADMINISTRATIVE SUBMISSIONS with TPD review

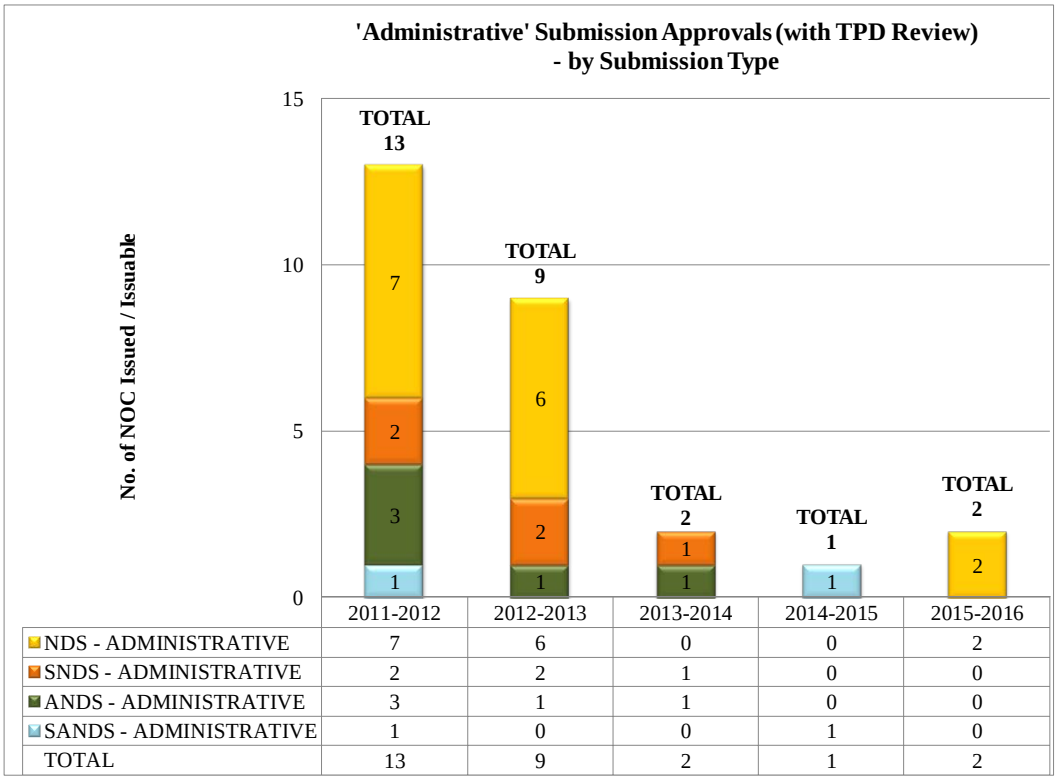
(such as product name change that requires a drug name review)

Administrative Submissions Received (with TPD review)



	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
DIND	58	61	90	0	0
DINA	123	135	90	0	0
PDC	0	1	0	0	0
NC	1	0	2	0	0
NDS	3	7	0	0	2
SNDS	0	2	1	0	0
ANDS	4	3	1	0	0
SANDS	1	0	1	1	0
TOTAL	190	209	185	1	2

Administrative Submission Approvals (with TPD Review)

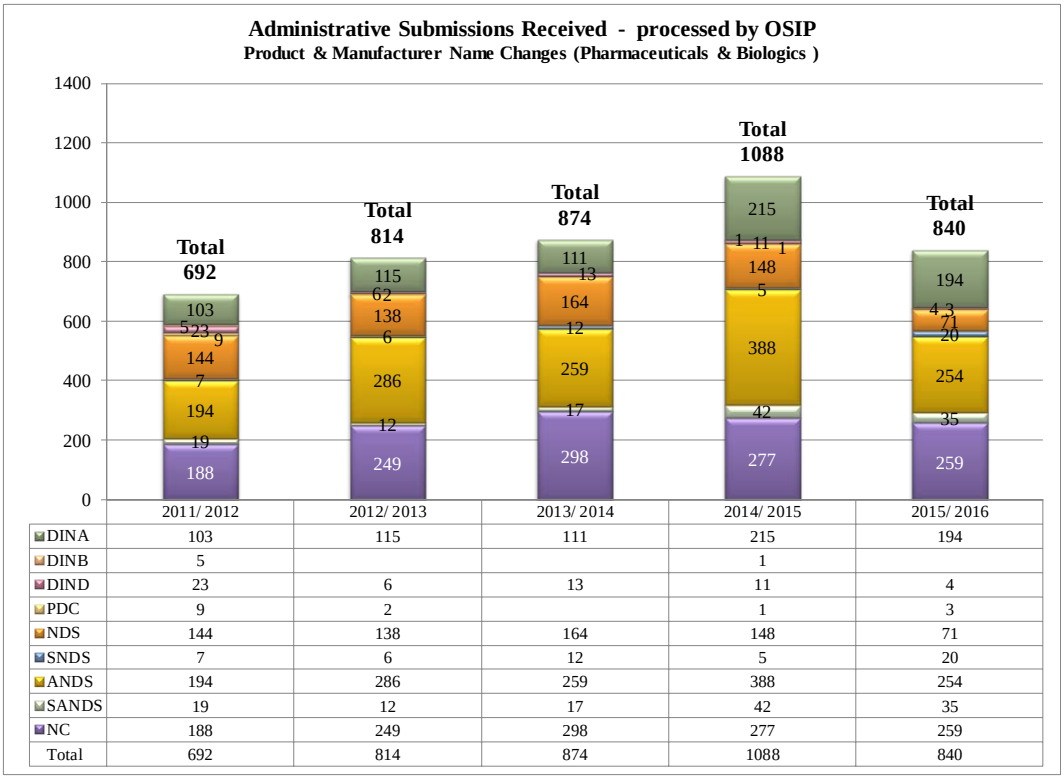


	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
NDS - ADMINISTRATIVE	7	6	0	0	2
SNDS - ADMINISTRATIVE	2	2	1	0	0
ANDS - ADMINISTRATIVE	3	1	1	0	0
SANDS - ADMINISTRATIVE	1	0	0	1	0
TOTAL	13	9	2	1	2

ADMINISTRATIVE SUBMISSIONS (Processed by OSIP)

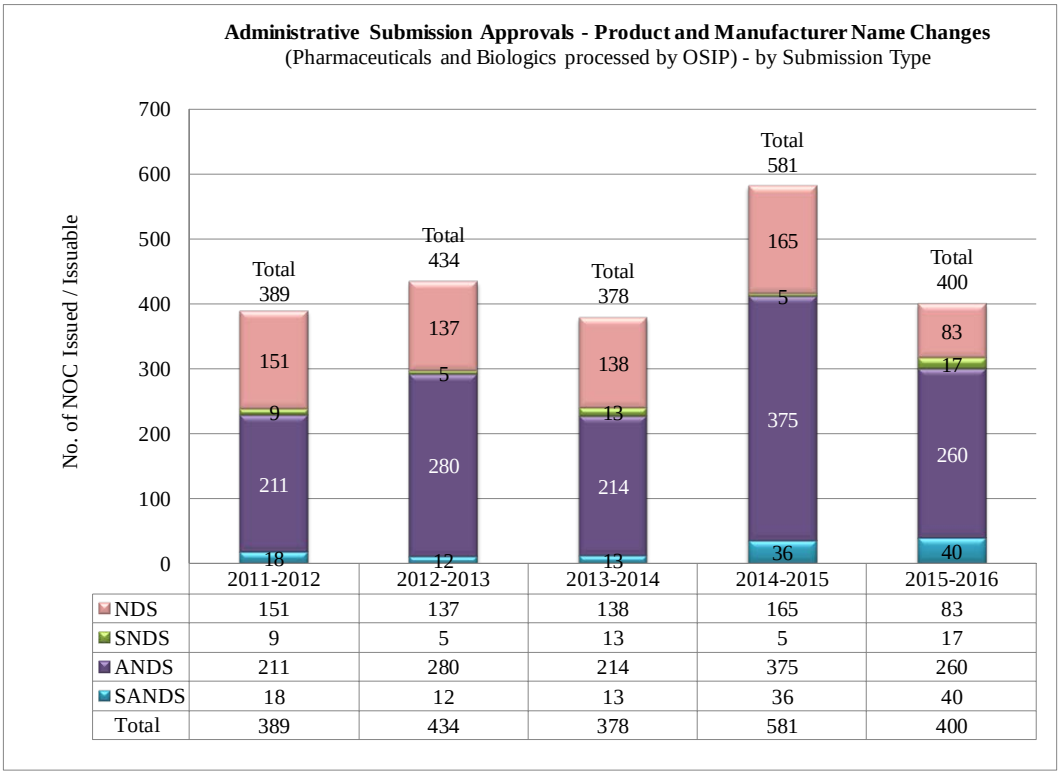
(Product & Manufacturer Name Changes)
(Admin Ncs are for cross-referenced changes)

Administrative Submissions Received by Submission Type (OSIP)



	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
DINA	103	115	111	215	194
DINB	5			1	
DIND	23	6	13	11	4
PDC	9	2		1	3
NDS	144	138	164	148	71
SNDS	7	6	12	5	20
ANDS	194	286	259	388	254
SANDS	19	12	17	42	35
NC	188	249	298	277	259
Total	692	814	874	1088	840

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



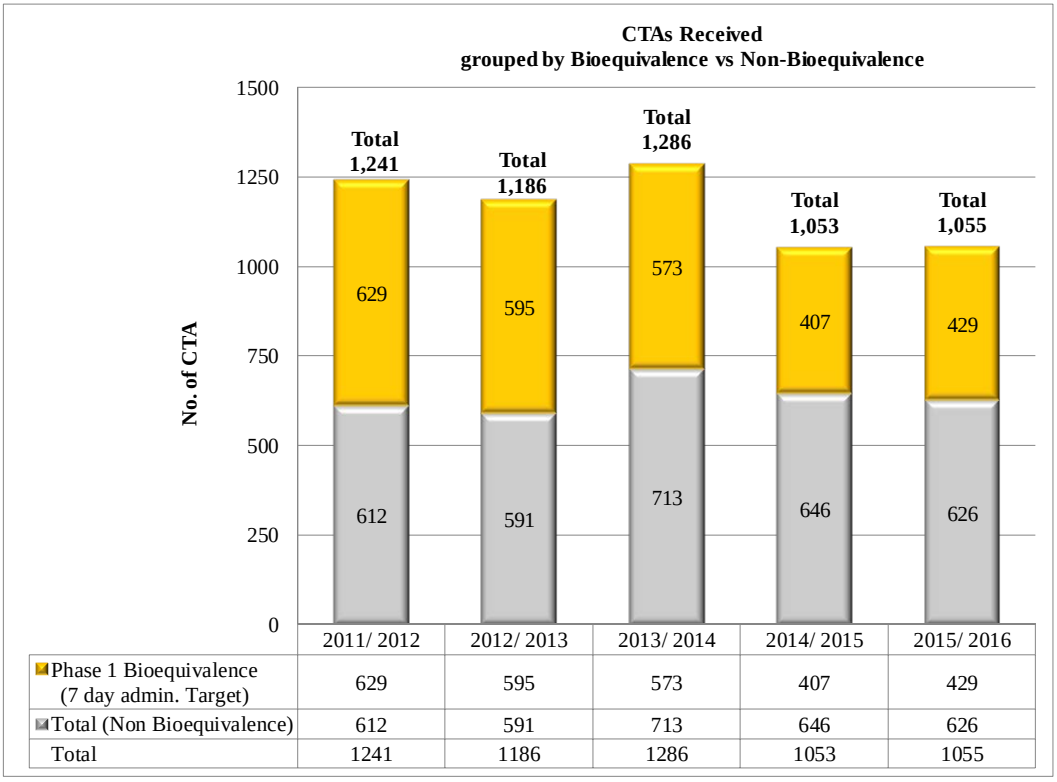
	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
NDS	151	137	138	165	83
SNDS	9	5	13	5	17
ANDS	211	280	214	375	260
SANDS	18	12	13	36	40
Total	389	434	378	581	400

Clinical Trial Applications and Amendments

(CTA & CTA-A)

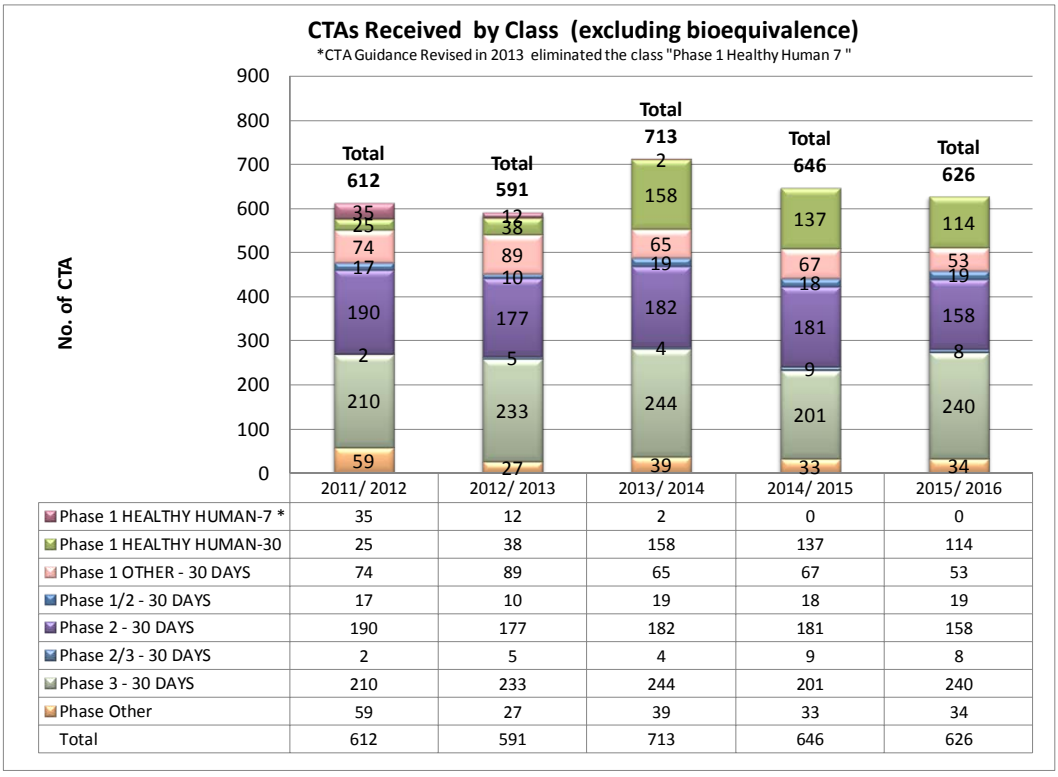
CLINICAL TRIAL APPLICATIONS

Number Received - Clinical Trial Application (CTA)



	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
Phase 1 Bioequivalence (7 day admin. Target)	629	595	573	407	429
Total (Non Bioequivalence)	612	591	713	646	626
Total	1241	1186	1286	1053	1055

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



	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
Phase 1 HEALTHY HUMAN-7 *	35	12	2	0	0
Phase 1 HEALTHY HUMAN-30	25	38	158	137	114
Phase 1 OTHER - 30 DAYS	74	89	65	67	53
Phase 1/2 - 30 DAYS	17	10	19	18	19
Phase 2 - 30 DAYS	190	177	182	181	158
Phase 2/3 - 30 DAYS	2	5	4	9	8
Phase 3 - 30 DAYS	210	233	244	201	240
Phase Other	59	27	39	33	34
Total	612	591	713	646	626

DECISION DOCUMENTS

Decision Documents - Clinical Trial Application (CTA)

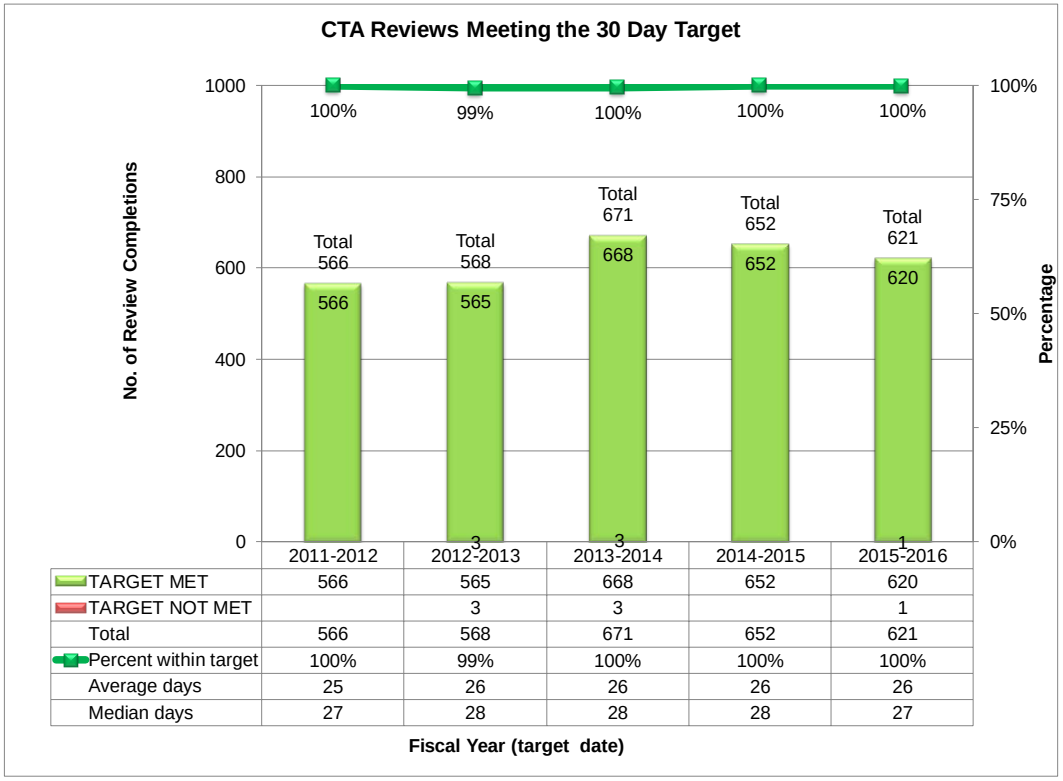
CTA (Total)					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER	1199	1139	1186	1021	994
CANCELLED BY COMPANY DURING REVIEW	28	39	54	48	44
CANCELLED BY COMPANY AT PROCESSING	10	0	17	7	8

CTA (7 day administrative target*)	*Phase 1 Bioequivalence (Class Phase 1 Healthy Human 7 eliminated in 2013)				
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER	649	596	553	410	405
CANCELLED BY COMPANY DURING REVIEW	10	13	16	6	12
CANCELLED BY COMPANY AT PROCESSING	5	0	2	0	0

CTA (30 day target)					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER	550	543	633	611	589
CANCELLED BY COMPANY DURING REVIEW	18	26	38	42	32
CANCELLED BY COMPANY AT PROCESSING	5	0	15	7	8

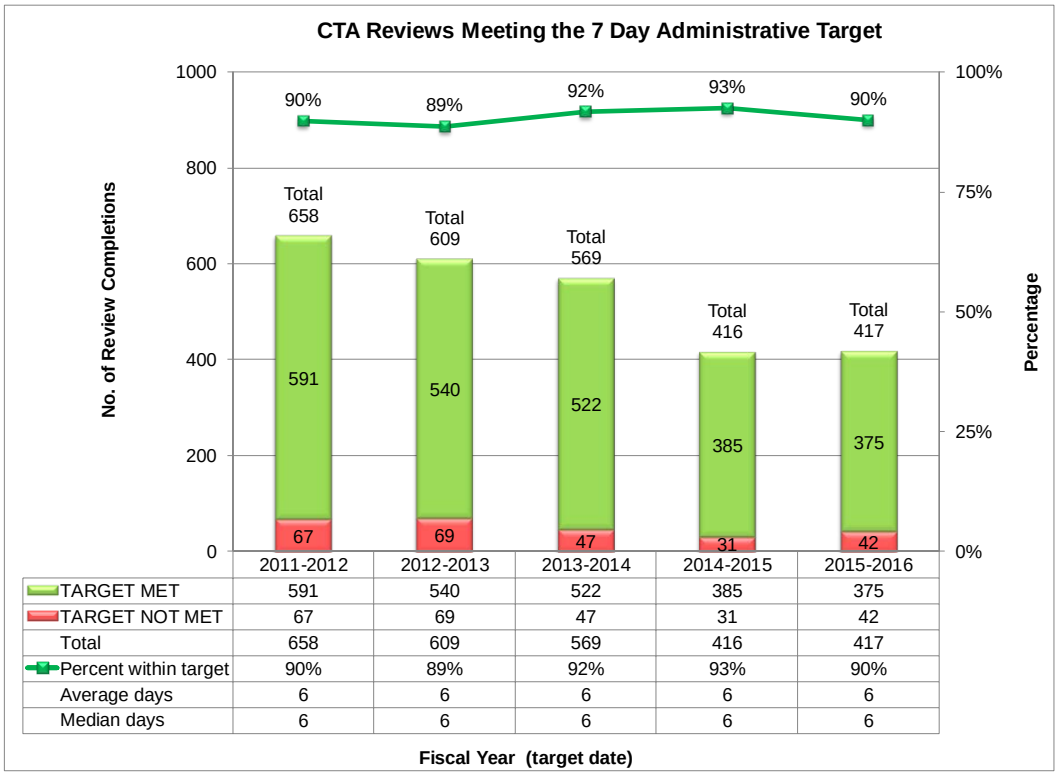
PERFORMANCE

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



	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
TARGET MET	566	565	668	652	620
TARGET NOT MET		3	3		1
Total	566	568	671	652	621
Percent within target	100%	99%	100%	100%	100%
Average days	25	26	26	26	26
Median days	27	28	28	28	27

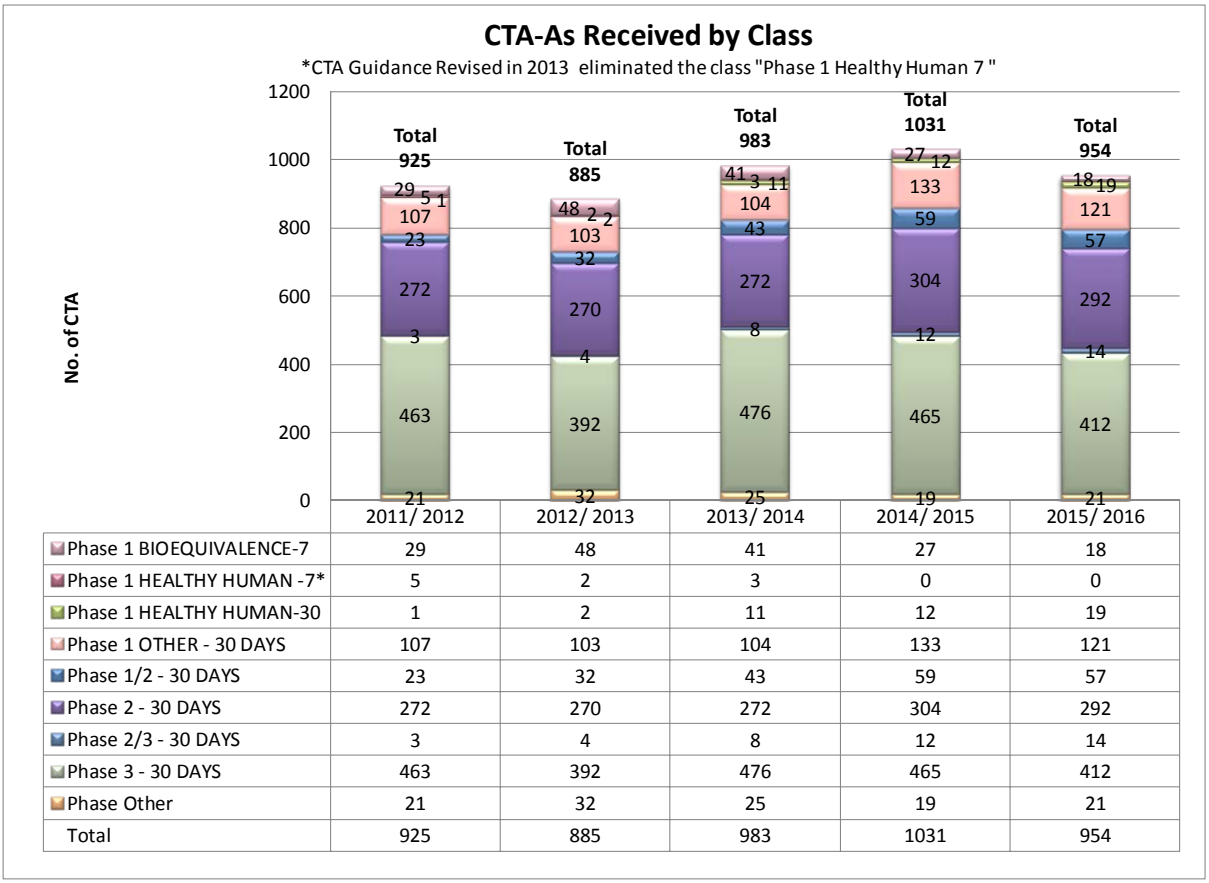
Performance – CTA Reviews Meeting the 7 Day Administrative Target



	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
TARGET MET	591	540	522	385	375
TARGET NOT MET	67	69	47	31	42
Total	658	609	569	416	417
Percent within target	90%	89%	92%	93%	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)



	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
Phase 1 BIOEQUIVALENCE-7	29	48	41	27	18
Phase 1 HEALTHY HUMAN -7*	5	2	3	0	0
Phase 1 HEALTHY HUMAN-30	1	2	11	12	19
Phase 1 OTHER - 30 DAYS	107	103	104	133	121
Phase 1/2 - 30 DAYS	23	32	43	59	57
Phase 2 - 30 DAYS	272	270	272	304	292
Phase 2/3 - 30 DAYS	3	4	8	12	14
Phase 3 - 30 DAYS	463	392	476	465	412
Phase Other	21	32	25	19	21
Total	925	885	983	1031	954

DECISION DOCUMENTS

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

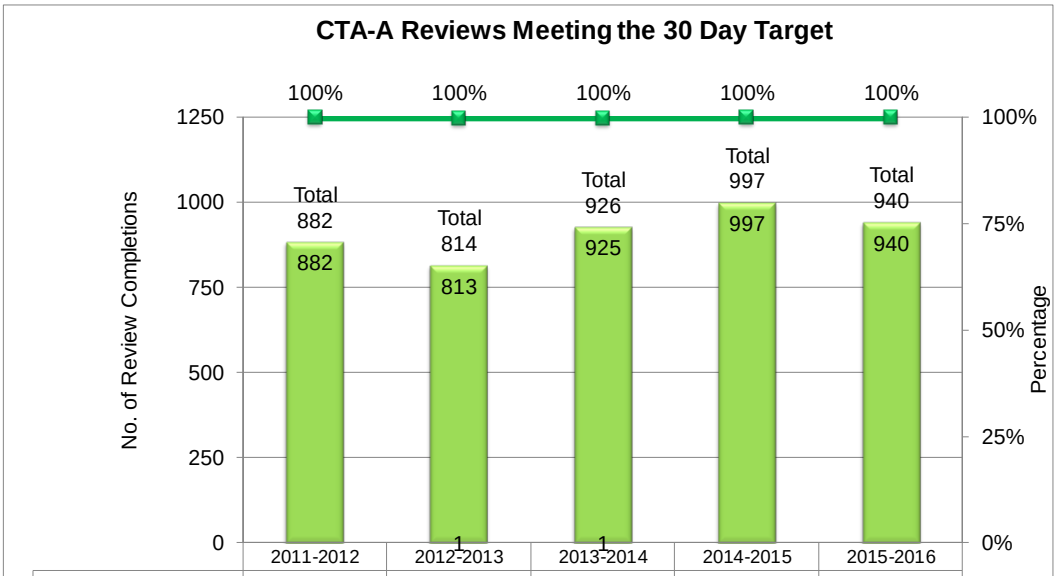
CTA-A (Total)					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER	905	859	963	1013	949
CANCELLED BY COMPANY DURING REVIEW	9	5	8	11	9
CANCELLED BY COMPANY AT PROCESSING	2	5	0	4	0

CTA-A (7 day administrative target)					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER	32	49	43	26	18
CANCELLED BY COMPANY DURING REVIEW	1	1	0	0	0
CANCELLED BY COMPANY AT PROCESSING	0	0	0	0	0

CTA-A (30 day target)					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER	873	810	920	987	931
CANCELLED BY COMPANY DURING REVIEW	8	4	8	11	9
CANCELLED BY COMPANY AT PROCESSING	3	5	0	4	0

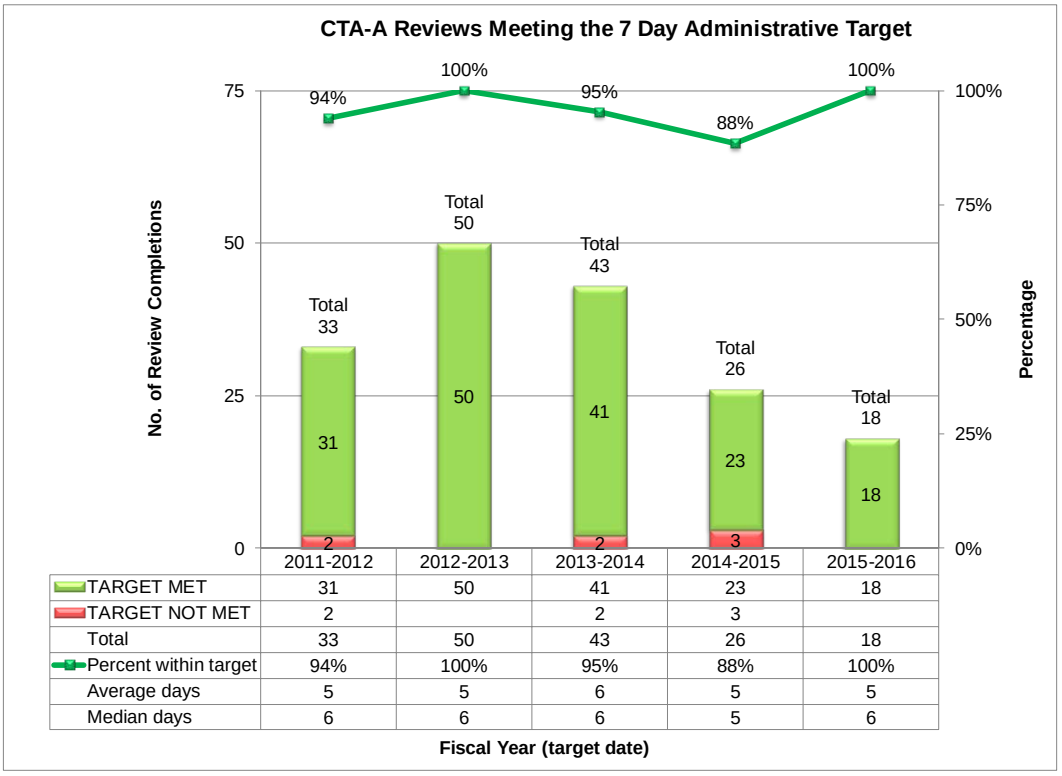
PERFORMANCE

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



	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
TARGET MET	882	813	925	997	940
TARGET NOT MET		1	1		
Total	882	814	926	997	940
Percent within target	100%	100%	100%	100%	100%
Average days	17	20	22	21	21
Median days	17	21	24	22	22

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



	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
TARGET MET	31	50	41	23	18
TARGET NOT MET	2		2	3	
Total	33	50	43	26	18
Percent within target	94%	100%	95%	88%	100%
Average days	5	5	6	5	5
Median days	6	6	6	5	6

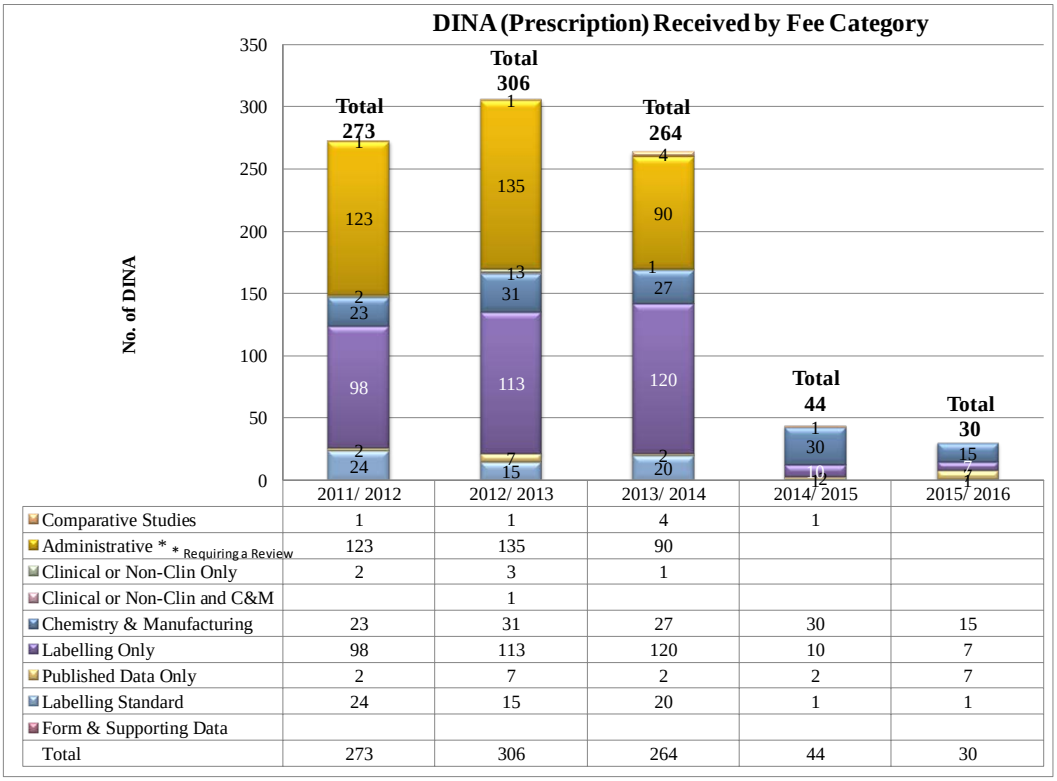
DINA (Prescription)

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 (2015-2016).

DINA (Prescription): APPLICATION FOR A DRUG IDENTIFICATION NUMBER[10]

Number Received – DINA (Prescription)

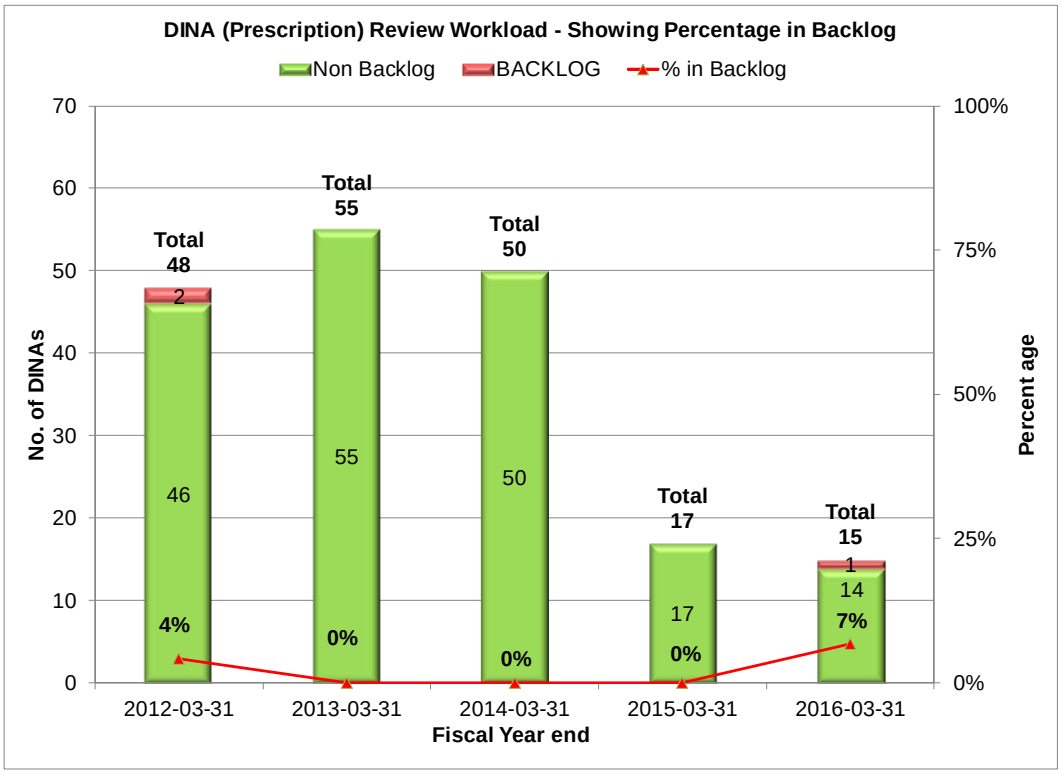


	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
Comparative Studies	1	1	4	1	
Administrative * * Requiring a Review	123	135	90		
Clinical or Non-Clin Only	2	3	1		
Clinical or Non-Clin and C&M		1			
Chemistry & Manufacturing	23	31	27	30	15
Labelling Only	98	113	120	10	7
Published Data Only	2	7	2	2	7
Labelling Standard	24	15	20	1	1
Form & Supporting Data					
Total	273	306	264	44	30

[10] 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

Review Workload / Backlog - Showing Percentage in Backlog – DINA (Prescription)

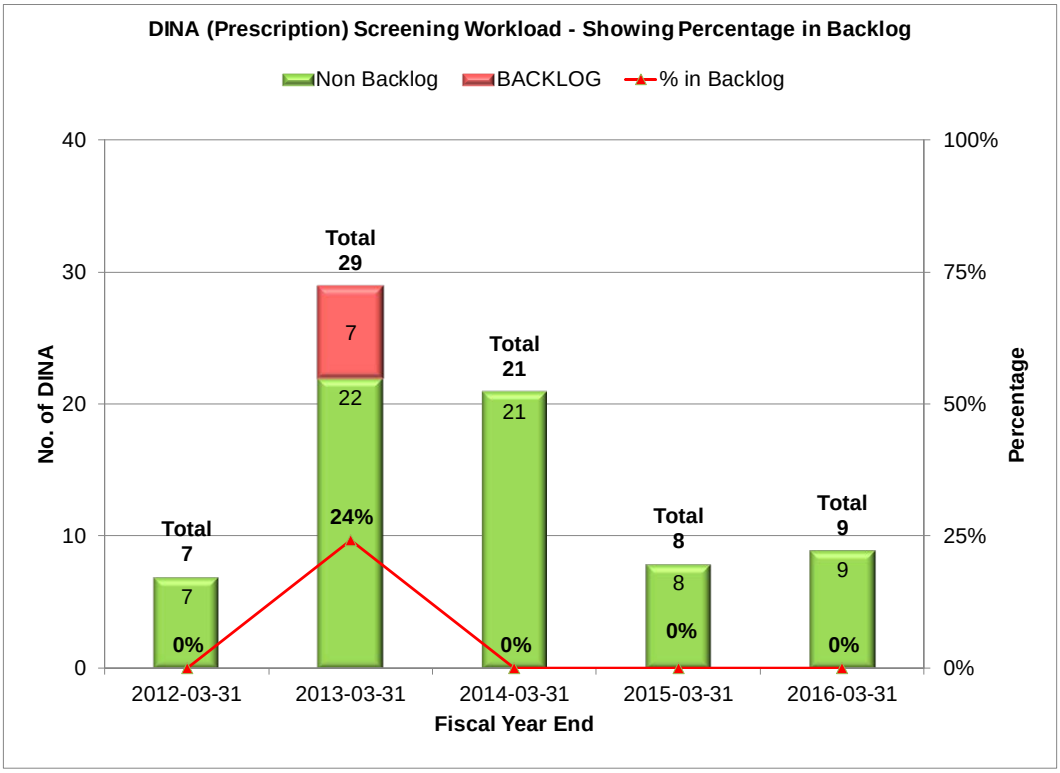


Review Workload by Class – DINA (Prescription)

TPD DINA (PRESCRIPTION) All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2012-03-31	2013-03-31	2014-03-31	2015-03-31	2016-03-31
Labelling Only (Form)	**31**	**44**	**32**	**2**	**4**
Backlog	*0*	*0*	*0*	*0*	*0*
Form and Supporting Data	**5**	**0**	**0**	**0**	**0**
Backlog	*2*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	**1**	**2**	**1**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**0**	**1**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**8**	**4**	**15**	**14**	**9**
Backlog	*0*	*0*	*0*	*0*	*1*
Published Data	**2**	**4**	**0**	**0**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**1**	**0**	**2**	**1**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**48**	**55**	**50**	**17**	**15**
Non Backlog	**46**	**55**	**50**	**17**	**14**
BACKLOG	**2**	**0**	**0**	**0**	**1**
% in Backlog	**4%**	**0%**	**0%**	**0%**	**7%**

SCREENING WORKLOAD

Screening Workload / Backlog - Showing Percentage in Backlog – DINA (Prescription)



Screening Workload by Class – DINA (Prescription)

TPD DINA (Prescription) All SCREENING WORKLOAD by User Fee Category (excluding administrative) and Fiscal Year End					
CLASS	**2012-03-31**	**2013-03-31**	**2014-03-31**	**2015-03-31**	**2016-03-31**
Labelling Only (Form)	**4**	**15**	**13**	**3**	**1**
Backlog	*0*	*1*	*0*	*0*	*0*
Form & Supporting Data	**0**	**1**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Standard	**0**	**1**	**4**	**0**	**0**
Backlog	*0*	*1*	*0*	*0*	*0*
Chemistry & Manufacturing	**3**	**10**	**3**	**3**	**5**
Backlog	*0*	*5*	*0*	*0*	*0*
Clinical or Non-Clinical Only	**0**	**1**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data Only	**0**	**2**	**0**	**1**	**3**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**0**	**0**	**1**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**7**	**29**	**21**	**8**	**9**
Non Backlog	**7**	**22**	**21**	**8**	**9**
BACKLOG	**0**	**7**	**0**	**0**	**0**
% in Backlog	**0%**	**24%**	**0%**	**0%**	**0%**

DECISION DOCUMENTS

Decision Documents – DINA (Prescription) by Fee Category

DINA - LABELLING ONLY					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NOTIFICATION FORM/DIN ISSUED	27	54	92	4	1
NO OBJECTION LETTER	1	11	21	6	5
CANCELLED BY COMPANY		16	10		1
DIN INCORR SUBTYPE-CLASS	13	20	17		
NEW DRUG LETTER SCREEN		1	3		
NON WITHDRAWAL LETTER		1			
NOTICE OF DEFICIENCY		1		2	
NOTICE OF NON-COMPLIANCE		3	8		
REJECTION LETTER (SCREENING)	2	4			
SCREENING DEFICIENCY NOTICE	1	30	17	4	2
SPONSOR SUB CHANGE ACCEPT	13	12	10		

DINA - ADMINISTRATIVE					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NOTIFICATION FORM/DIN ISSUED	18	90	87	-	-
NO OBJECTION LETTER		1	1	-	-
REJECTION LETTER (SCREENING)	8	31	10	-	-
SCREENING DEFICIENCY NOTICE		6	6	-	-
CANCELLED BY COMPANY	1	3	2	-	-

DINA - LABELLING STANDARD					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NOTIFICATION FORM/DIN ISSUED	4	10	16		
NO OBJECTION LETTER		1			
NEW DRUG LETTER SCREEN		1	1		
REJECTION LETTER (SCREENING)	2				
SCREENING DEFICIENCY NOTICE	1	1	1	1	
SPONSOR SUB CHANGE ACCEPT	1				
DIN INCORR SUBTYPE-CLASS	1				
CANCELLED BY COMPANY	1	2	1	1	

DINA - PUBLISHED DATA ONLY					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER		2			3
NOTICE OF DEFICIENCY		1			
REJECTION LETTER (SCREENING)				1	
SCREENING DEFICIENCY NOTICE	1	2			
CANCELLED BY COMPANY			2		1
NOTICE OF NON-COMPLIANCE					1

DINA - CHEMISTRY & MANUFACTURING					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NOTIFICATION FORM/DIN ISSUED		19	8	17	12
NOD WITHDRAWAL LETTER		1			
NOTICE OF DEFICIENCY		1		3	2
REJECTION LETTER (SCREENING)		4	3		
SCREENING DEFICIENCY NOTICE		5	15	11	12
CANCELLED BY COMPANY		1	5		3
NO OBJECTION LETTER		6	3	8	6
NEW DRUG LETTER SCREEN			1		
NOTICE OF NON-COMPLIANCE			6	3	4

DINA - CLINICAL OR NON-CLINICAL DATA					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NOTIFICATION FORM/DIN ISSUED		1	1		
NOTICE OF DEFICIENCY		1			
NO OBJECTION LETTER			3		

DINA - COMPARATIVE STUDIES					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NOTIFICATION FORM/DIN ISSUED		2	1	2	1
NO OBJECTION LETTER			1		
NOTICE OF DEFICIENCY			1	1	1
SCREENING DEFICIENCY NOTICE			1		

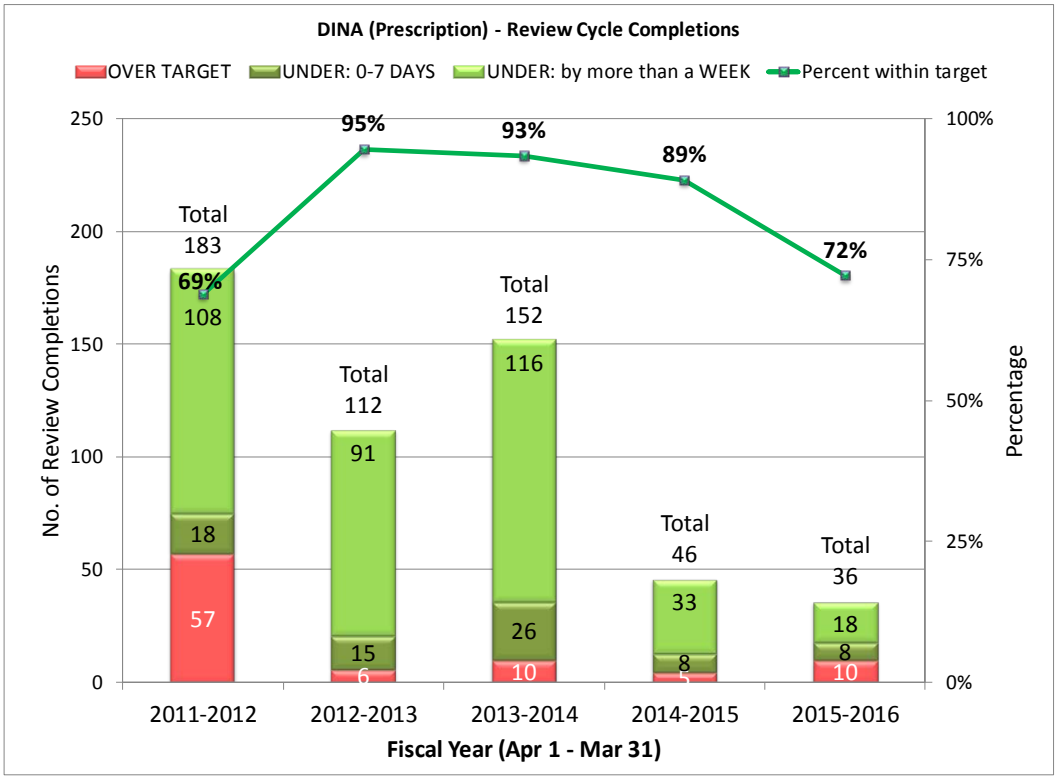
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – DINA

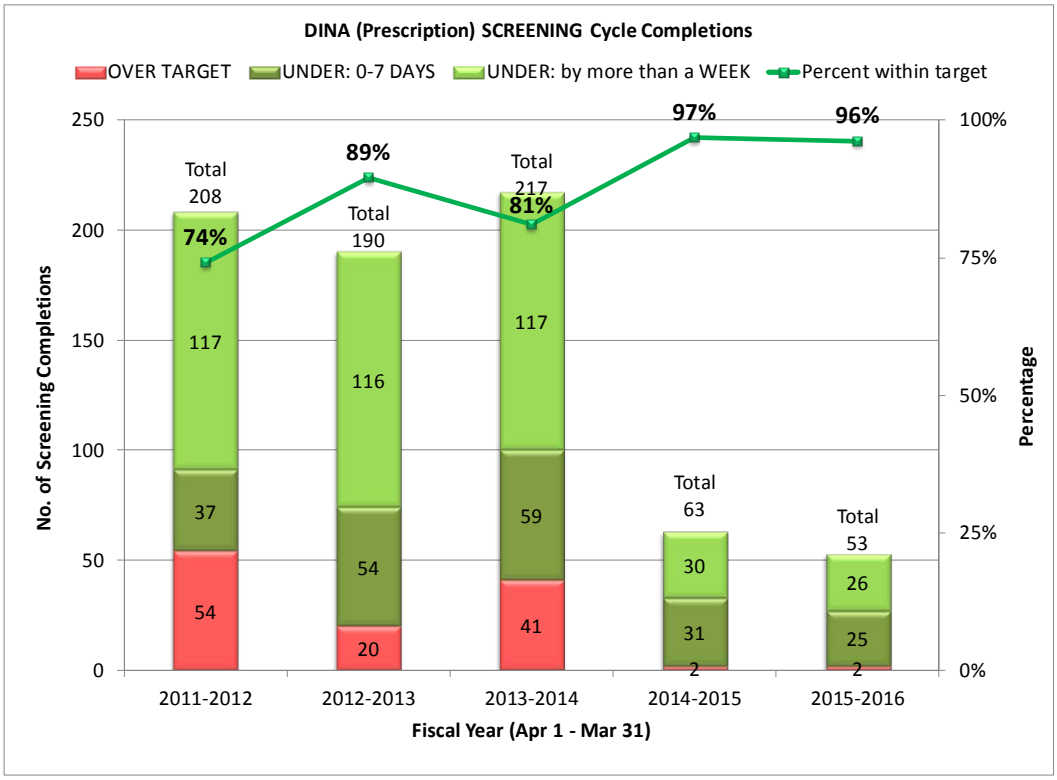
DINA - Reconsideration of Final Decisions by Year Requested							
Fiscal Year of Request (Apr - Mar)							
Breakdown by Reconsideration Decision	**11-12**	**12-13**	**13-14**	**14-15**	**15-16**	**Final Decision in Dispute**	**Submission Status as of Apr 18 2016**
Total Received	**2**	**0**	**0**	**1**	**0**		
Total Pending	**0**	**0**	**0**	**1**	**0**		
				1		New Drug Letter	Under Reconsideration
Total Denied	***2***	***0***	***0***	***0***	***0***		
Denied	1					New Drug Letter	Rejected
Denied	1					NOD-Withdrawal	Withdrawn
Total Cancelled	***0***	***0***	***0***	***0***	***0***		

PERFORMANCE

Review Cycle Completions – DINA (Prescription)

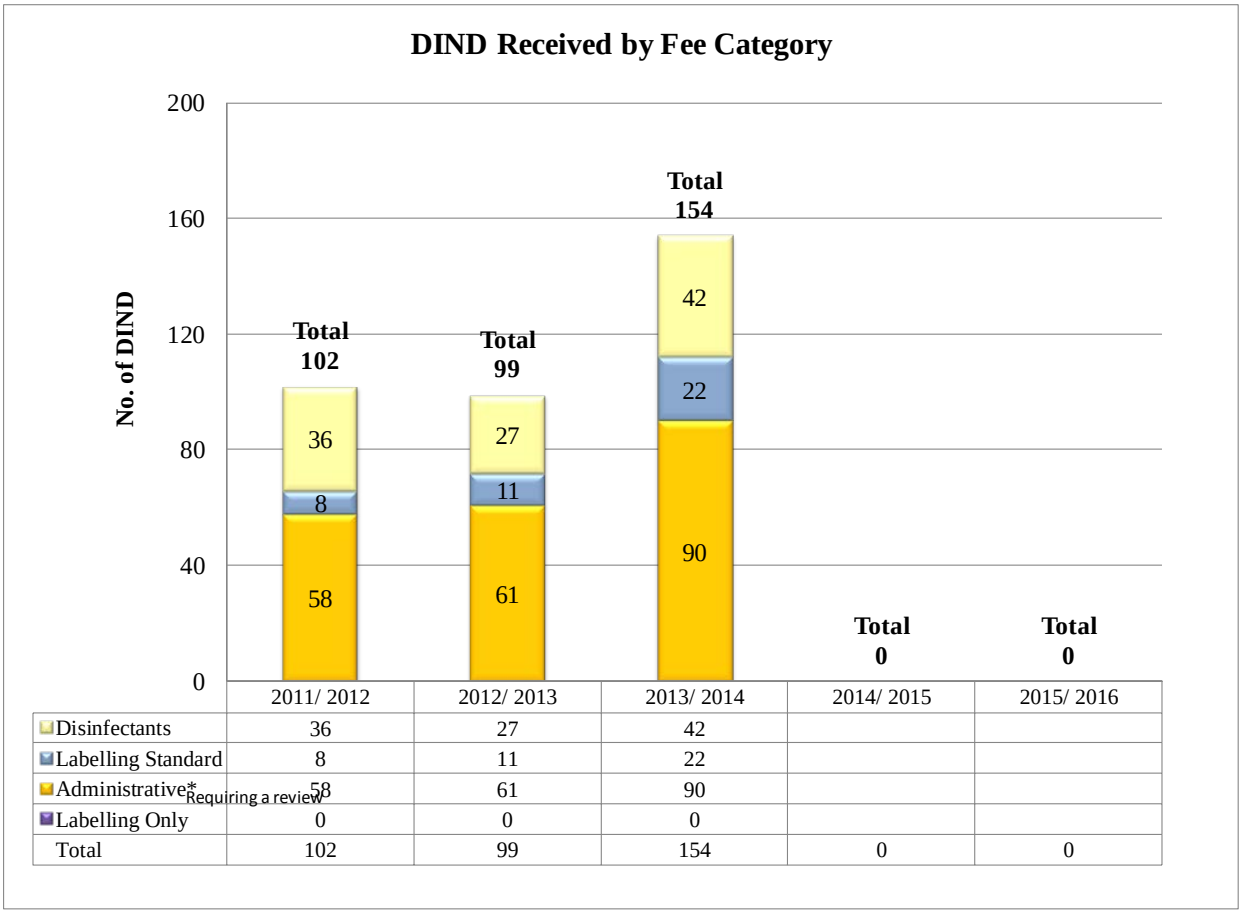


Screening Cycle Completions – DINA (Prescription)



DIND: Application for a Drug Identification Number - DISINFECTANT PRODUCT[11]

Number Received - DIND

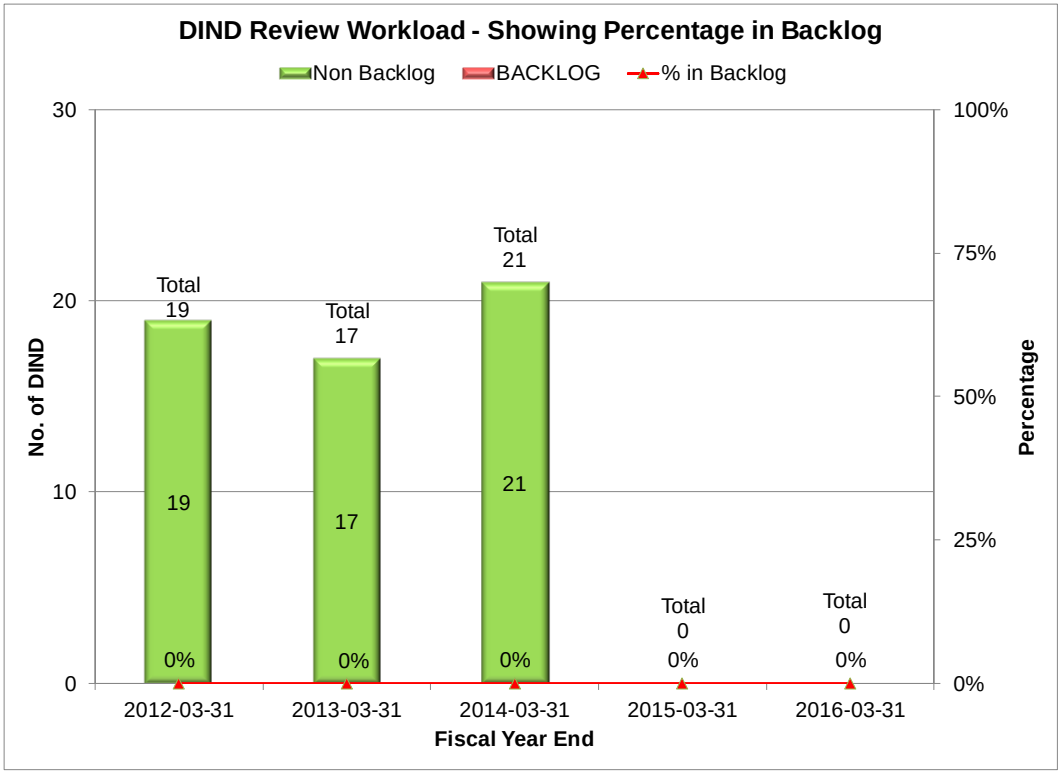


	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
Disinfectants	36	27	42		
Labelling Standard	8	11	22		
Administrative* Requiring a review	58	61	90		
Labelling Only	0	0	0		
Total	102	99	154	0	0

[11] 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.

REVIEW WORKLOAD

Review Workload / Backlog - Showing Percentage in Backlog - DIND

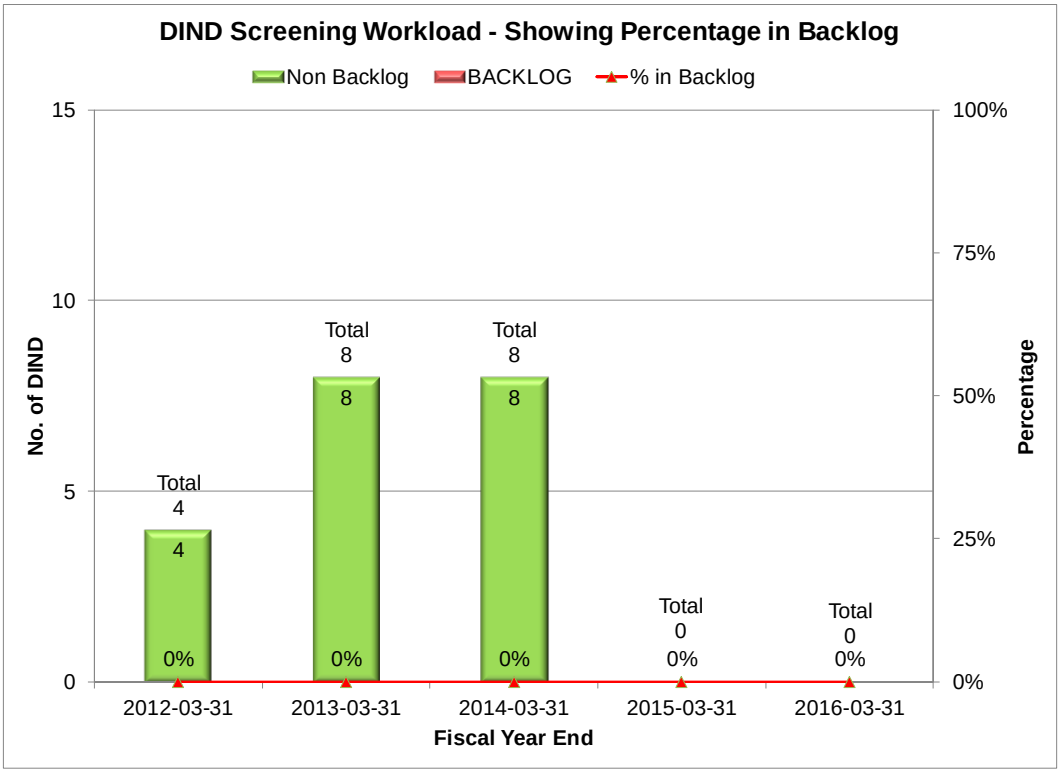


Review Workload by User Fee Category - DIND

TPD DIND All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2012-03-31	2013-03-31	2014-03-31	2015-03-31	2016-03-31
Labelling Only (Form)	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Disinfectant (Form and Supporting Data)	**19**	**17**	**21**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**19**	**17**	**21**	**0**	**0**
Non Backlog	**19**	**17**	**21**	*0*	*0*
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

SCREENING WORKLOAD

Screening Workload / Backlog - Showing Percentage in Backlog - DIND



Screening Workload by Class - DIND

TPD DIND All SCREENING WORKLOAD BY User Fee Category (excluding administrative) and Fiscal Year End					
CLASS	**2012-03-31**	**2013-03-31**	**2014-03-31**	**2015-03-31**	**2016-03-31**
Labelling Only (Form)	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Disinfectant (Form & Supportin	**3**	**3**	**7**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Standard	**1**	**5**	**1**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**4**	**8**	**8**	**0**	**0**
Non Backlog	**4**	**8**	**8**	**0**	**0**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

DECISION DOCUMENTS

Decision Documents – DIND by Class

DIND - LABELLING ONLY					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NOTIFICATION FORM/DIN ISSUED	10			-	-
NO OBJECTION LETTER	3			-	-
CANCELLED BY COMPANY				-	-
NEW DRUG LETTER SCREEN				-	-
NON WITHDRAWAL LETTER				-	-
NOTICE OF NON-COMPLIANCE				-	-
REJECTION LETTER (SCREENING)				-	-
SCREENING DEFICIENCY NOTICE				-	-

DIND - Form and Supporting Data					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NOTIFICATION FORM/DIN ISSUED	8			-	-
NO OBJECTION LETTER	21			-	-
CANCELLED BY COMPANY				-	-
NEW DRUG LETTER REVIEW				-	-
NEW DRUG LETTER SCREEN				-	-
NOTICE OF NON-COMPLIANCE	7			-	-
NOTICE OF DEFICIENCY				-	-
NON WITHDRAWAL LETTER	1			-	-
REJECTION LETTER (SCREENING)				-	-
SCREENING DEFICIENCY NOTICE	2			-	-
WITHDRAWAL NO RESP TO NON	3			-	-
WITHDRAWAL NO RESP TO NOD				-	-
WITH.UNACCEPT.RESP.NON SC	1			-	-

DIND - ADMINISTRATIVE					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NOTIFICATION FORM/DIN ISSUED	58	62	75	-	-
NO OBJECTION LETTER	2	3	1	-	-
CANCELLED BY COMPANY				-	-
REJECTION LETTER (SCREENING)	3	1		-	-
SCREENING DEFICIENCY NOTICE	19	21	18	-	-

DIND - LABELLING STANDARD					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NOTIFICATION FORM/DIN ISSUED	3	6	25	-	-
REJECTION LETTER (SCREENING)				-	-
SCREENING DEFICIENCY NOTICE	4	5	17	-	-
CANCELLED BY COMPANY	1	1		-	-
REJECTION LETTER (SCREENING)				-	-
NEW DRUG LETTER SCREEN		1	1	-	-

DIND - DIS NONCLIN/CLINICAL					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NOTIFICATION FORM/DIN ISSUED	2	28	24	-	-
DIN INCORR SUBTYPE-CLASS	2			-	-
NO OBJECTION LETTER	2	3	7	-	-
NOTICE OF NON-COMPLIANCE		7	4	-	-
REJECTION LETTER (SCREENING)	1			-	-
SCREENING DEFICIENCY NOTICE	13	9		-	-
SPONSOR SUB CHANGE ACCEPT	1			-	-
CANCELLED BY COMPANY		2	1	-	-
NON WITHDRAWAL LETTER			1	-	-

DIND - DIS NONCLIN/C&M					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
SCREENING DEFICIENCY NOTICE	1			-	-

DIND - DISINFECT LABEL ONLY					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
SCREENING DEFICIENCY NOTICE		1	2	-	-
CANCELLED BY COMPANY		3		-	-

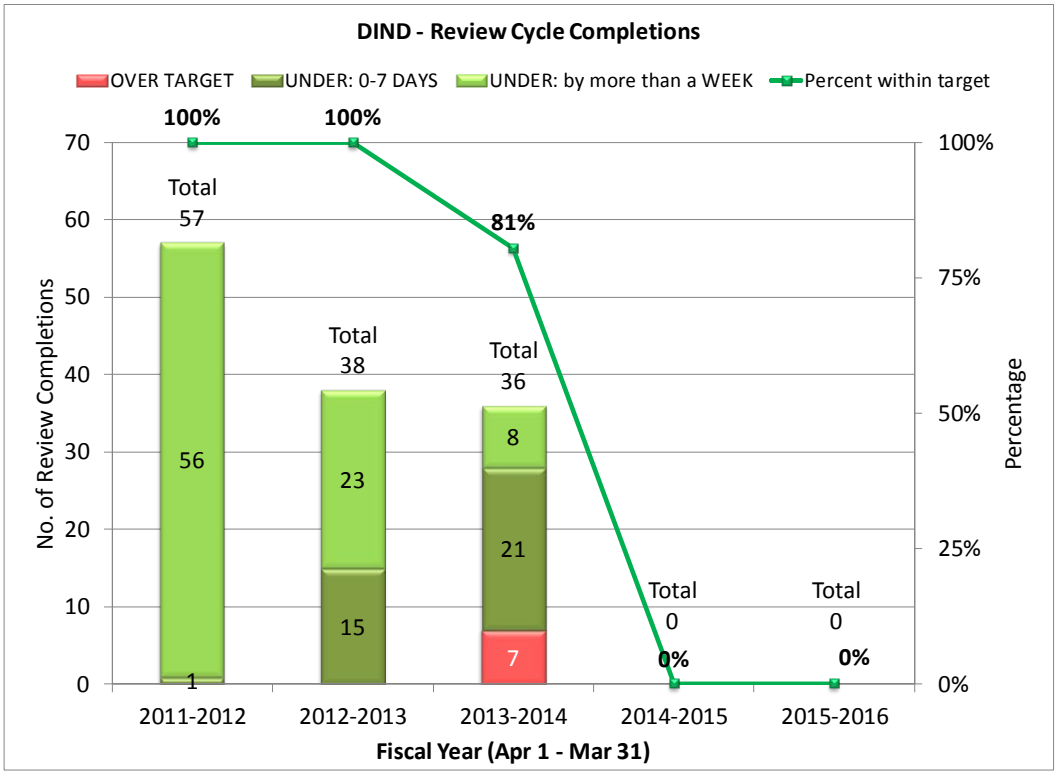
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – DIND

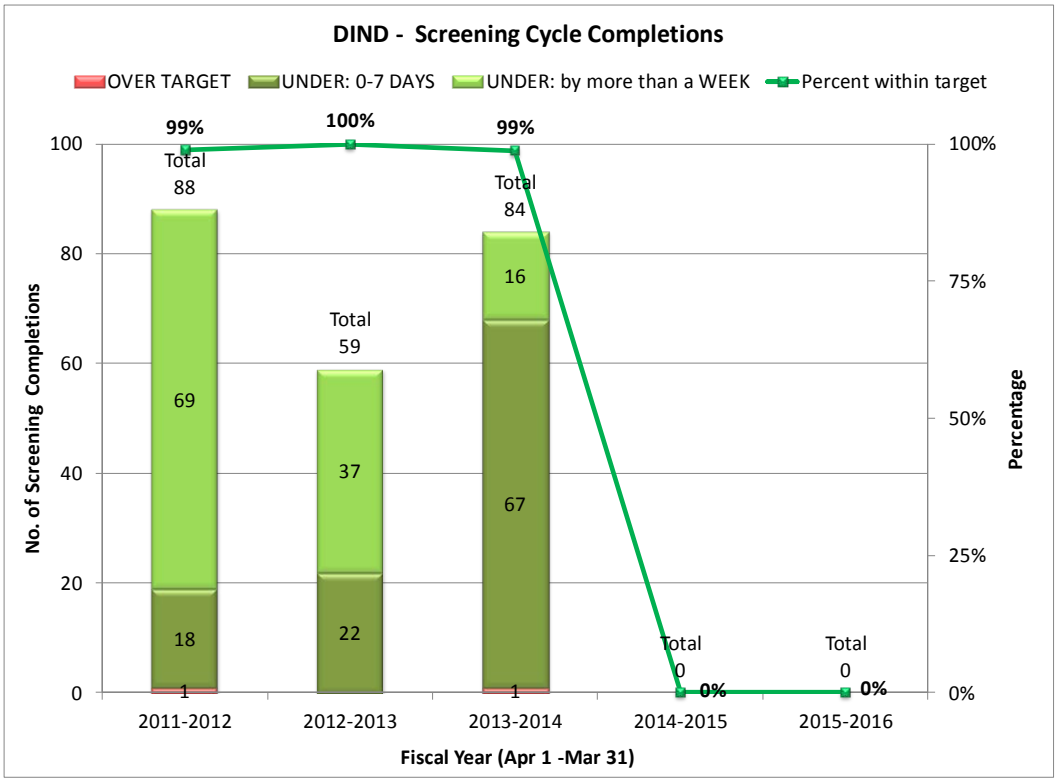
DIND - Reconsideration of Final Decisions by Year Requested							
Fiscal Year of Request (Apr - Mar)							
Breakdown by Reconsideration Decision	**11-12**	**12-13**	**13-14**	**14-15**	**15-16**	**Final Decision in Dispute**	**Submission Status as of Apr 18 2016**
Total Received	**1**	**0**	**0**	**0**	**0**		
Total Denied	***1***	***0***	***0***	***0***	***0***		
Denied	1					New Drug Letter	Rejected

PERFORMANCE

Review Cycle Completions - DIND

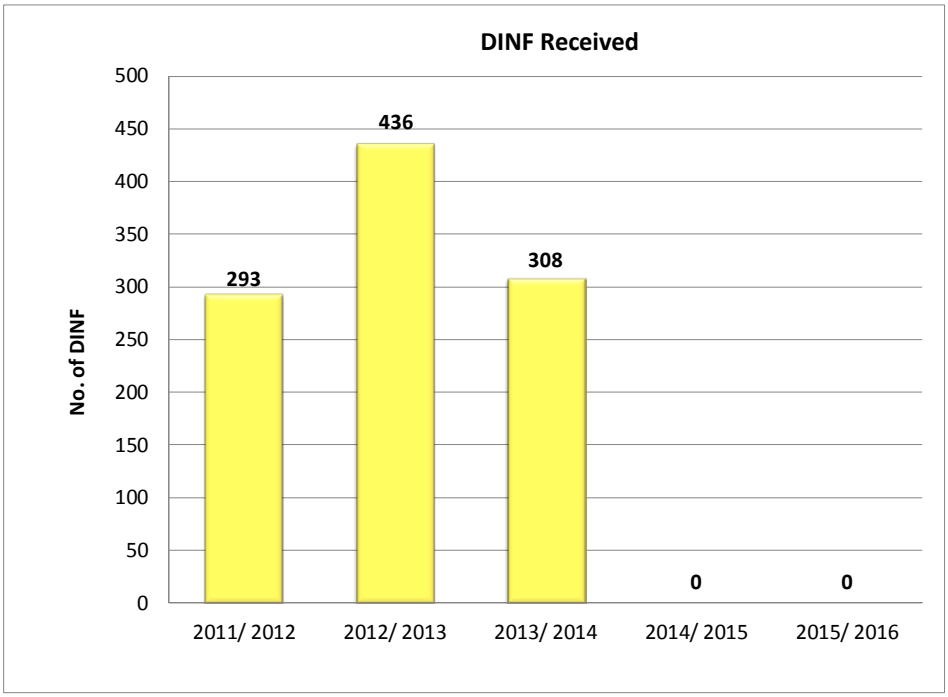


Screening Cycle Completions - DIND

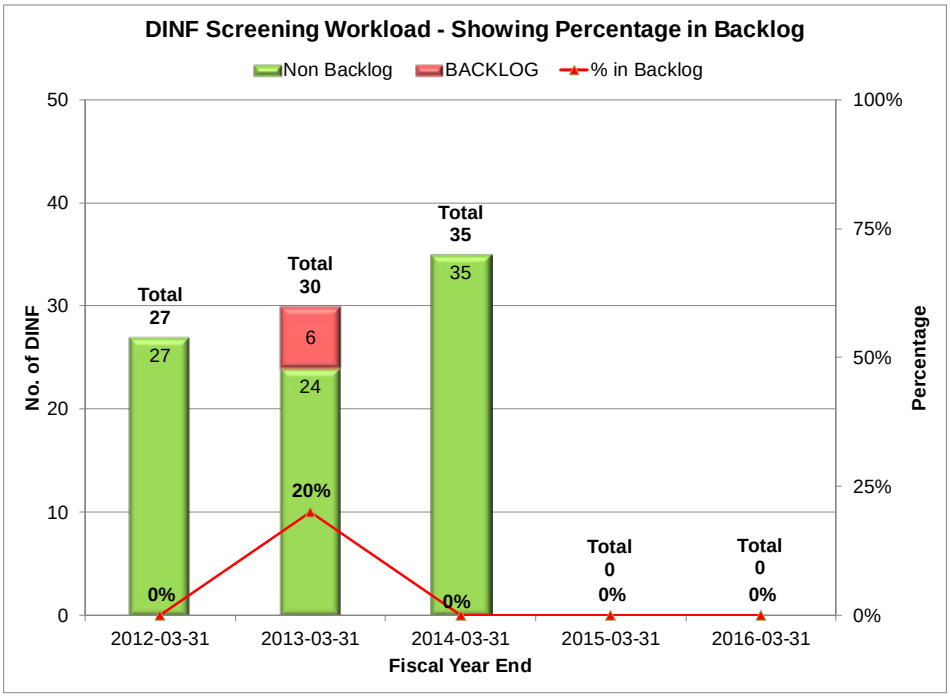


DINF: CATEGORY IV PRODUCT - (LABELLING STANDARD)[12]

Number Received - DINF



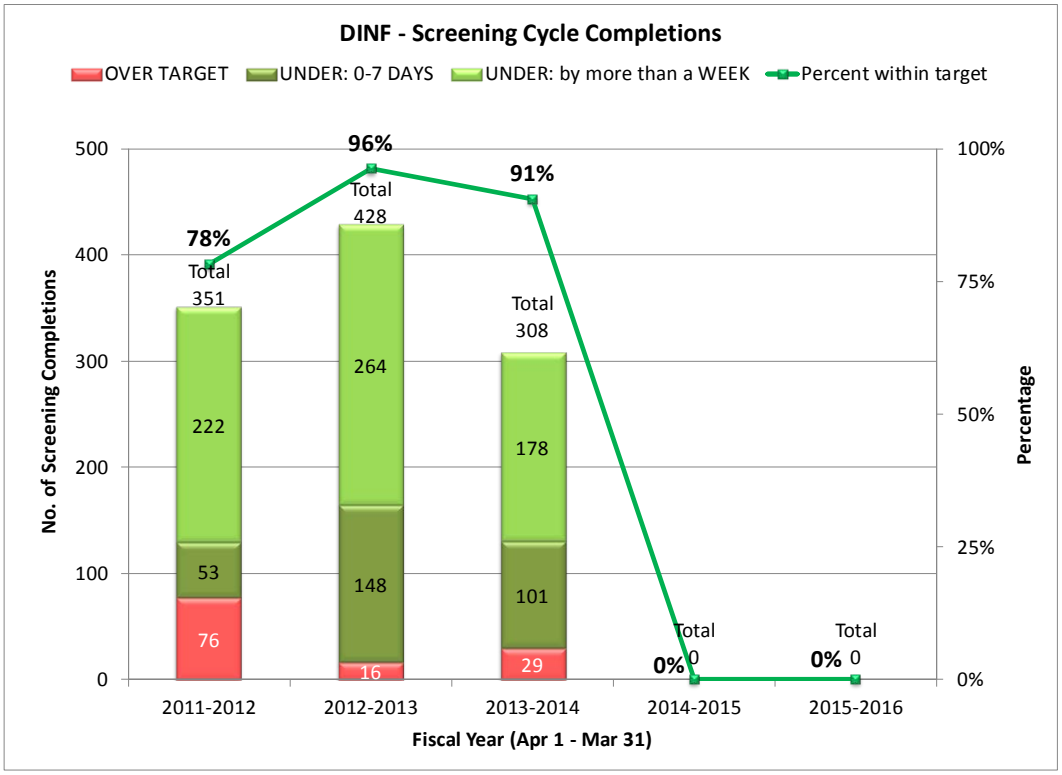
Screening Workload / Backlog – Showing Percentage in Backlog – DINF



[12] 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.

PERFORMANCE

Screening Cycle Completions - DINF



DECISION DOCUMENTS

Decision Documents – DINF - Labelling Standard

DINF - LABELLING STANDARD					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NOTIFICATION FORM/DIN ISSUED	176	325	286	-	-
NO OBJECTION LETTER	2	4	1	-	-
CANCELLED BY COMPANY	16	74	11	-	-
DIN INCORR SUBTYPE-CLASS	6	5	1	-	-
NEW DRUG LETTER SCREEN	1	1		-	-
NOT SATISFACTORY NOTICE				-	-
REJECTION LETTER (SCREENING)	69	32	8	-	-
SCREENING DEFICIENCY NOTICE	25	45	12	-	-
SPONSOR SUB CHANGE ACCEPT			1	-	-

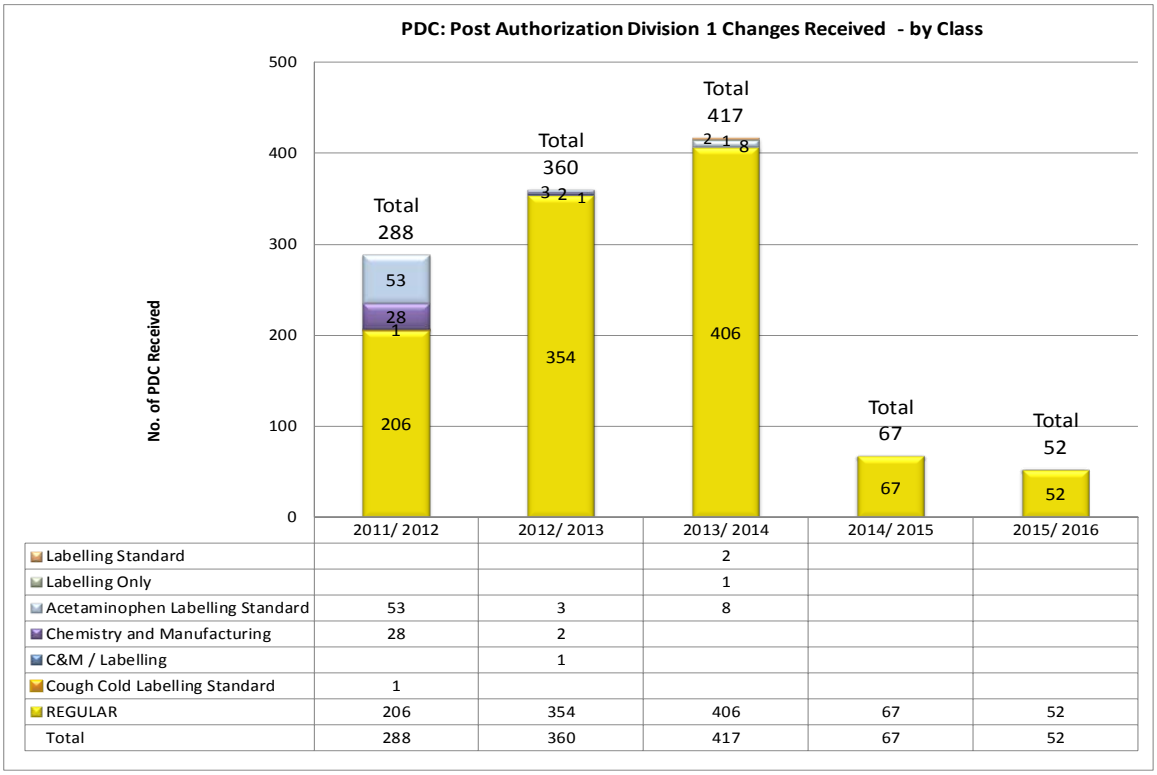
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – DINF

DINF - Reconsideration of Final Decisions by Year Requested							
Fiscal Year of Request (Apr - Mar)							
Breakdown by Reconsideration Decision	**11-12 * revised**	**12-13**	**13-14**	**14-15**	**15-16**	**Final Decision in Dispute**	**Submission Status as of Apr 18 2016**
Total Received	**1**	**2**	**0**	**0**	**0**		
Total Granted	**0**	**0**	**0**	**0**	**0**		
Total Denied	1	1	0	0	0	Rejection at Screening	Rejected
Total Cancelled by Company	0	1	0	0	0	Rejection at Screening	Rejected

PDC: POST-AUTHORIZATION DIVISION 1 CHANGES[13],[14]

Post-Authorization Division 1 Changes (PDC) Received



	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
Labelling Standard			2		
Labelling Only			1		
Acetaminophen Labelling Standard	53	3	8		
Chemistry and Manufacturing	28	2			
C&M / Labelling		1			
Cough Cold Labelling Standard	1				
REGULAR	206	354	406	67	52
Total	288	360	417	67	52

[13] The Guidance Document on Post-Drug Identification Number (DIN) Changes was posted on Sept 29, 2009 and applies to drugs regulated under part C, Division 1 of the Regulations that have received a DIN pursuant to Section C.01.01.4.2. The guidance came into full effect on December 29, 2009.

[14] 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.

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

PDC					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
COUGH COLD LABELLING STANDARD					
NO OBJECTION LETTER	1				
NOT SATISFACTORY NOTICE					
ACETAMINOPHEN LS					
CANCELLED BY COMPANY	1				
NO OBJECTION LETTER	69	1	10		
NOT SATISFACTORY NOTICE	10				
REGULAR					
CANCELLED BY COMPANY	8	17	16	7	11
NO OBJECTION LETTER	174	251	362	67	43
NOT SATISFACTORY NOTICE	16	51	15		
NOTIFICATION FORM/DIN ISSUED	1				
REJECTION LETTER (SCREENING)	1				
C&M ONLY					
NO OBJECTION LETTER	3	5			
CANCELLED BY COMPANY	1				
C&M LABELLING					
NO OBJECTION LETTER	3				
CANCELLED BY COMPANY	1				
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 (Apr - Mar)

Breakdown by Reconsideration Decision	11-12	12-13	13-14	14-15	15-16	Final Decision in Dispute	Submission Status as of Apr 18 2016
Total Received	**1**	**0**	**2**	**0**	**0**		
Total Cancelled by Company			2			Not Satisfactory Notice	Rejected
Total DENIED	1					Not Satisfactory Notice	Rejected

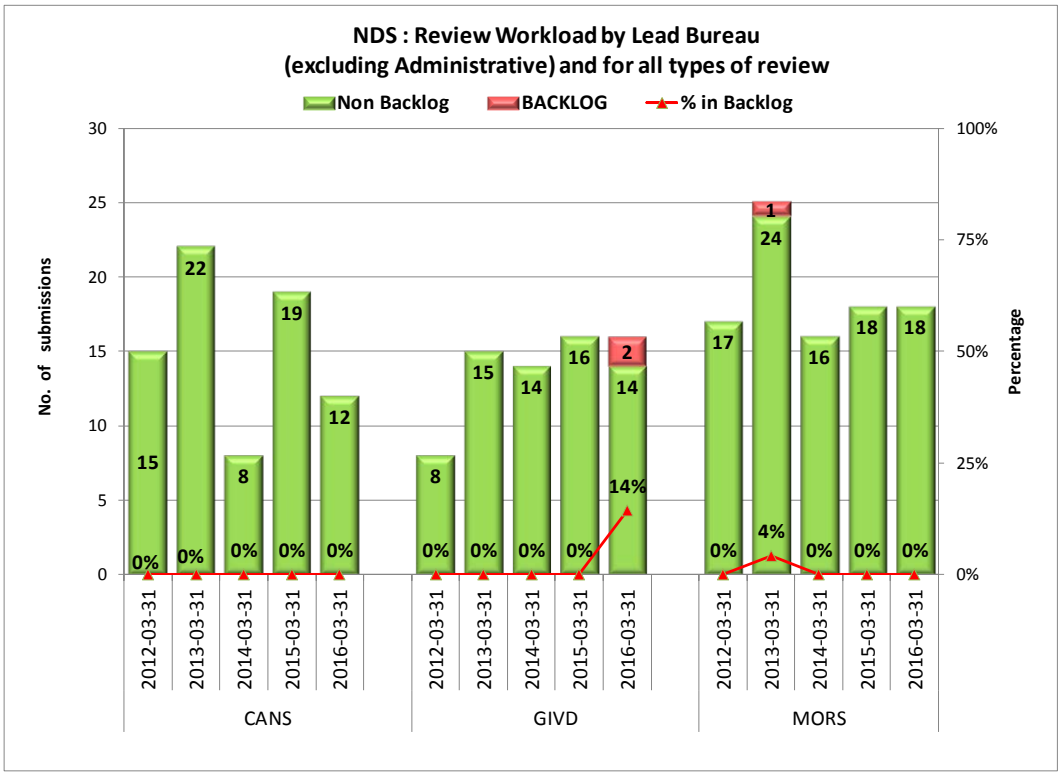
This page is left blank intentionally.

APPENDIX A - Lead Bureau Summaries

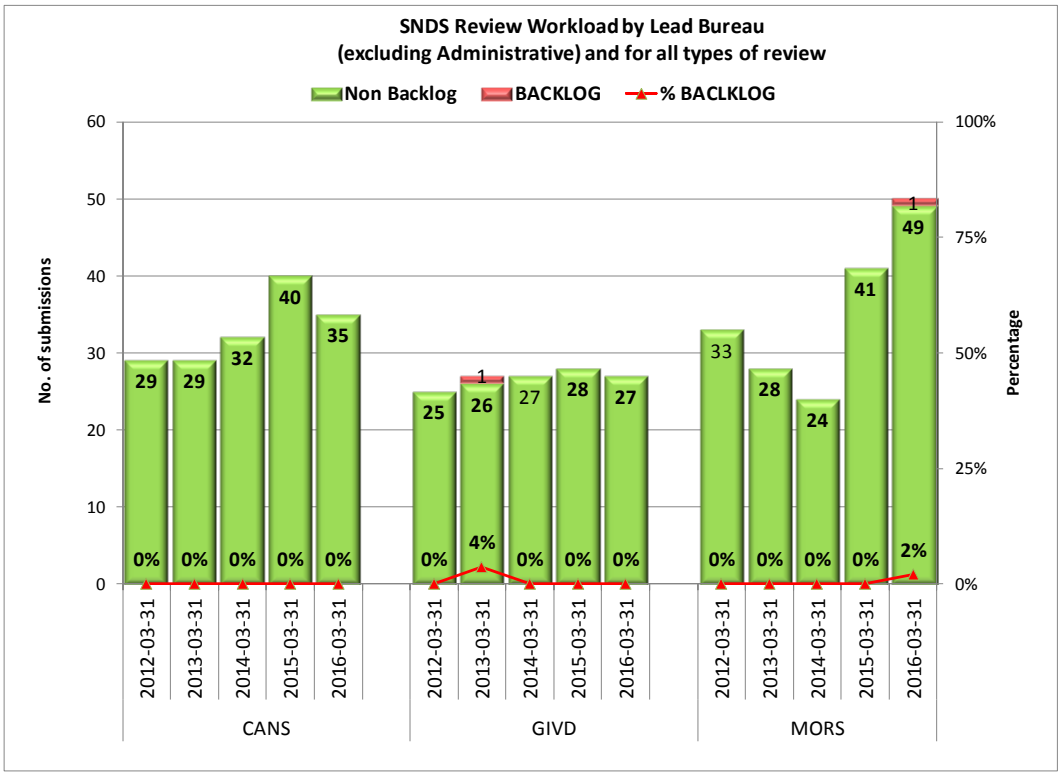
NDS & SNDS

WORKLOAD by Lead Bureau

NDS Review Workload by Lead Bureau

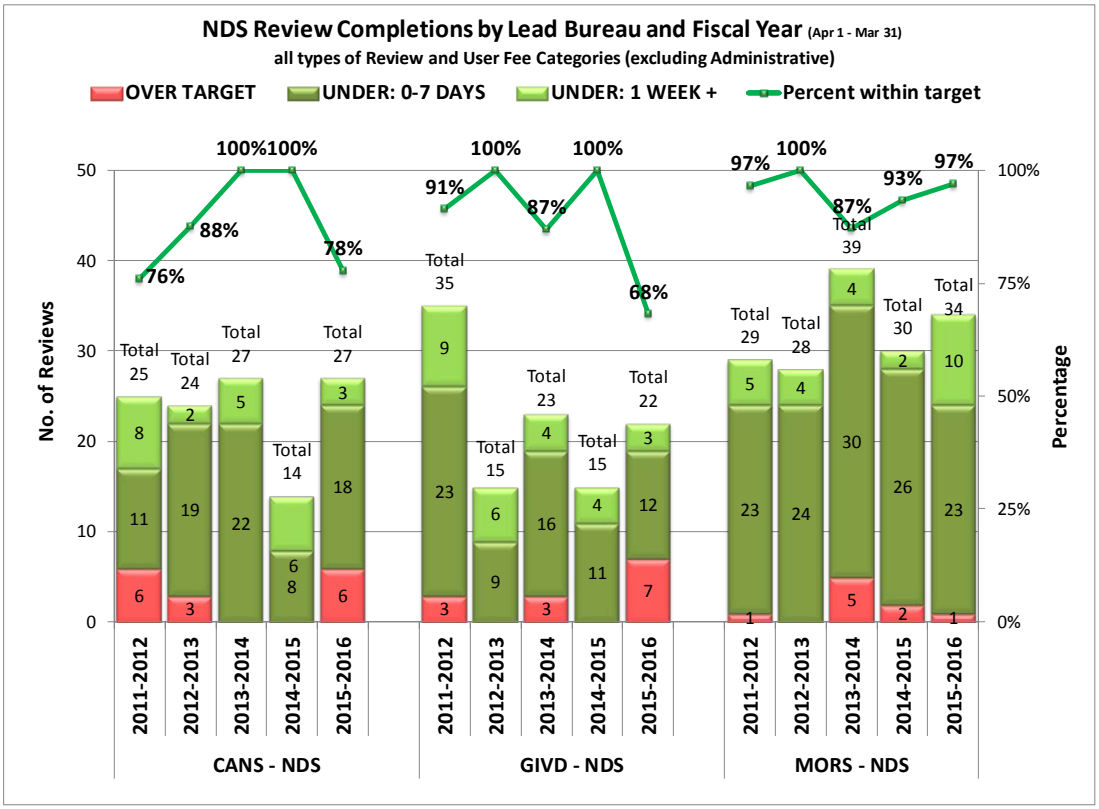


SNDS Review Workload by Lead Bureau

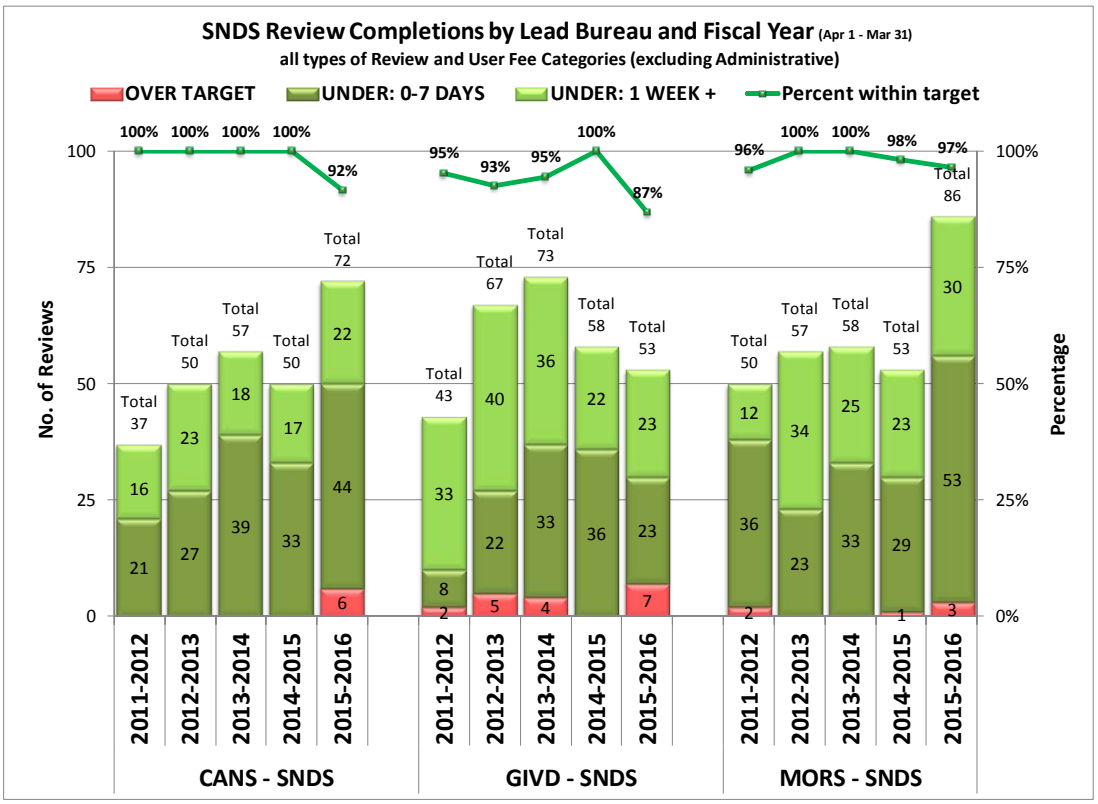


PERFORMANCE by Lead Bureau

NDS Review Performance by Lead Bureau

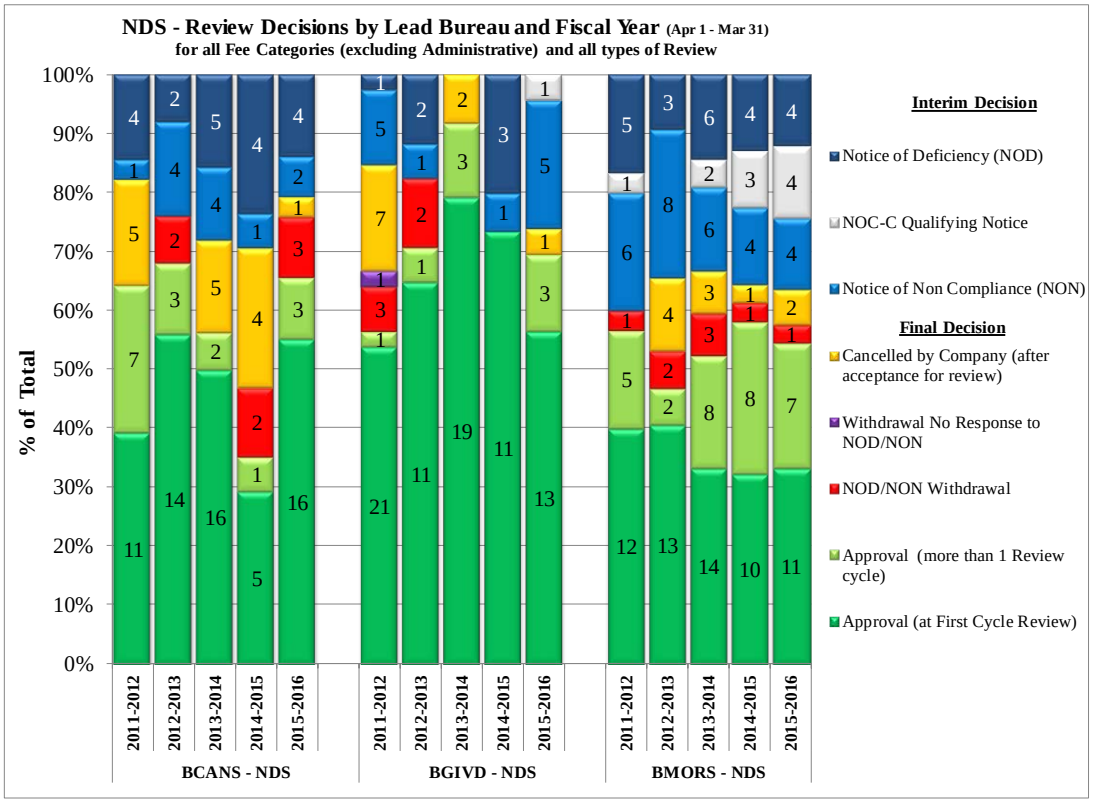


SNDS Review Performance by Lead Bureau

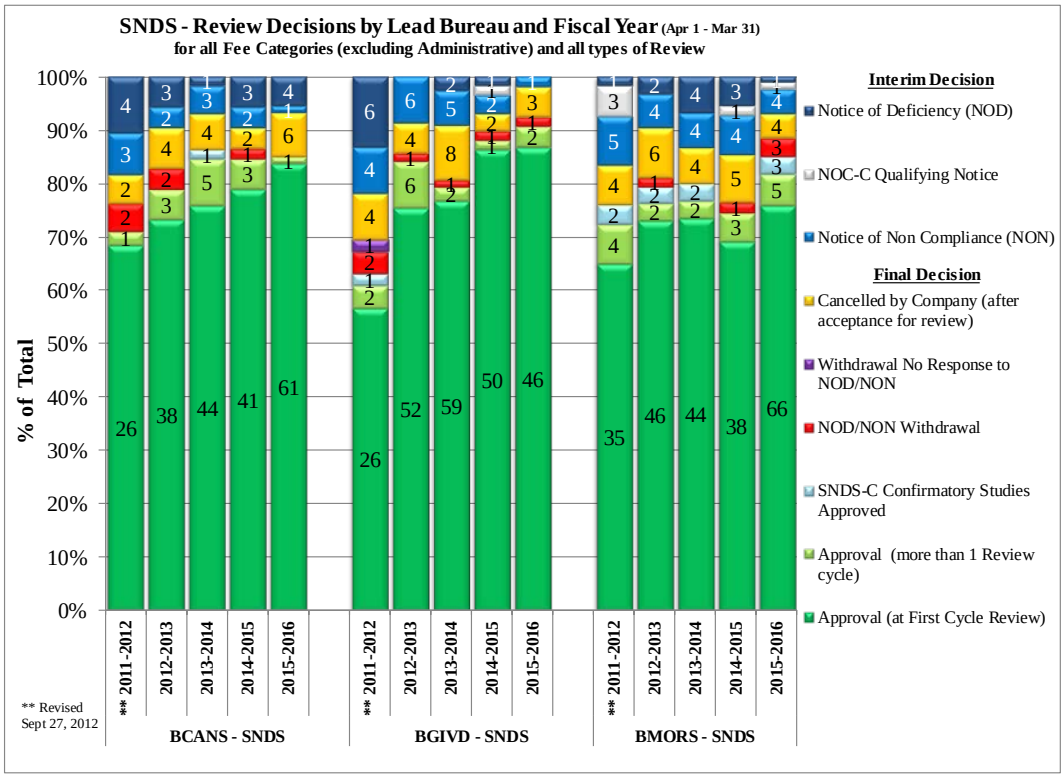


REVIEW DECISIONS by Lead Bureau

NDS Review Decisions by Lead Bureau

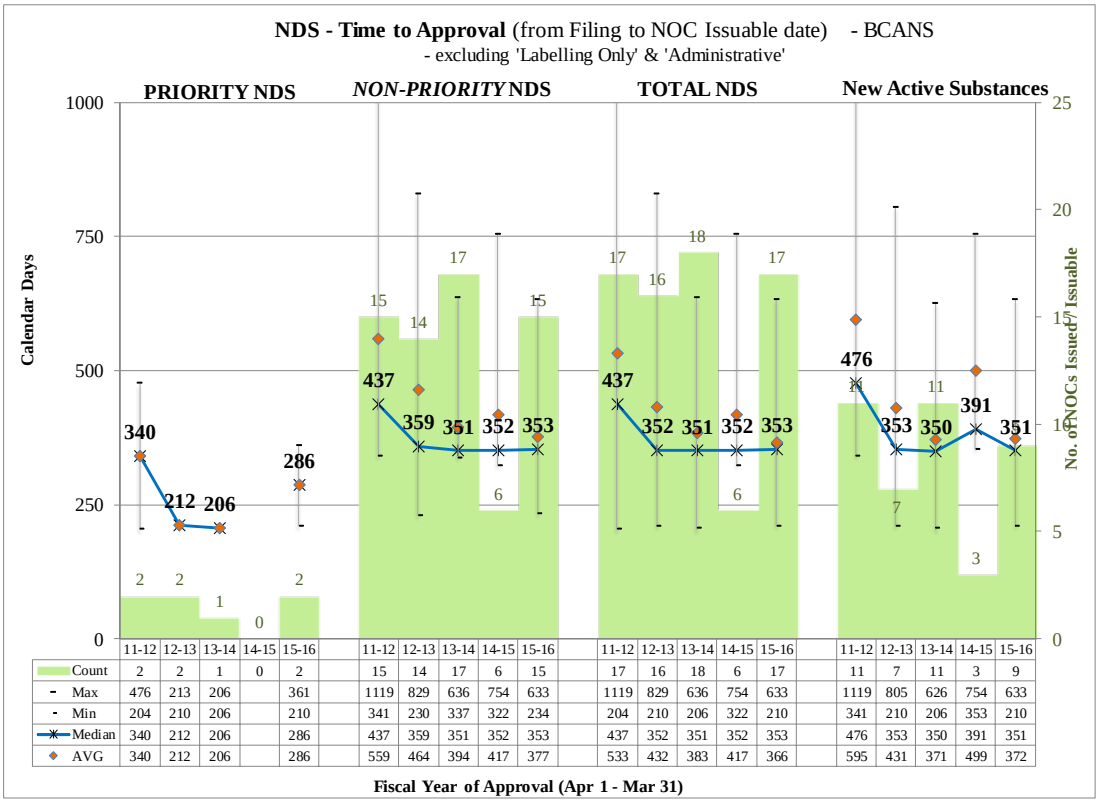


SNDS Review Decisions by Lead Bureau



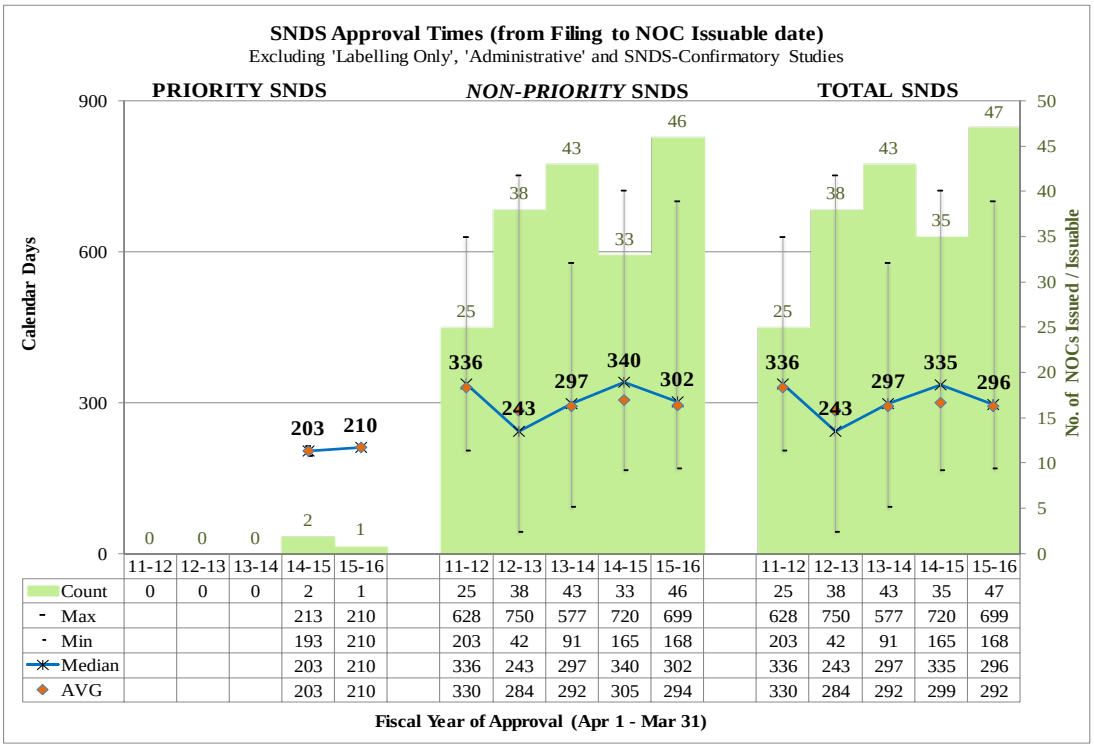
APPROVALS by Lead Bureau

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



	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16
Count	2	2	1	0	2	15	14	17	6	15	17	16	18	6	17	11	7	11	3	9
Max	476	213	206		361	1119	829	636	754	633	1119	829	636	754	633	1119	805	626	754	633
Min	204	210	206		210	341	230	337	322	234	204	210	206	322	210	341	210	206	353	210
Median	340	212	206		286	437	359	351	352	353	437	352	351	352	353	476	353	350	391	351
AVG	340	212	206		286	559	464	394	417	377	533	432	383	417	366	595	431	371	499	372

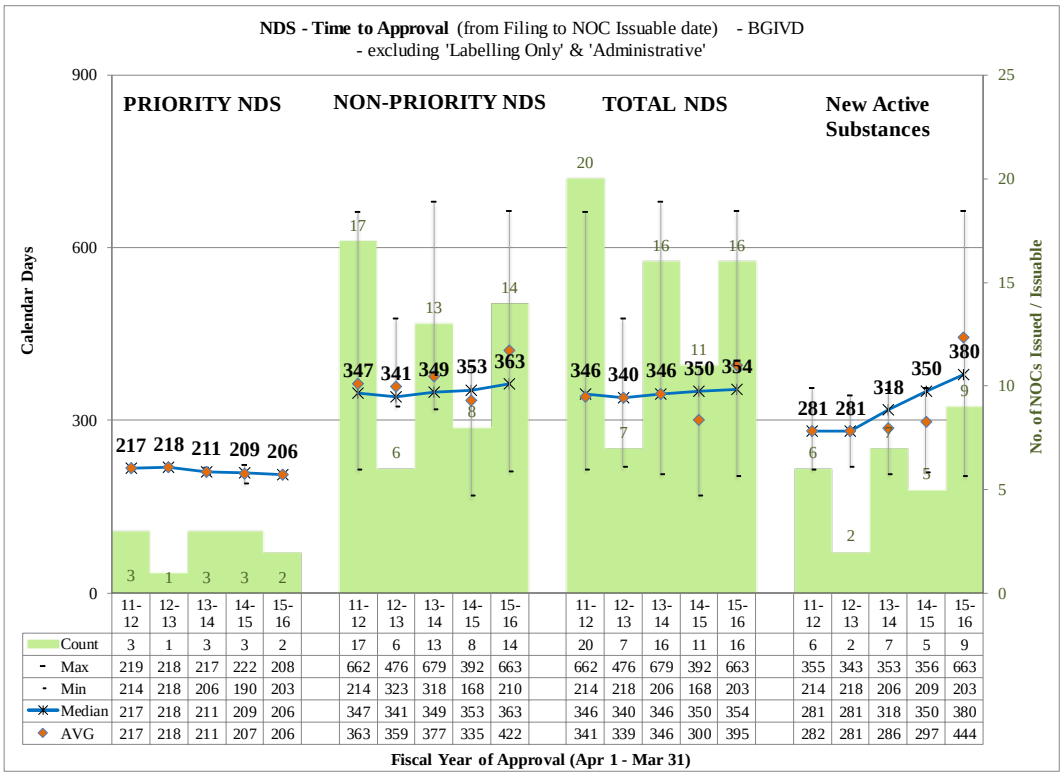
SNDS Approvals – Bureau of Cardiology, Allergy and Neurological Sciences (BCANS)



	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16
Count	0	0	0	2	1	25	38	43	33	46	25	38	43	35	47
Max				213	210	628	750	577	720	699	628	750	577	720	699
Min				193	210	203	42	91	165	168	203	42	91	165	168
Median				203	210	336	243	297	340	302	336	243	297	335	296
AVG				203	210	330	284	292	305	294	330	284	292	299	292

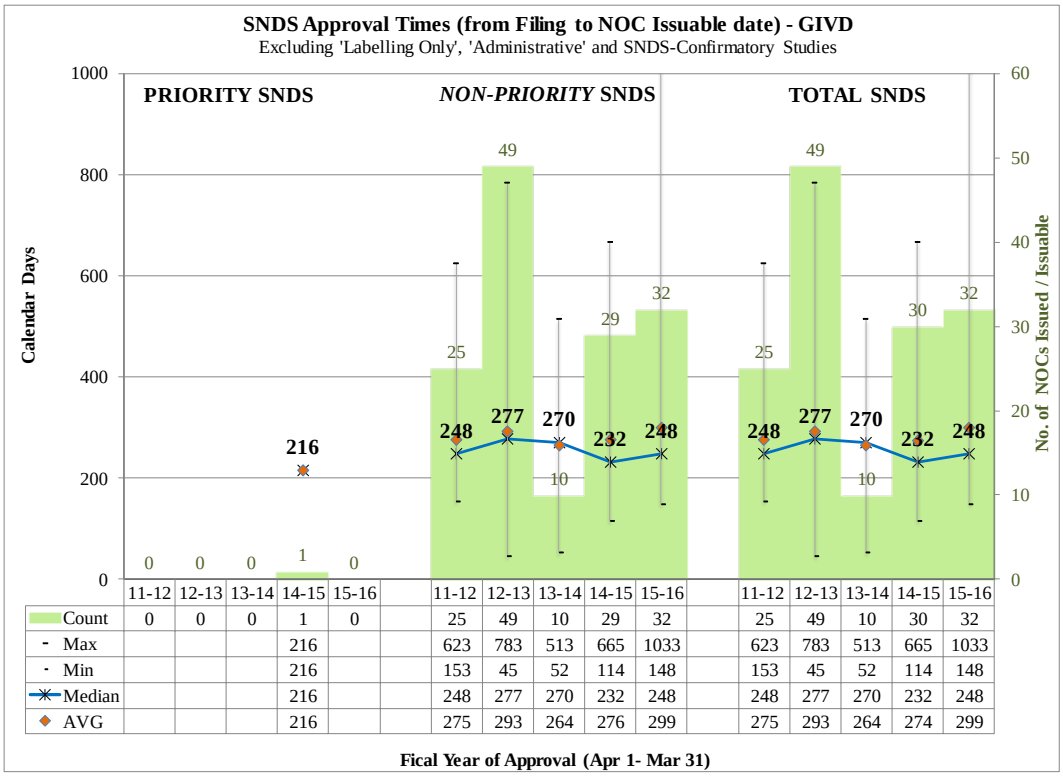
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

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



	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16
Count	3	1	3	3	2	17	6	13	8	14	20	7	16	11	16	6	2	7	5	9
Max	219	218	217	222	208	662	476	679	392	663	662	476	679	392	663	355	343	353	356	663
Min	214	218	206	190	203	214	323	318	168	210	214	218	206	168	203	214	218	206	209	203
Median	217	218	211	209	206	347	341	349	353	363	346	340	346	350	354	281	281	318	350	380
AVG	217	218	211	207	206	363	359	377	335	422	341	339	346	300	395	282	281	286	297	444

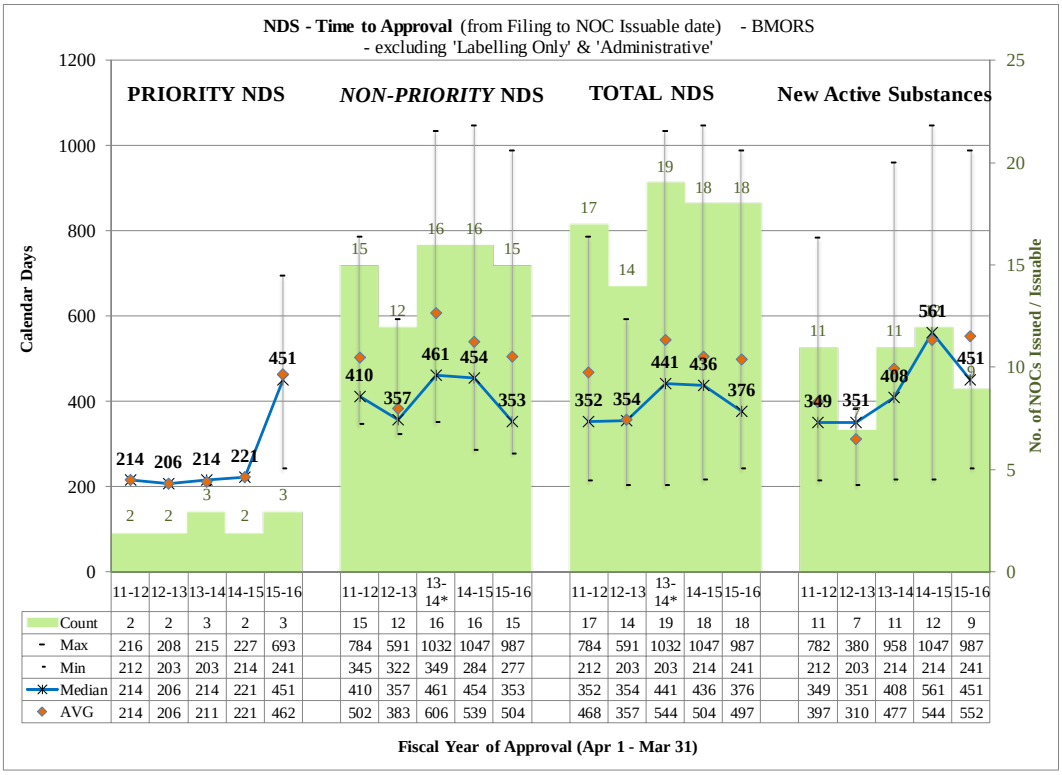
SNDS Approvals – Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD)



	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16
Count	0	0	0	1	0	25	49	10	29	32	25	49	10	30	32
Max				216		623	783	513	665	1033	623	783	513	665	1033
Min				216		153	45	52	114	148	153	45	52	114	148
Median				216		248	277	270	232	248	248	277	270	232	248
AVG				216		275	293	264	276	299	275	293	264	274	299

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.

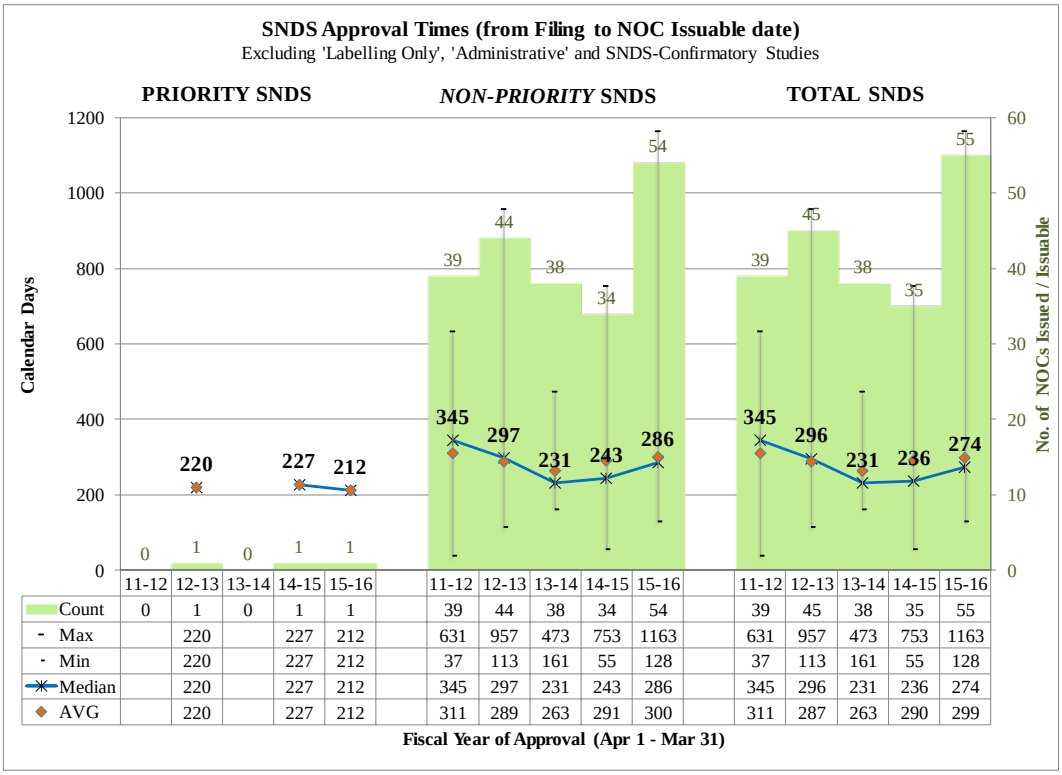
NDS Approvals – Bureau of Metabolism, Oncology & Reproductive Sciences (BMORS)



	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14*	14-15	15-16	11-12	12-13	13-14*	14-15	15-16	11-12	12-13	13-14	14-15	15-16
Count	2	2	3	2	3	15	12	16	16	15	17	14	19	18	18	11	7	11	12	9
Max	216	208	215	227	693	784	591	1032	1047	987	784	591	1032	1047	987	782	380	958	1047	987
Min	212	203	203	214	241	345	322	349	284	277	212	203	203	214	241	212	203	214	214	241
Median	214	206	214	221	451	410	357	461	454	353	352	354	441	436	376	349	351	408	561	451
AVG	214	206	211	221	462	502	383	606	539	504	468	357	544	504	497	397	310	477	544	552

*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)



	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16
Count	0	1	0	1	1	39	44	38	34	54	39	45	38	35	55
Max		220		227	212	631	957	473	753	1163	631	957	473	753	1163
Min		220		227	212	37	113	161	55	128	37	113	161	55	128
Median		220		227	212	345	297	231	243	286	345	296	231	236	274
AVG		220		227	212	311	289	263	291	300	311	287	263	290	299

APPENDIX B – Regulatory Activities in eCTD Format

Regulatory Activities in eCTD Format

Overview

This section of the Annual Drug Submission Performance Report for fiscal year 2015-2016 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-NoHealth Product Directorate (NNHPD-NDED). The time period for which data is displayed in this report ranges from April 1st, 2011 to March 31st, 2016. 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)".*

This is an advanced notice that Health Canada is considering **January 1st, 2018** for mandatory filing of all NDS, SNDS, SANDS and ANDS regulatory activities and their subsequent transactions (such as NC, PSUR, RMP, etc) in eCTD format.

Common Electronic Submission Gateway (CESG)

The Common Electronic Submission Gateway (CESG) has been available in Health Canada since January 31, 2014. Health Canada would like to announce that **January 1st, 2017** is the date for mandatory filing of all regulatory activities, as per the *Frequently Asked Questions – Common Electronic Submission Gateway* document, via the CESG for transactions under 10GB in size. Because most transactions fall within this size limit, sponsors are strongly advised to obtain CESG accounts as soon as possible.

GLOSSARY OF TERMS

eCTD: Electronic Common Technical Document
Dossier: A collection of all regulatory activities throughout the life cycle of a product.

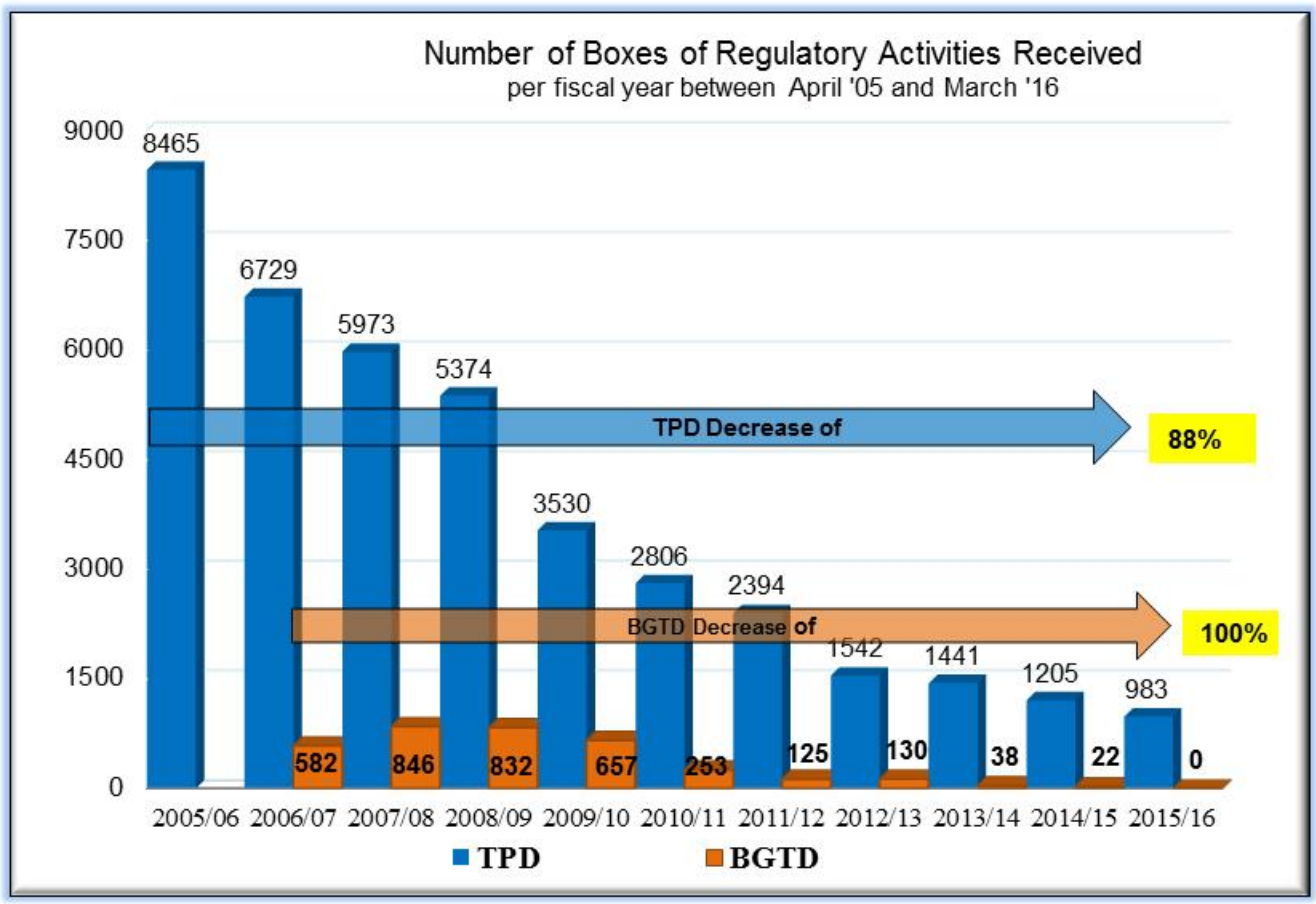
Regulatory Activity: a collection of all regulatory transactions throughout the process of a specific activity which includes, but is not limited to, NDS, ANDS, DIN Application, YBPR.

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):

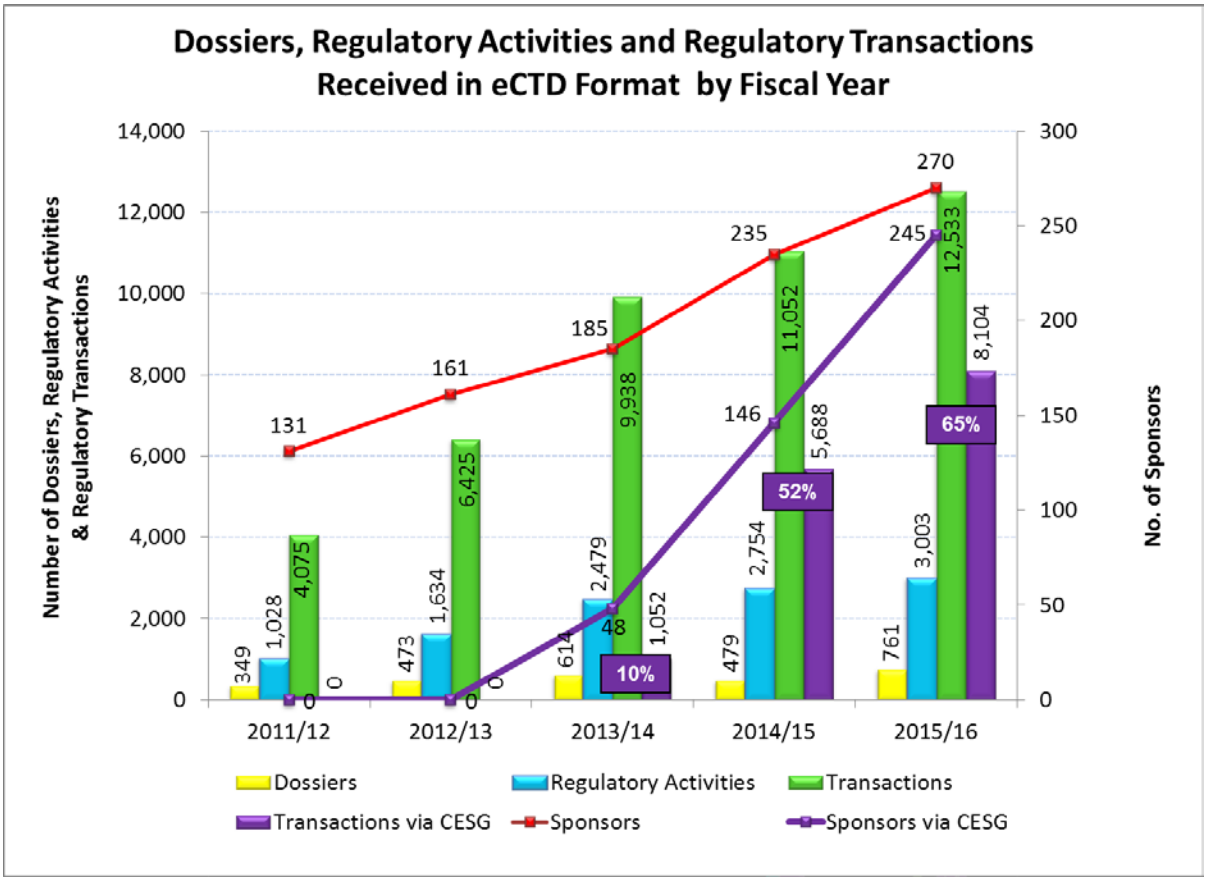
- **PSUR-C:** Periodic Safety Update Reports – Confirmatory
- **PBRER-C:** Periodic Benefit-Risk Evaluation Reports - Confirmatory
- **PSUR-PV:** Periodic Safety Update Reports - Pharmacovigilance
- **PBRER-PV:** Periodic Benefit-Risk Evaluation Reports - Pharmacovigilance
- **RMP-PV:** Risk Management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

Number of Boxes of Regulatory Activities Received



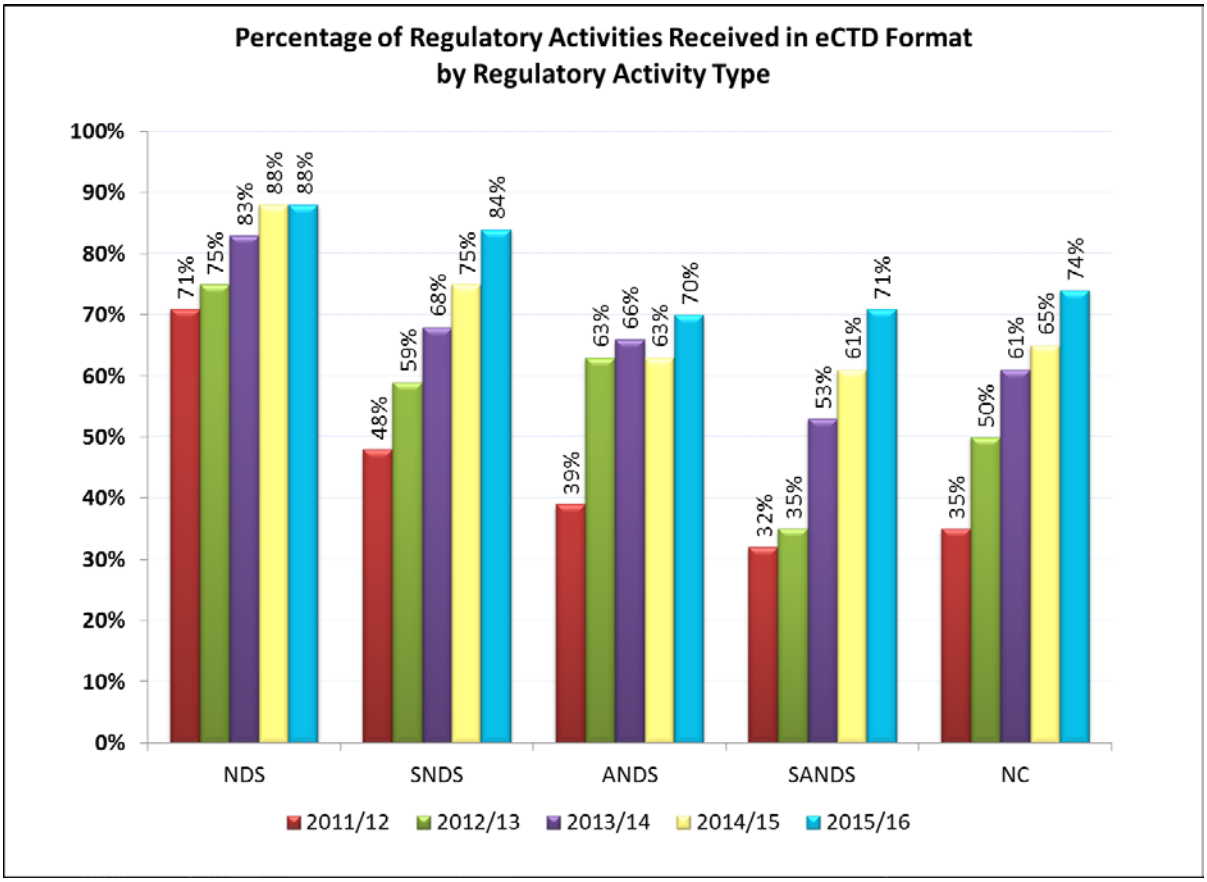
The above chart displays the reduction in boxes of paper Health Canada has received as a result of accepting regulatory activities electronically, both in CTD and eCTD formats.

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 Activities Received in eCTD Format by Regulatory Activity Type



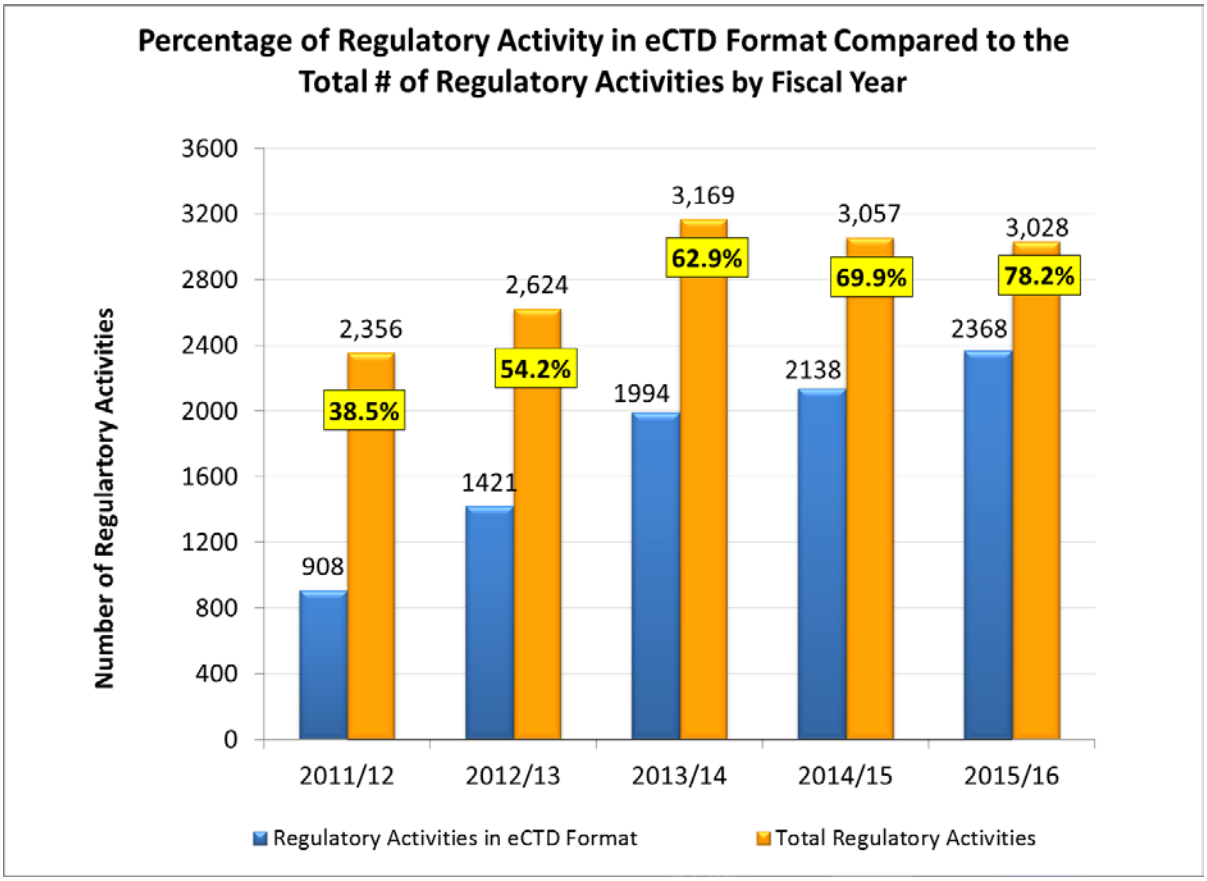
Number of Regulatory Activities Received in eCTD Format by Regulatory Activity Type

Year Filed	NDS	SNDS*	ANDS	SANDS	NC	Total
2015/16	78	304	116	103	1,160	**1,761**
2014/15	81	250	111	78	1,072	**1,592**
2013/14	63	188	161	61	1,023	**1,496**
2012/13	70	150	129	25	698	**1,072**
2011/12	44	109	94	22	468	**737**
Total	**336**	**1,001**	**611**	**289**	**4,421**	**6,658**

* SNDS totals include SNDS-C Regulatory Activities

The above chart and table only reflect 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. The reflected data includes all administrative class types with the exception of those processed only by OSIP.

Percentage of Regulatory Activity in eCTD Format Compared to the Total # 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.

This page is left blank intentionally.