Health Canada Santé Canada

July 3, 2015

Notice

Our File Number: 15-107942-526

Errata – Therapeutic Products Directorate's (TPD) Drug Submission Performance Annual Report Fiscal Year 2014-2015

A revised version of the Therapeutic Products Directorate's (TPD) Drug Submission Performance Annual Report, Fiscal Year 2014-2015 is now available. The original version was dated June 8, 2015, and the revised version is dated July 3, 2015. Two missing New Active Substance (NAS) have been added to the detailed list of New Active Substance Approvals on pages 21 to 25:

1. Ferriprox (Deferiprone)
2. Zykadia (Ceritinib)

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

Canada

Health Canada Santé Canada

Your health and safety… our priority. *Votre santé et votre sécurité… notre priorité.*

Therapeutic Products Directorate

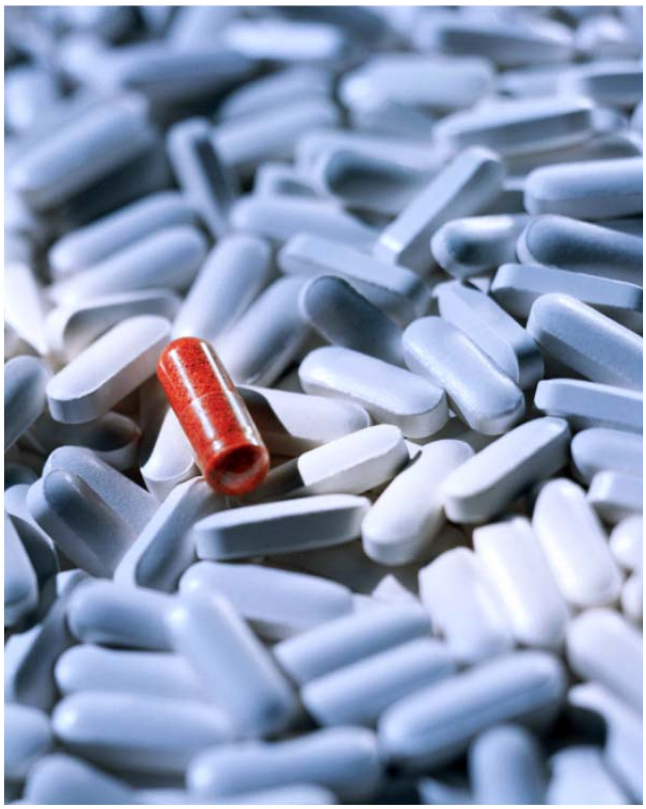
Drug Submission Performance Annual Report

Fiscal Year

2014 – 2015

Apr 1 2014 – Mar 31 2015

(Revisions to pages 21 to 25 – July 3, 2015)



Canada

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 2010-11 to 2014-15.

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 2014-15 fiscal year (from Apr 1 2014 to March 31 2015).

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 **Appendix B: Non-Prescription and Disinfectant Drugs**.

Clinical Trials figures are now provided by Class. In accordance with the revision of the CTA guidance in 2013, the "Phase 1 Healthy Human (7 day admin target)" has been eliminated and the "Phase 1 (30 day target)" has been split into "Phase 1 Healthy Human (30 day)" and "Phase 1 Other (30 day)".

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. Beginning April 1, 2014, these products will be reported separately in Appendix B: Non-prescription and disinfectant drug.

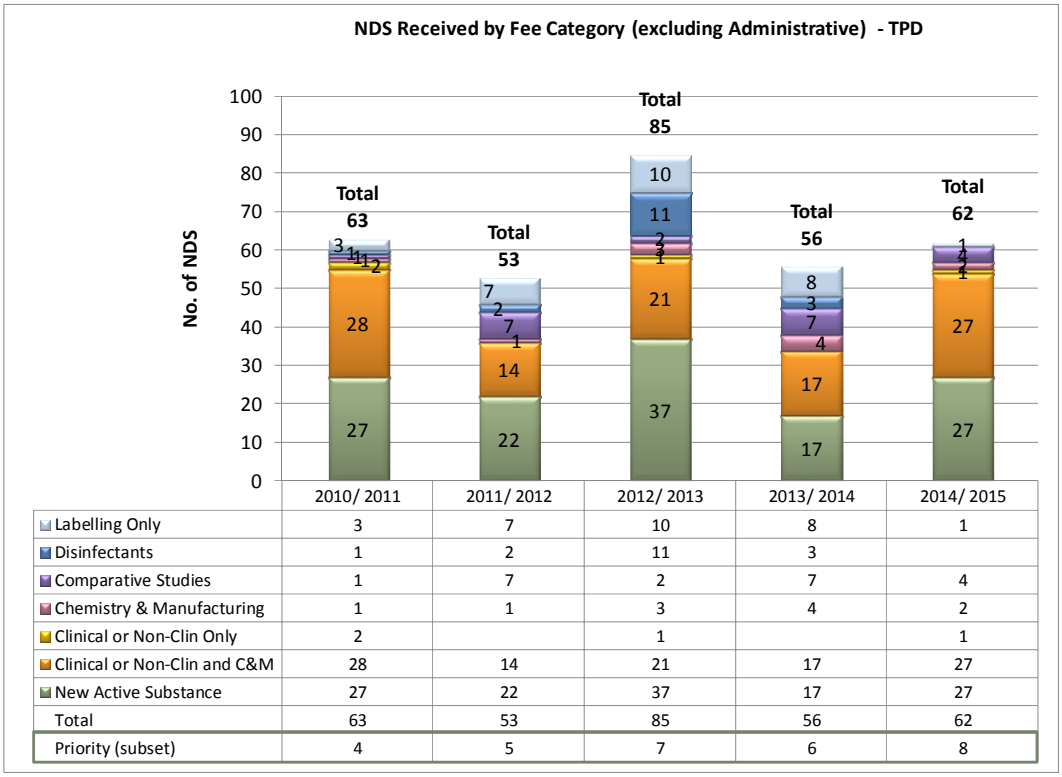
New Drug Submission (NDS)

&

Supplemental New Drug Submission (SNDS)

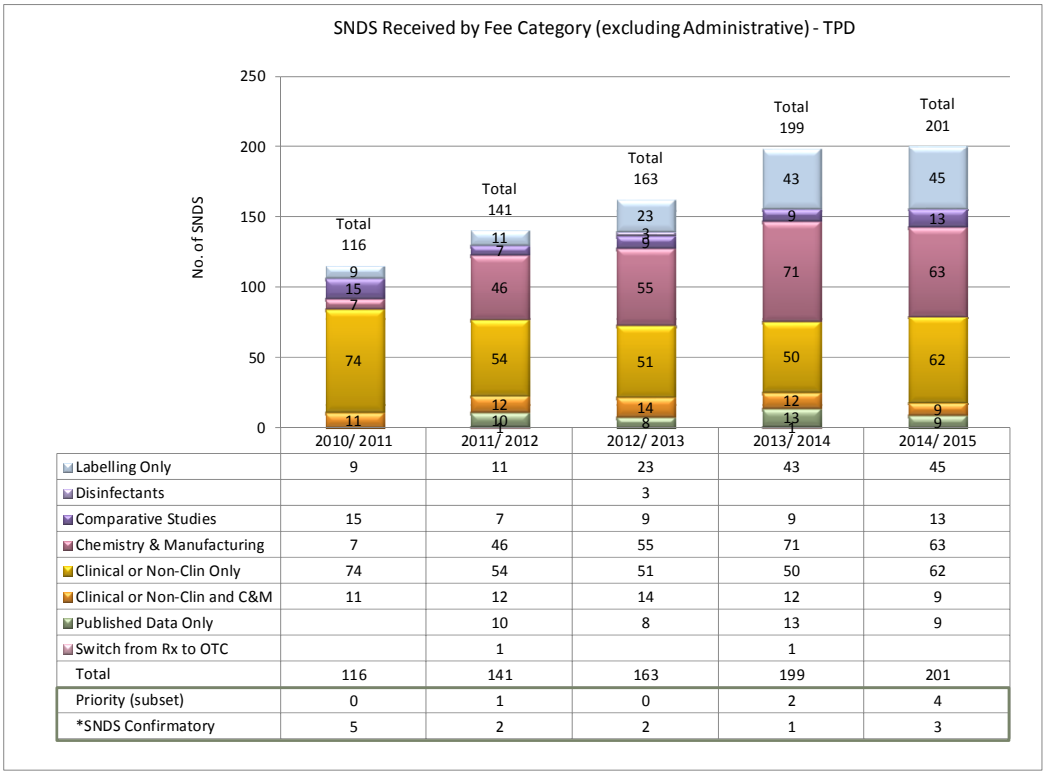
SUBMISSIONS RECEIVED[5]

New Drug Submissions (NDS) Received by Fee Category



	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
Labelling Only	3	7	10	8	1
Disinfectants	1	2	11	3	
Comparative Studies	1	7	2	7	4
Chemistry & Manufacturing	1	1	3	4	2
Clinical or Non-Clin Only	2		1		1
Clinical or Non-Clin and C&M	28	14	21	17	27
New Active Substance	27	22	37	17	27
Total	63	53	85	56	62
Priority (subset)	4	5	7	6	8

Supplemental New Drug Submissions (SNDS) Received by Fee Category

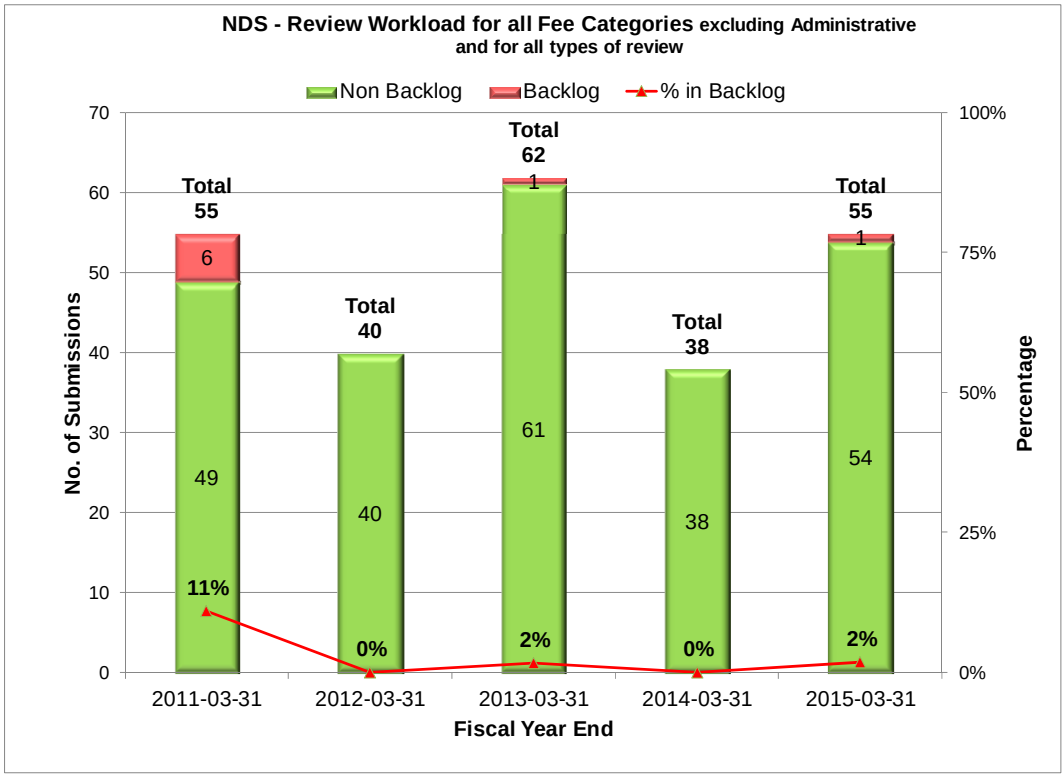


	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
Labelling Only	9	11	23	43	45
Disinfectants			3		
Comparative Studies	15	7	9	9	13
Chemistry & Manufacturing	7	46	55	71	63
Clinical or Non-Clin Only	74	54	51	50	62
Clinical or Non-Clin and C&M	11	12	14	12	9
Published Data Only		10	8	13	9
Switch from Rx to OTC		1		1	
Total	116	141	163	199	201
Priority (subset)	0	1	0	2	4
*SNDS Confirmatory	5	2	2	1	3

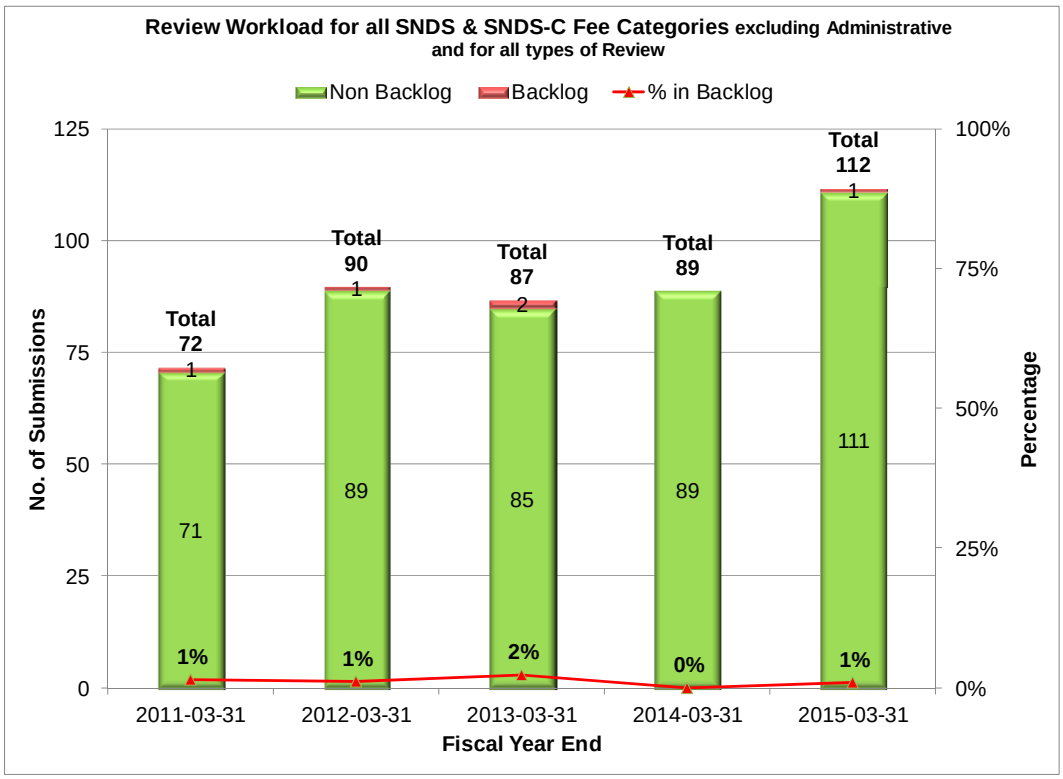
[5] On July 1, 2013 the non-prescription (or over-the-counter) and disinfectant drug review functions moved from TPD to the Natural Health Products Directorate (NHPD). As of April 1 2014, the associated DINA, DINF and DIND figures will be reported separately in APPENDIX B of the TPD performance report until further notice.

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

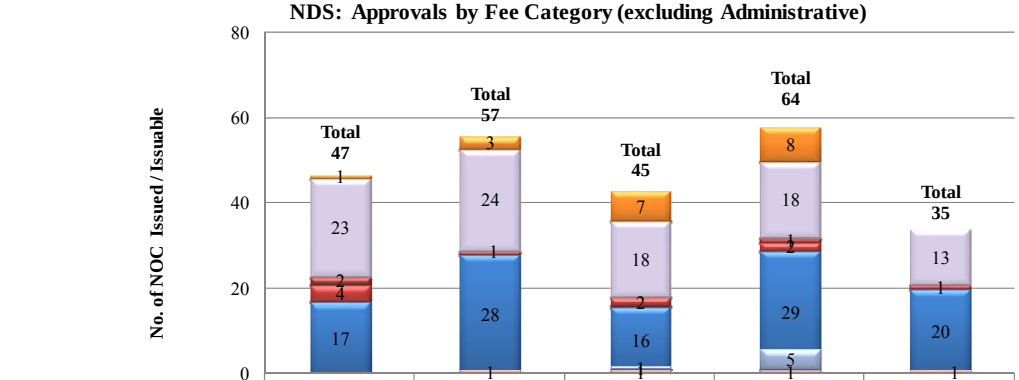
TPD NDS: All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2011-03-31	2012-03-31	2013-03-31	2014-03-31	2015-03-31
Labelling Only	0	1	1	0	1
Backlog	*0*	*0*	*0*	*0*	*0*
Disinfectant	1	1	4	3	0
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	0	2	0	3	2
Backlog	*0*	*0*	*0*	*0*	*1*
Chemistry & Manufacturing	1	0	2	3	2
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	1	0	0	0	1
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	26	19	20	15	26
Backlog	*3*	*0*	*0*	*0*	*0*
New Active Substance	26	17	35	14	23
Backlog	*3*	*0*	*1*	*0*	*0*
Total	**55**	**40**	**62**	**38**	**55**
Non Backlog	**49**	**40**	**61**	**38**	**54**
Backlog	**6**	**0**	**1**	**0**	**1**
% in Backlog	**11%**	**0%**	**2%**	**0%**	**2%**
Priority (subset)	**5**	**2**	**5**	**0**	**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					
	2011-03-31	2012-03-31	2013-03-31	2014-03-31	2015-03-31
Labelling Only	**1**	**0**	**1**	**7**	**9**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**7**	**5**	**2**	**4**	**8**
Backlog	*0*	*1*	*0*	*0*	*0*
Chemistry & Manufacturing	**2**	**21**	**29**	**22**	**29**
Backlog	*0*	*0*	*2*	*0*	*1*
Clinical or Non-Clin Only	**50**	**47**	**39**	**39**	**51**
Backlog	*1*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**12**	**10**	**11**	**10**	**9**
Backlog	*0*	*0*	*0*	*0*	*0*
Disinfectants	**0**	**0**	**1**	**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	**0**	**7**	**5**	**7**	**6**
Backlog	0	0	0	0	0
Total	**72**	**90**	**87**	**89**	**112**
Non Backlog	**71**	**89**	**85**	**89**	**111**
Backlog	**1**	**1**	**2**	**0**	**1**
% in Backlog	**1%**	**1%**	**2%**	**0%**	**1%**
Priority (subset)	0	1	0	1	2
Backlog	0	0	0	0	0
***SNDS-C (Confirmatory)**	4	3	1	0	3
Backlog	0	0	0	0	0

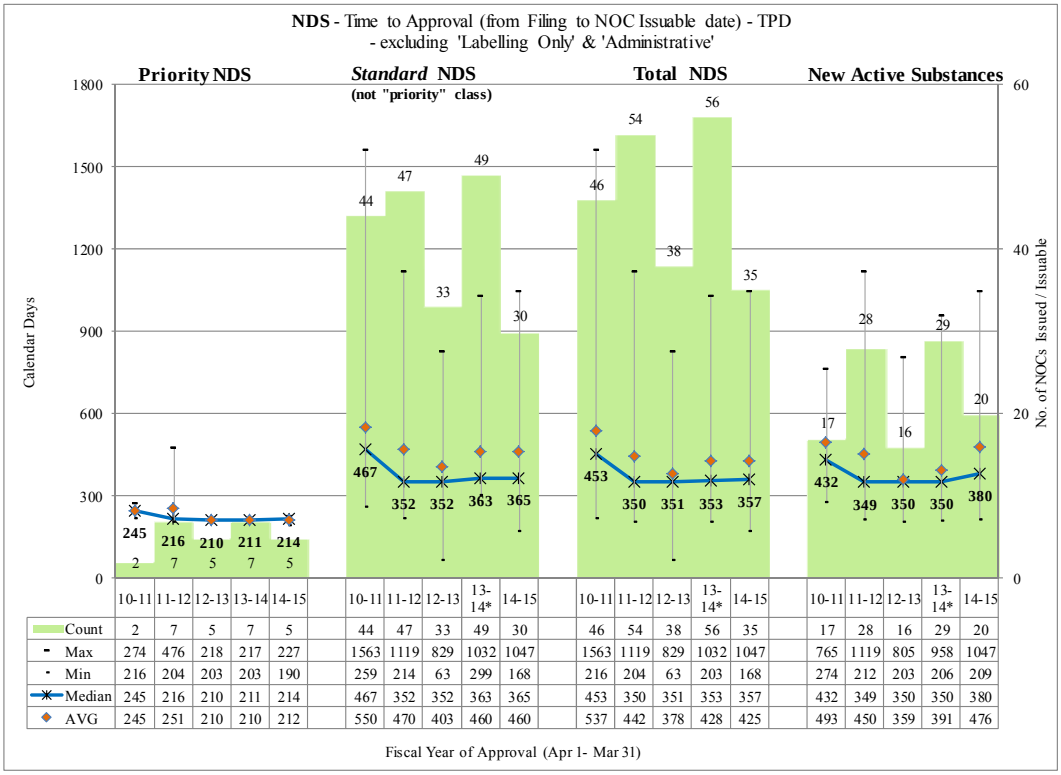
APPROVALS

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



	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
Labelling Only	1	3	7	8	
Clinical or Non-Clin and C&M	23	24	18	18	13
Clinical or Non-Clin Only	2			1	
Comparative Studies	4	1	2	2	1
New Active Substance	17	28	16	29	20
Disinfectants			1	5	
Chemistry & Manufacturing		1	1	1	1
Total	47	57	45	64	35
Notice of Compliance	44	56	43	61	32
NOC on Hold (Patent)	1	1		1	1
NOC on Hold (Switch)	1		1		
NOC with Conditions	1		1	2	2
Priority (subset)	2	7	5	7	5

NDS Approval Times

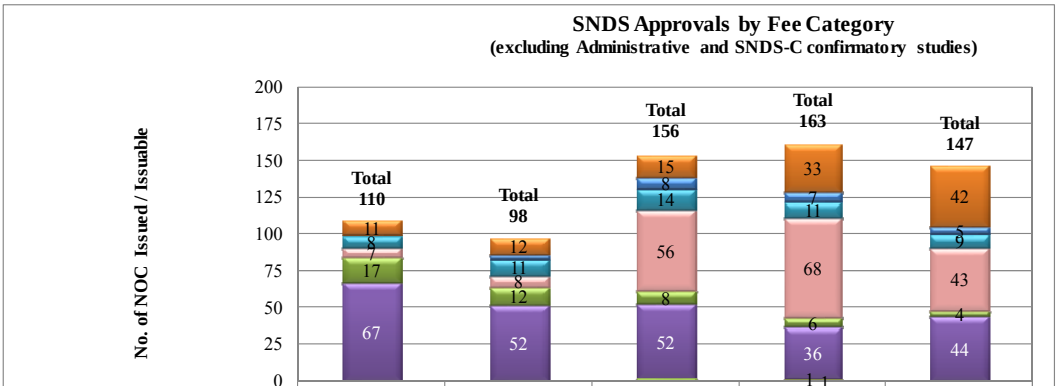


	Priority NDS					Standard NDS (not "priority" class)					Total NDS					New Active Substances				
	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14*	14-15	10-11	11-12	12-13	13-14*	14-15	10-11	11-12	12-13	13-14*	14-15
Count	2	7	5	7	5	44	47	33	49	30	46	54	38	56	35	17	28	16	29	20
Max	274	476	218	217	227	1563	1119	829	1032	1047	1563	1119	829	1032	1047	765	1119	805	958	1047
Min	216	204	203	203	190	259	214	63	299	168	216	204	63	203	168	274	212	203	206	209
Median	245	216	210	211	214	467	352	352	363	365	453	350	351	353	357	432	349	350	350	380
AVG	245	251	210	210	212	550	470	403	460	460	537	442	378	428	425	493	450	359	391	476

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.

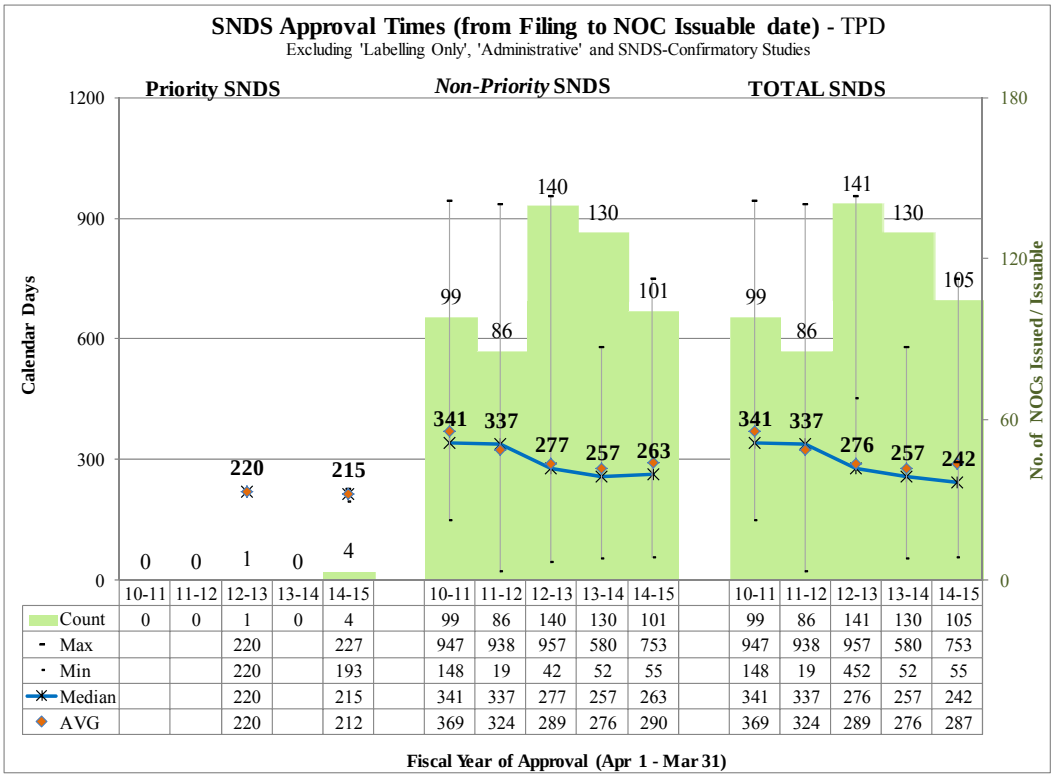
*One outlier is included for fiscal year 2013-14. The NDS was in rejected status for over 4 years but following a judicial review decision, screening was resumed. For this "outlier NDS", the dates used to calculate the time to approval are the date the screening resumed and the date the submission was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

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



	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
Labelling Only	11	12	15	33	42
Published Data Only	0	3	8	7	5
Clinical or Non-Clin and C&M	8	11	14	11	9
Chemistry & Manufacturing	7	8	56	68	43
Comparative Studies	17	12	8	6	4
Clinical or Non-Clin Only	67	52	52	36	44
Switch from Rx to OTC	0	0	1	1	
Disinfectants	0	0	2	1	
Total	110	98	156	163	147
Notice of Compliance	108	95	152	156	141
NOC on Hold (Patent)				1	1
NOC on Hold (Switch)			3	4	
NOC with Conditions	2	3	1	2	5
Priority (subset)	0	0	1	0	4

SNDS Approval Times



	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15
Count	0	0	1	0	4	99	86	140	130	101	99	86	141	130	105
Max			220		227	947	938	957	580	753	947	938	957	580	753
Min			220		193	148	19	42	52	55	148	19	452	52	55
Median			220		215	341	337	277	257	263	341	337	276	257	242
AVG			220		212	369	324	289	276	290	369	324	289	276	287

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

New Active Substance (NAS) Approvals

And

Priority Submission Approvals

New Active Substance (NAS) Approvals - TPD - Fiscal Year 2014-2015 (Revised July 3, 2015)

New Active Substance Approvals – TPD Fiscal Year 2014-2015 (April 1 2014 – March 31 2015)				
Brand Name (Active Ingredient(s) - Indication(s))	**Class**	**Company**	**Filing (CR[6]) Date**	**Approval Date (dd-mon-yy)**
APTIOM (Eslicarbazepine Acetate) - is indicated as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy who are not satisfactorily controlled with conventional therapy.	NAS	Sunovion Pharmaceuticals Canada Inc.	12 Jun 13	8 Jul 14
DUAVIVE (Conjugated Estrogens and Bazedoxifene Acetate) - is indicated in women with a uterus for the treatment of moderate to severe vasomotor symptoms associated with menopause.	NAS	Pfizer Canada Inc.	4 Dec 12	23 Oct 14
DYMISTA (Azelastine Hydrochloride and Fluticasone Propionate) - is indicated for the symptomatic treatment of moderate to severe seasonal allergic rhinitis (SAR) and associated ocular symptoms in adults and adolescents aged 12 years and older for whom monotherapy with either antihistamines or intranasal corticosteroids is not considered sufficient.	NAS	Meda Pharmaceuticals Ltd.	4 Nov 13	23 Oct 14
EGRIFTA (Tesamorelin Acetate) - is indicated for the treatment of excess visceral adipose tissue (VAT), as assessed by waist circumference ≥ 95 cm for males and ≥ 94 cm for females, and confirmed by a VAT level > 130 cm2 by CT scan, in treatment-experienced adult HIV-infected patients with lipodystrophy..	NAS	Theratechnologies Inc.	17 Jun 11	29 Apr 14
FERRIPROX (Deferiprone) - is indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.	NOC-C NAS	ApoPharma Inc.	7 Mar 2013	13 Feb 2015
FIRAZYR (Icatibant Acetate) - is indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults with C1-esterase inhibitor deficiency.	NAS	Shire Orphan Therapies Inc.	5 Mar 13	4 Jun 14

[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 2014-2015 (April 1 2014 – March 31 2015)				
Brand Name (Active Ingredient(s) - Indication(s))	**Class**	**Company**	**Filing (CR[6]) Date**	**Approval Date (dd-mon-yy)**
FORXIGA (Dapagliflozin) - is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus for whom metformin is inappropriate due to contraindications or intolerance. As an add-on combination: Forxiga is indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with metformin, a sulfonylurea, or insulin (alone or with metformin) when the existing therapy, along with diet and exercise, does not provide adequate glycemic control.	NAS	AstraZeneca Canada Inc.	7 Dec 12	12 Dec 14
HARVONI (Ledipasvir and Sofosbuvir) - is indicated for the treatment of chronic hepatitis C virus (CHC) genotype 1 infection in adults.	Priority -NAS	Gilead Sciences Canada Inc.	20 Mar 14	15 Oct 14
HOLKIRA PAK (Ritonavir, Paritaprevir, Ombitasvir, Dasabuvir) - is indicated for the treatment of adults with genotype 1 chronic hepatitis C (CHC) infection, including those with compensated cirrhosis with ribavirin in non-cirrhotic patients with genotype 1a infection; without ribavirin in non-cirrhotic patients with genotype 1b infection and with ribavirin in patients with compensated cirrhosis.	Priority -NAS	Abbvie Corporation	14 May 14	22 Dec 14
IMBRUVICA (Ibrutinib) - is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL), including those with 17p deletion, who have received at least one prior therapy, or for the frontline treatment of patients with CLL with 17p deletion.	Priority -NAS	Janssen Inc.	17 Apr 14	17 Nov 14

New Active Substance Approvals – TPD
Fiscal Year 2014-2015
(April 1 2014 – March 31 2015)

Brand Name (Active Ingredient(s) - Indication(s))	Class	Company	Filing (CR[6]) Date	Approval Date (dd-mon-yy)
INVOKANA (Canagliflozin) - Monotherapy: INVOKANA™ (canagliflozin) is indicated 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. **Combination with Metformin or a Sulfonylurea:** INVOKANA™ is indicated in combination with metformin or a sulfonylurea in adult patients with type 2 diabetes mellitus to improve glycemic control when diet and exercise plus monotherapy with one of these agents does not provide adequate glycemic control. **Combination with Metformin and either a Sulfonylurea or Pioglitazone:** INVOKANA™ is indicated in combination with metformin and either a sulfonylurea or pioglitazone in adult patients with type 2 diabetes mellitus to improve glycemic control when diet, exercise, and dual therapy (with metformin plus either a sulfonylurea or pioglitazone) do not provide adequate glycemic control. **Combination with Insulin:** INVOKANA™ is indicated as add-on combination therapy with insulin (with or without metformin) in adult patients with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control when diet and exercise, and therapy with insulin (with or without metformin) do not provide adequate glycemic control.	NAS	Janssen Inc.	27 Jul 12	23 May 14
OTEZLA (Apremilast) - is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.	NAS	Celgene Inc.	8 Nov 13	12 Nov 14

New Active Substance Approvals – TPD
Fiscal Year 2014-2015
(April 1 2014 – March 31 2015)

Brand Name (Active Ingredient(s) - Indication(s))	Class	Company	Filing (CR[6]) Date	Approval Date (dd-mon-yy)
PHEBURANE (Sodium Phenylbutyrate) - is indicated as adjunctive therapy in the chronic management of urea cycle disorders, involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase. Pheburane 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). Pheburane is indicated in patients with neonatal-onset presentation (complete enzyme deficiencies, presenting within the first 28 days of life). It is also indicated in patients with late-onset disease (partial enzyme deficiencies, presenting after the first month of life) who have a history of hyperammonemic encephalopathy.	Priority -NAS	Medunik Canada	13 Jun 14	26 Jan 15
PROLENSA (Bromfenac Sodium Sesquihydrate) - is indicated for: treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.	NAS	Bausch & Lomb Inc.	4 Apr 14	26 Mar 15
SAFLUTAN (Tafluprost) - is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.	NAS	Merck Canada Inc.	10 Jun 13	26 May 14
SIVEXTRO (Tedizolid Phosphate) - is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible strains of the following gram-positive microorganisms in adults 18 years of age older: Staphylococcus aureus (including methicillin-resistant [MRSA]), Streptococcus pyogenes, Streptococcus agalactiae, and Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus).	NAS	Cubist Pharmaceuticals Canada Inc.	1 Apr 14	17 Mar 15
TRINTELLIX (Vortioxetine Hydrobromide) - is indicated for the treatment of major depressive disorder (MDD) in adults.	NAS	Lundbeck Canada Inc.	28 Sep 12	22 Oct 14
XELJANZ (Tofacitinib Citrate) - in combination with methotrexate (MTX), is indicated for reducing the signs and symptoms of rheumatoid arthritis (RA), in adult patients with moderately to severely active RA who have had an inadequate response to MTX. In cases of intolerance to MTX, physicians may consider the use of XELJANZ (tofacitinib) as monotherapy.	NAS	Pfizer Canada Inc.	3 Apr 12	17 Apr 14

New Active Substance Approvals – TPD Fiscal Year 2014-2015 (April 1 2014 – March 31 2015)				
Brand Name (Active Ingredient(s) - Indication(s))	**Class**	**Company**	**Filing (CR[6]) Date**	**Approval Date (dd-mon-yy)**
ZYDELIG (Idelalisib) - is indicated in combination with rituximab for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL). ZYDELIG (idelalisib) is indicated as a monotherapy for the treatment of patients with follicular lymphoma who have received at least two prior systemic regimens and are refractory to both rituximab and an alkylating agent.	NAS	Gilead Sciences Canada Inc.	28 Feb 14	27 Mar 15 NOC-C
ZYKADIA – (Ceritinib) - is indicated as monotherapy for use in patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC) who have progressed on or who were intolerant to crizotinib.	NOC-C NAS	Novartis Pharmaceuticals Canada Inc.	16 Jun 2014	27 Mar 2015 NOC-C

Priority Submission Approvals - TPD - Fiscal Year 2014-2015

Priority Submission Approvals – TPD Fiscal Year 2014-2015 (April 1 2014 – March 31 2015)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR) Date**	**Approval Date**
HARVONI (Ledipasvir and Sofosbuvir) - is indicated for the treatment of chronic hepatitis C virus (CHC) genotype 1 infection in adults.	Priority-NAS	Gilead Sciences Canada Inc.	20 Mar 14	15 Oct 14
HOLKIRA PAK (Ritonavir, Paritaprevir, Ombitasvir, Dasabuvir) - is indicated for the treatment of adults with genotype 1 chronic hepatitis C (CHC) infection, including those with compensated cirrhosis with ribavirin in non-cirrhotic patients with genotype 1a infection; without ribavirin in non-cirrhotic patients with genotype 1b infection and with ribavirin in patients with compensated cirrhosis.	Priority-NAS	Abbvie Corporation	14 May 14	22 Dec 14
IMBRUVICA (Ibrutinib) - is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL), including those with 17p deletion, who have received at least one prior therapy, or for the frontline treatment of patients with CLL with 17p deletion.	Priority-NAS	Janssen Inc.	17 Apr 14	17 Nov 14
KALYDECO (Ivacaftor) - is indicated for the treatment of cystic fibrosis (CF) in patients age 6 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. Limitation of use: KALYDECO is not effective in patients with CF who are homozygous for the F508del mutation in the CFTR gene.	Priority-Clin Only (SNDS)	Vertex Pharmaceuticals (Canada) Incorporated	25 Nov 13	6 Jun 14
KALYDECO (Ivacaftor) - to expand the indication to include treatment of cystic fibrosis (CF) in patients age 18 years and older with an R117H mutation in the CFTR gene.	Priority-Clin Only (SNDS)	Vertex Pharmaceuticals (Canada) Incorporated	12 Aug 14	13 Mar 15

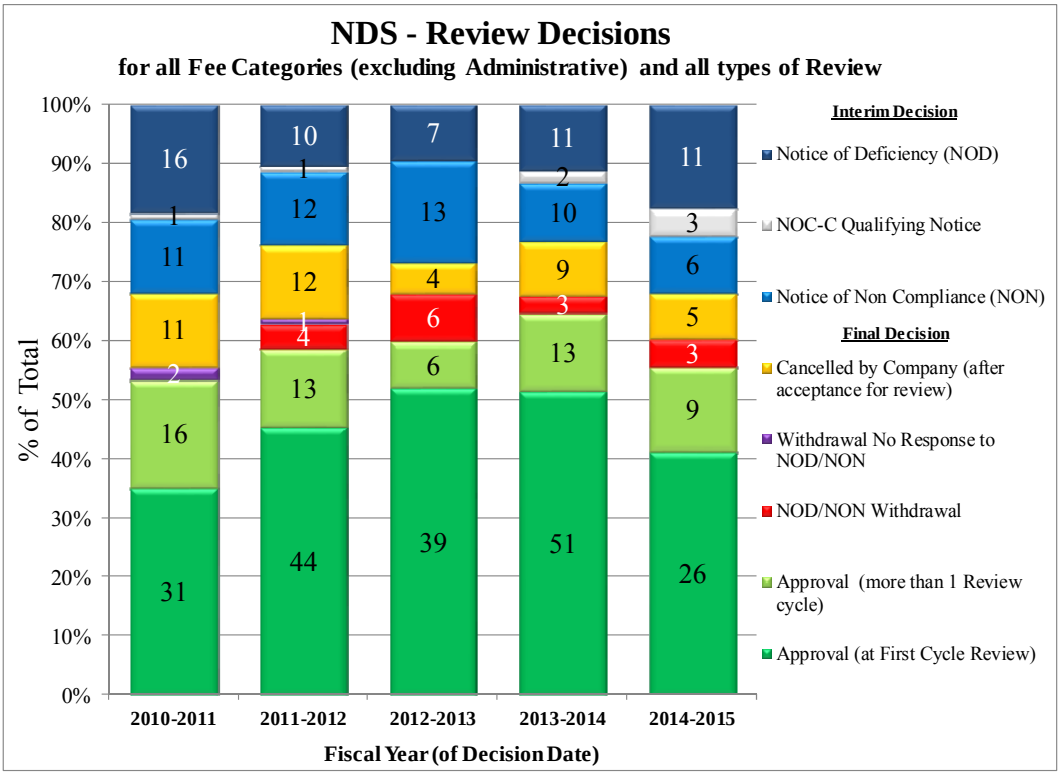
Priority Submission Approvals – TPD
Fiscal Year 2014-2015
(April 1 2014 – March 31 2015)

Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR) Date	Approval Date
MODERIBA (Ribavirin) - is indicated in combination with other agents for the treatment of chronic hepatitis C virus (HCV) infection in adults including patients with compensated cirrhosis.	Priority-Clin/ C&M (NDS)	Abbvie Corporation	10 Jul 14	16 Jan 15
PHEBURANE (Sodium Phenylbutyrate) - is indicated as adjunctive therapy in the chronic management of urea cycle disorders, involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase. Pheburane 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). Pheburane is indicated in patients with neonatal-onset presentation (complete enzyme deficiencies, presenting within the first 28 days of life). It is also indicated in patients with late-onset disease (partial enzyme deficiencies, presenting after the first month of life) who have a history of hyperammonemic encephalopathy.	Priority-NAS	Medunik Canada	13 Jun 14	26 Jan 15
SOVALDI (Sofosbuvir) - is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C virus (CHC) infection as a component of a combination antiviral treatment regimen. The following points should be considered when initiating treatment with SOVALDI: SOVALDI must not be administered as monotherapy (see WARNINGS AND PRECAUTIONS, General). Treatment regimen and duration are dependent on both viral genotype and patient population (see DOSAGE AND ADMINISTRATION). Treatment response varies based on baseline host and viral factors.	Priority-Clin Only (SNDS)	Gilead Sciences Canada Inc.	26 Feb 14	30 Sep 14
VELCADE (Bortezomib Mannitol Boronic Ester) - is indicated as follows: • as part of combination therapy for the treatment of patients with previously untreated multiple myeloma who are unsuitable for stem cell transplantation. • as part of a medically recognized combination therapy for induction treatment of patients with previously untreated multiple myeloma who are suitable for stem cell transplantation (studies were conducted with intravenous administration of VELCADE®). • for the treatment of progressive multiple myeloma in patients who have received at least one prior	Priority-Clin Only (SNDS)	Janssen Inc.	1 Aug 14	16 Mar 15

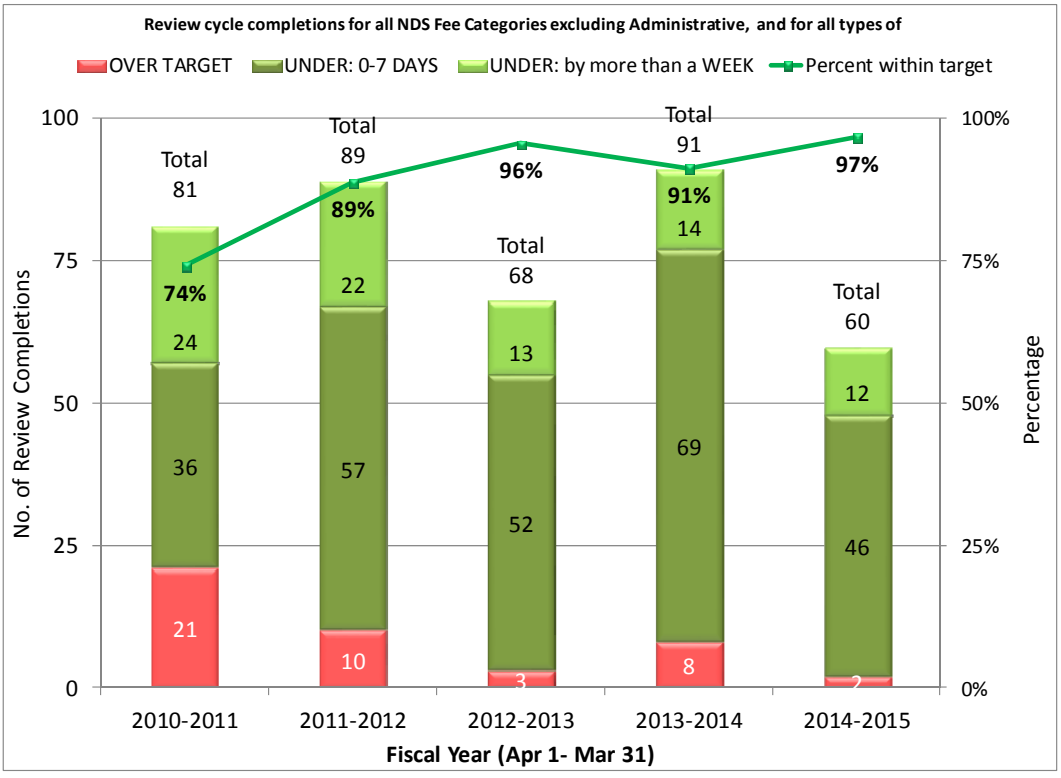
Priority Submission Approvals – TPD Fiscal Year 2014-2015 (April 1 2014 – March 31 2015)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR) Date**	**Approval Date**
therapy and who have already undergone or are unsuitable for stem cell transplantation. VELCADE® administered subcutaneously was studied in this patient population where it was shown to be non-inferior to the intravenous administration (defined as retaining at least 60% of the intravenous administration effect) (see Product Monograph PART II, CLINICAL TRIALS). • as part of combination therapy for the treatment of patients with previously untreated mantle cell lymphoma who are unsuitable for stem cell transplantation. • for the treatment of patients with mantle cell lymphoma who have relapsed or were refractory to at least 1 prior therapy.				

REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

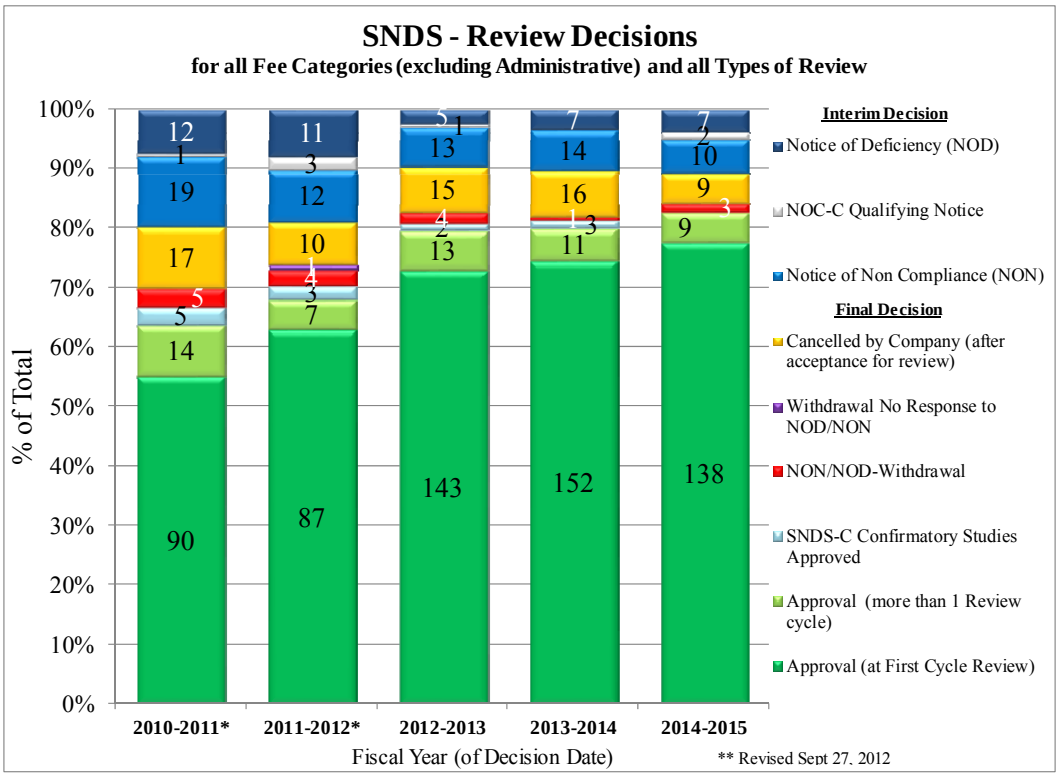


NDS - Review Cycle Completions Showing Percentage Within Target

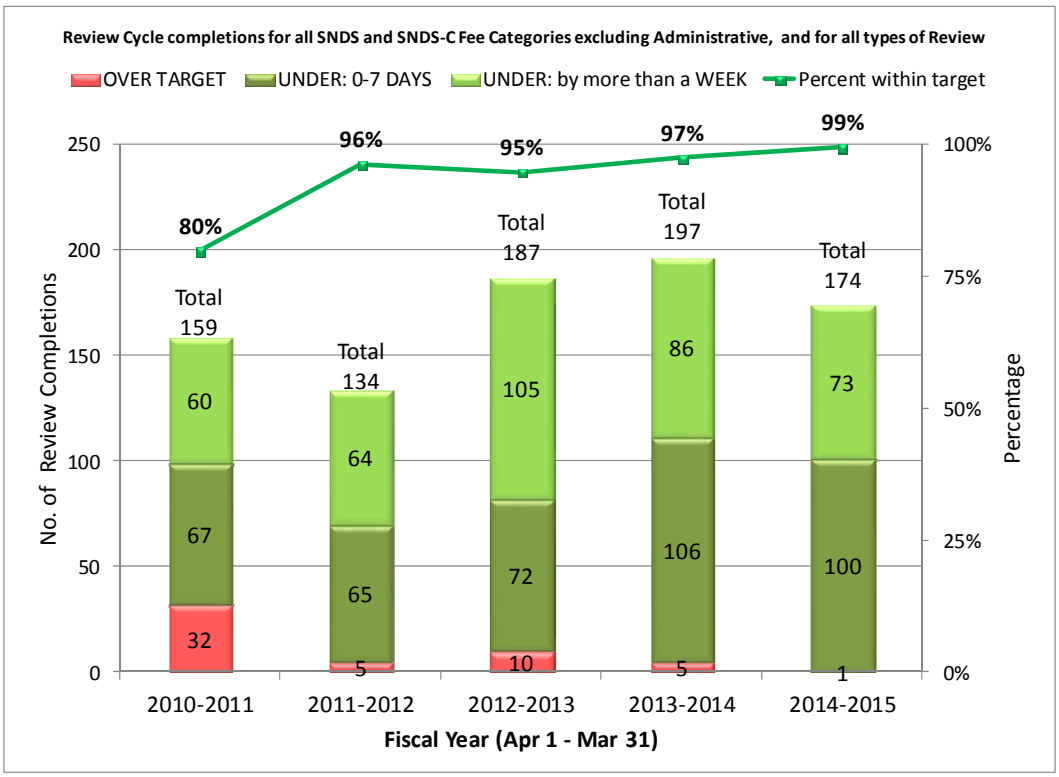


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

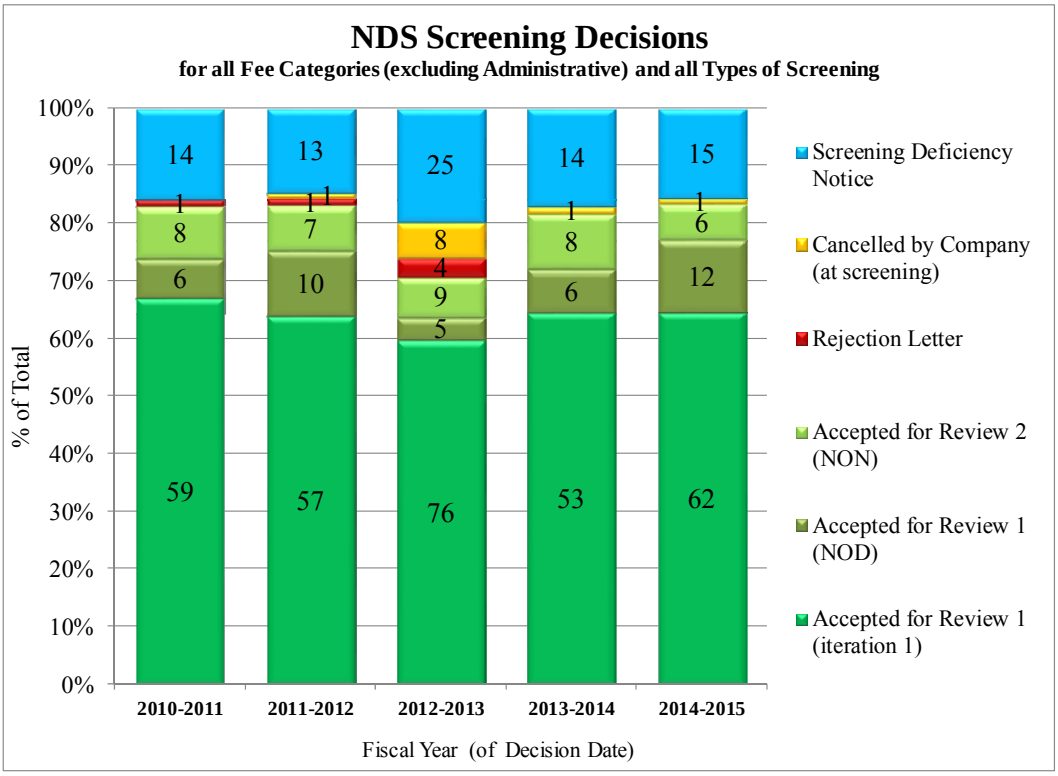


SNDS - Review Cycle Completions Showing Percentage Within Target

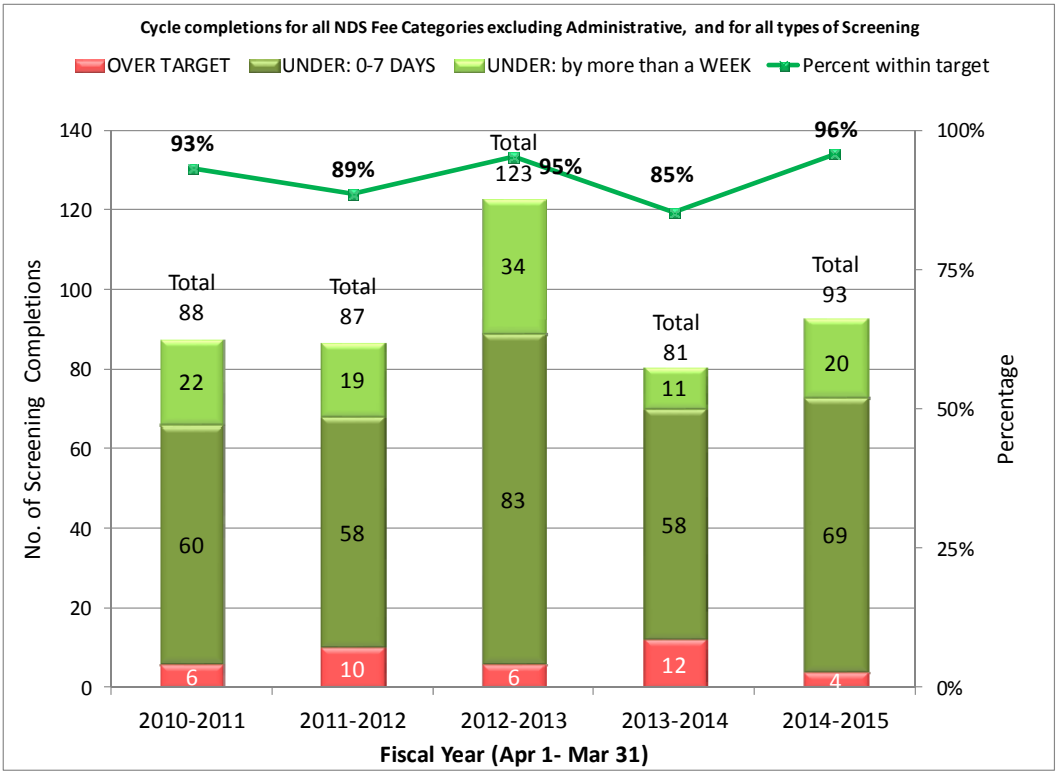


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

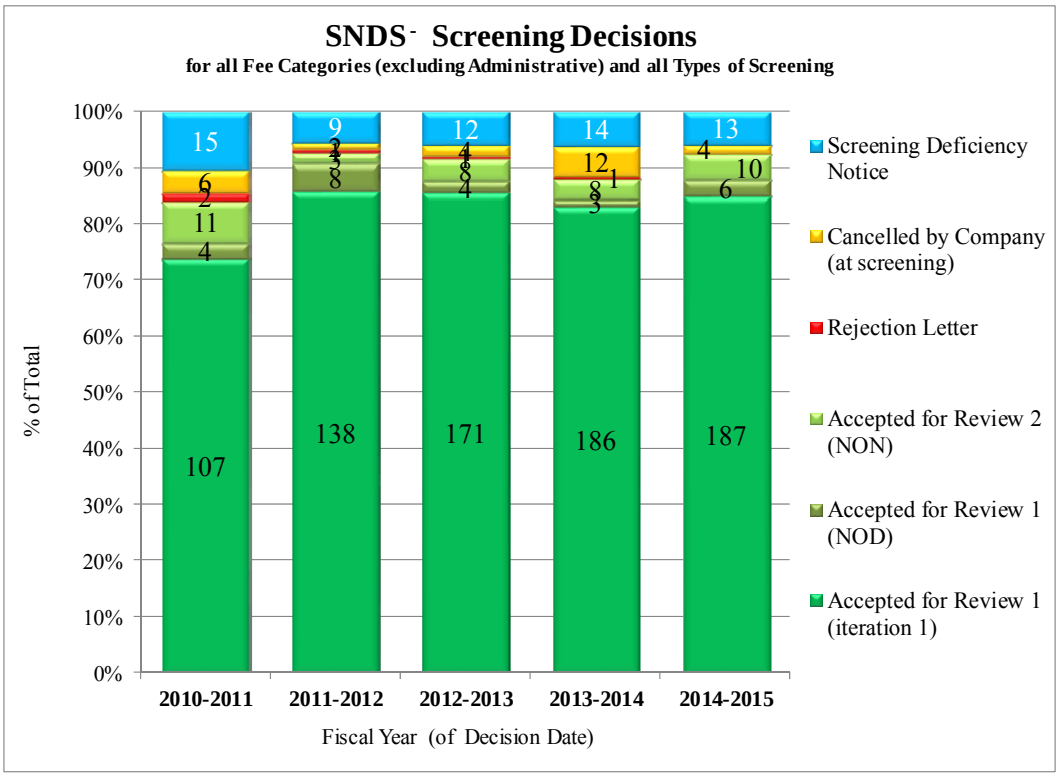


NDS - Screening Cycle Completions Showing Percentage Within Target

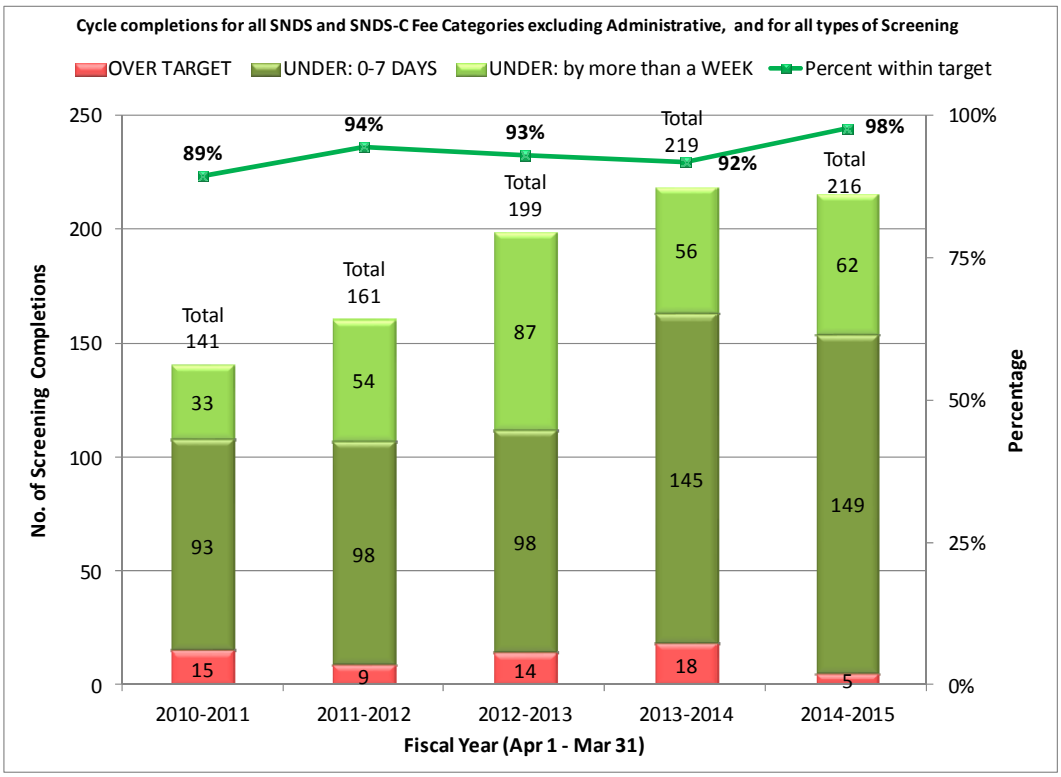


SCREENING CYCLE DECISIONS

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 (Arpil 1 - March 31)							
Breakdown by Reconsideration Decision	**10-11**	**11-12**	**12-13* revised**	**13-14**	**14-15**	**Final Decision in Dispute**	**NDS Status (as of May 25 2015)**
Total Received	**0**	**1**	**2**	**1**	**0**		
Total Pending	***0***	***0***	***0***	***0***	***0***		
PENDING							
Total Granted	***0***	***0***	***1***	***1***	***0***		
GRANTED				*1*		NON-Withdrawal	Review Reconsideration
GRANTED			1			NON-Withdrawal	Cleared
GRANTED						NON-Withdrawal	Cancelled by Company
Total Denied	***0***	***1***	***1***	***0***	***0***		
DENIED		1				NON-Withdrawal	Withdrawn
DENIED			1			Screening Rejection Letter	Rejected

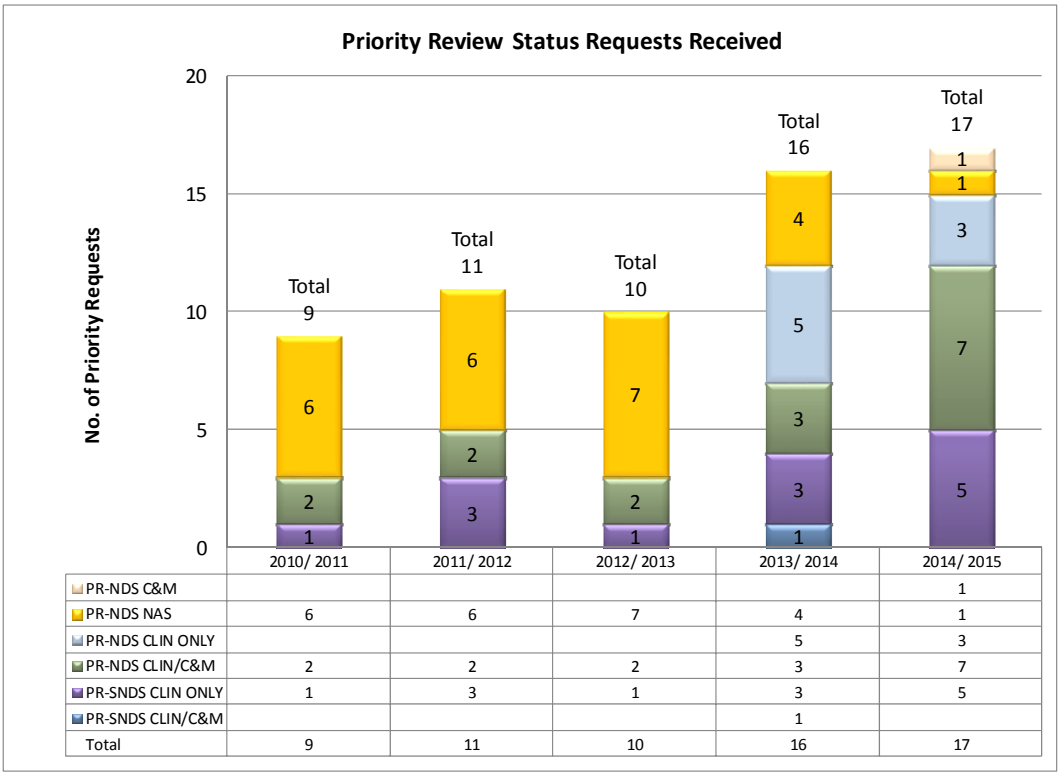
Requests for Reconsideration of Final Decisions – Supplemental New Drug Submissions (SNDS)

SNDS - Reconsideration of Final Decisions Requests Received Fiscal Year of Request (Arp - Mar)							
Breakdown by Reconsideration Decision	**10-11**	**11-12**	**12-13**	**13-14**	**14-15**	**Final Decision in Dispute**	**SNDS Status (as of May 25 2015)**
Total Received	**3**	**0**	**2**	**0**	**0**		
Total Denied	***3***	***0***	***2***	***0***	***0***		
DENIED			2			NOD-Withdrawal	Withdrawn
DENIED	3					NON-Withdrawal	Withdrawn

This page is left blank intentionally.

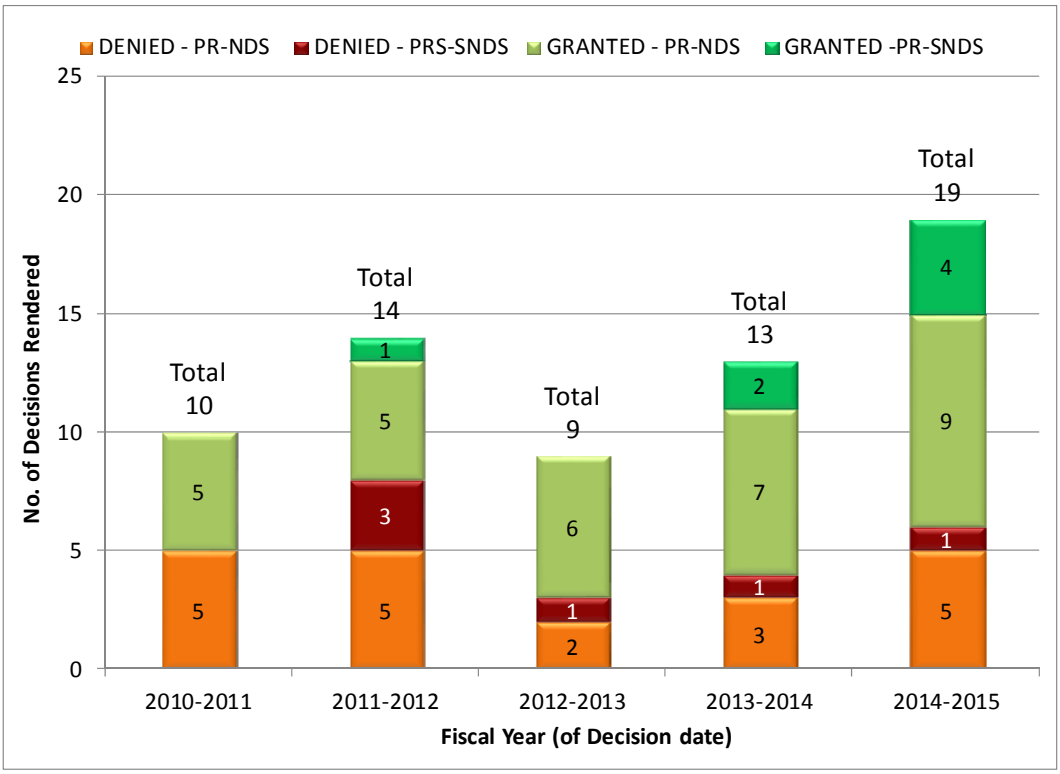
PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests Received



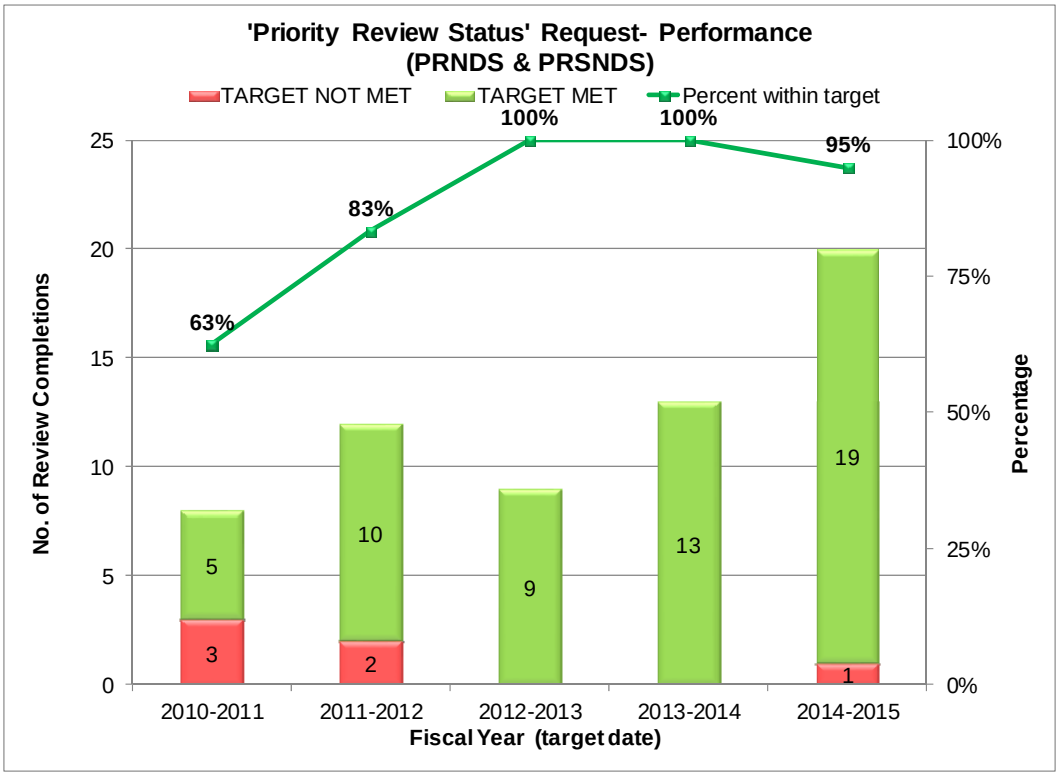
	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
PR-NDS C&M					1
PR-NDS NAS	6	6	7	4	1
PR-NDS CLIN ONLY				5	3
PR-NDS CLIN/C&M	2	2	2	3	7
PR-SNDS CLIN ONLY	1	3	1	3	5
PR-SNDS CLIN/C&M				1	
Total	9	11	10	16	17

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 (Arp - Mar)							
Breakdown by Reconsideration Decision	**10-11**	**11-12 * revised**	**12-13**	**13-14**	**14-15**	**Final Decision in Dispute**	**Submission Status as May 25 2015**
Total Received	**0**	**1**	**0**	**0**	**0**		

Abbreviated New Drug Submissions (ANDS)

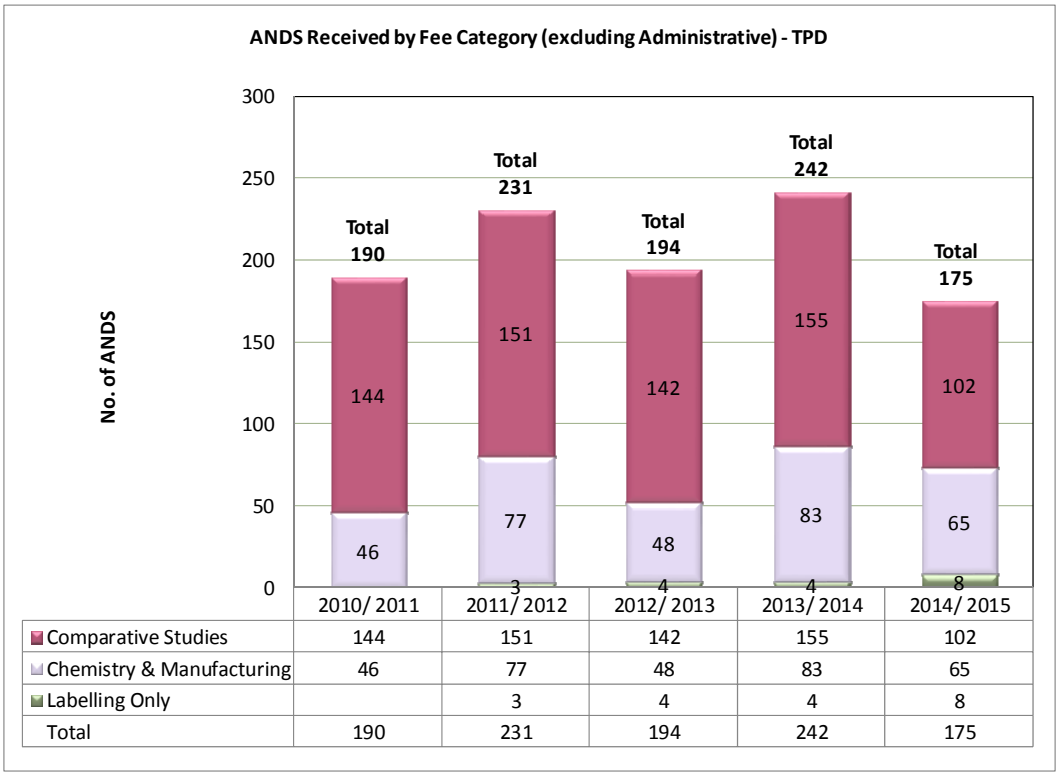
&

Supplemental Abbreviated New Drug Submissions

(SANDS)

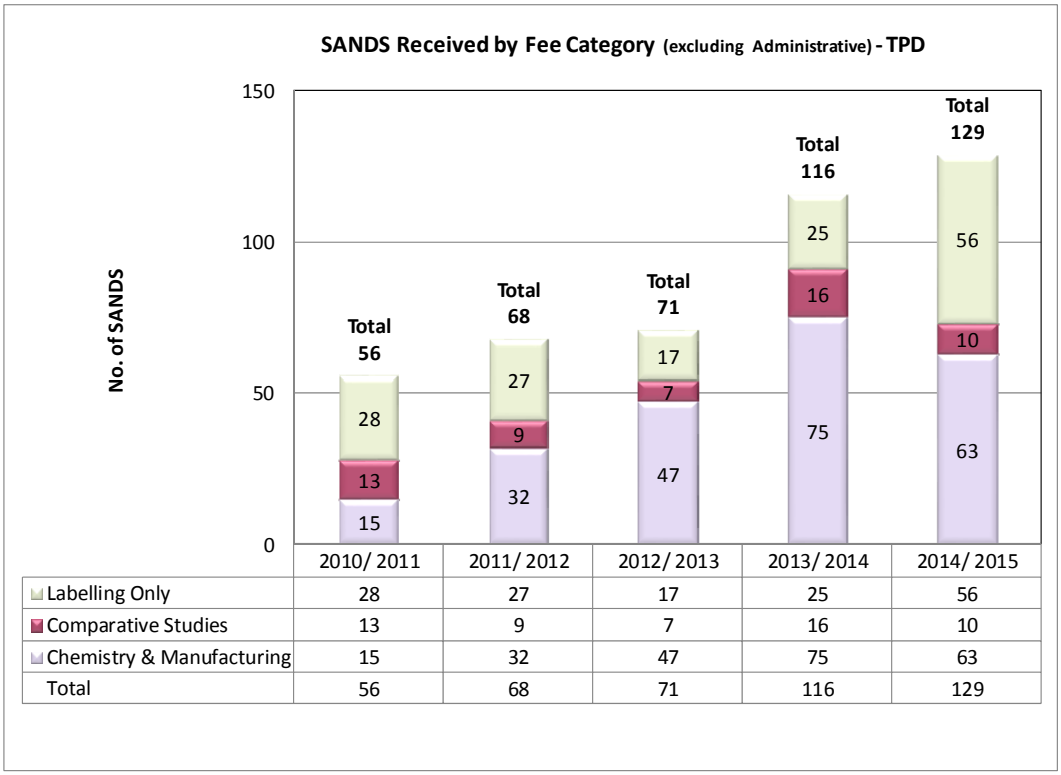
SUBMISSIONS RECEIVED

Abbreviated New Drug Submissions (ANDS) Received by Fee Category



	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
Comparative Studies	144	151	142	155	102
Chemistry & Manufacturing	46	77	48	83	65
Labelling Only		3	4	4	8
Total	190	231	194	242	175

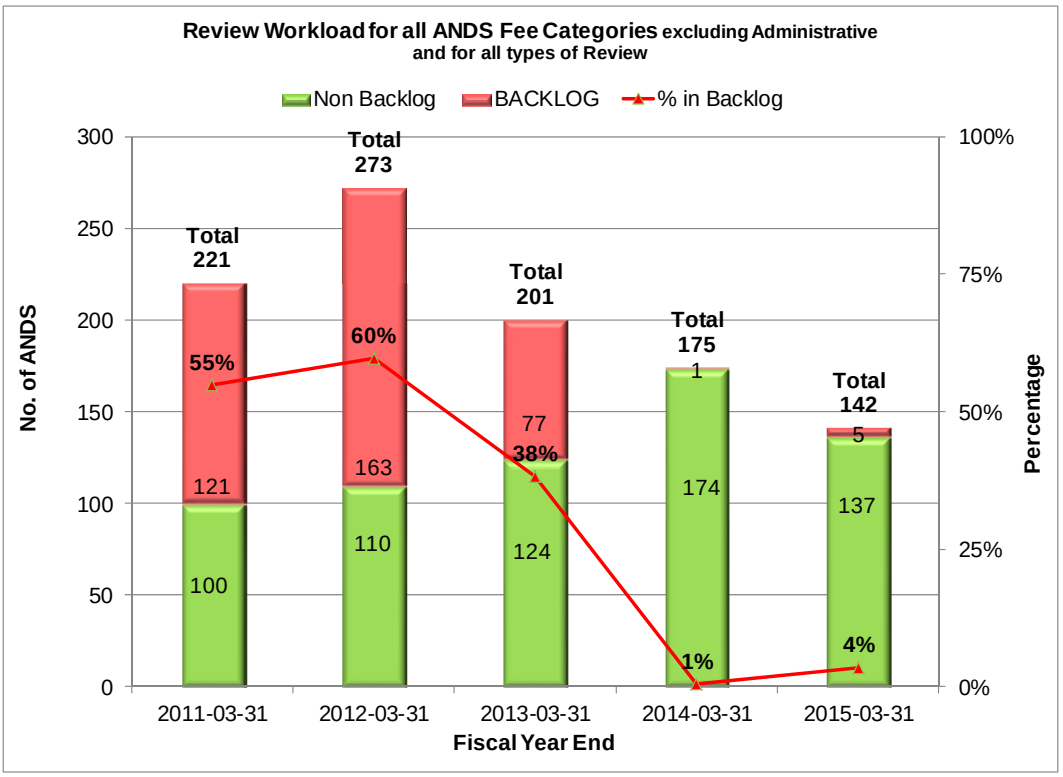
Supplemental Abbreviated New Drug Submission (SANDS) Received by Fee Category



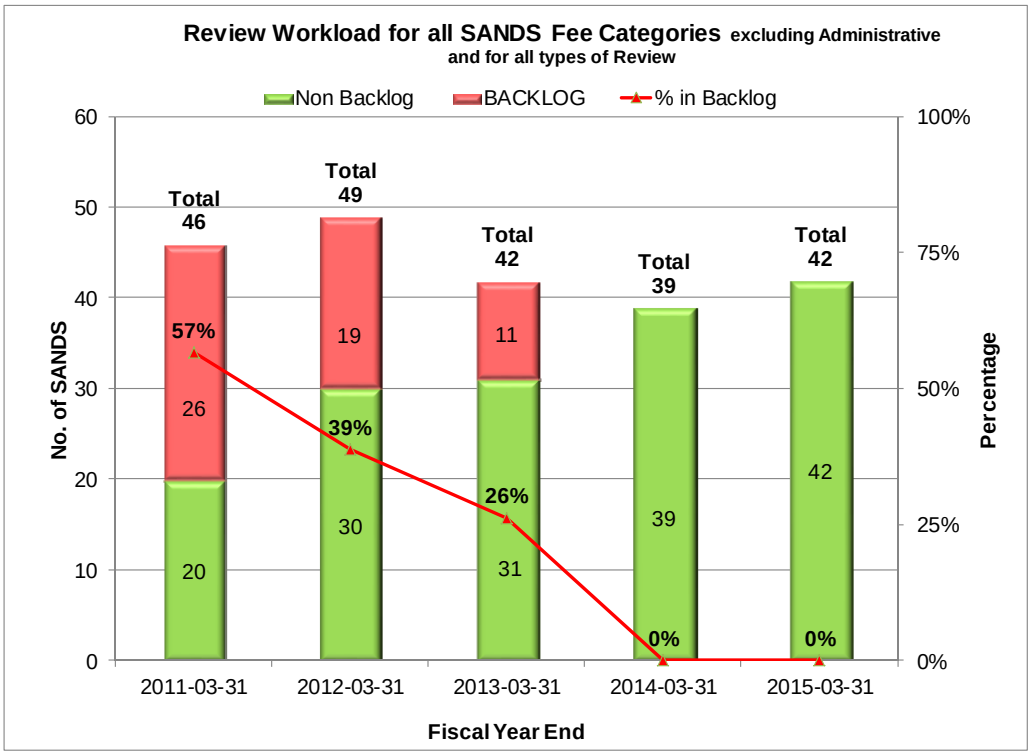
	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
Labelling Only	28	27	17	25	56
Comparative Studies	13	9	7	16	10
Chemistry & Manufacturing	15	32	47	75	63
Total	56	68	71	116	129

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

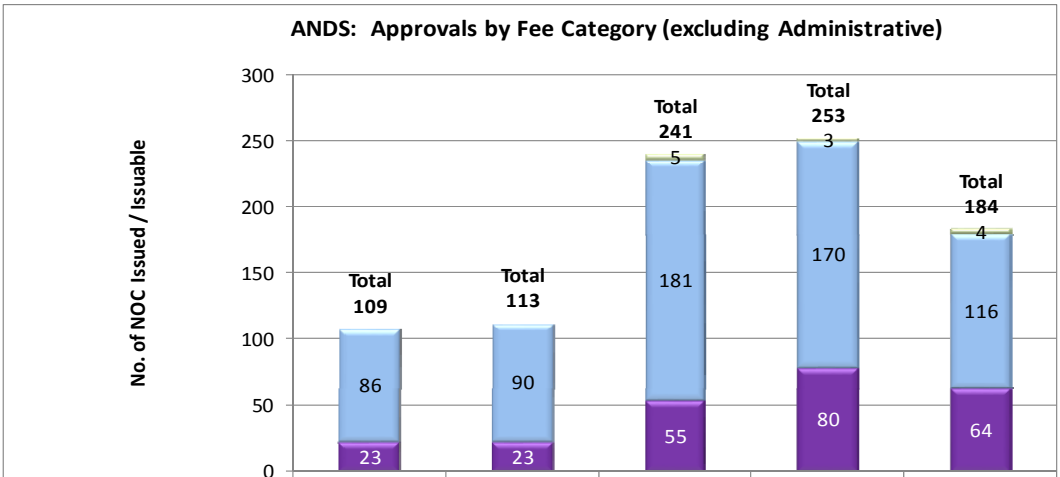
TPD ANDS All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2011-03-31	2012-03-31	2013-03-31	2014-03-31	2015-03-31
Chemistry & Manufacturing	**65**	**84**	**79**	**58**	**59**
Backlog	*37*	*46*	*44*	*1*	*1*
Comparative Studies	**156**	**186**	**122**	**117**	**83**
Backlog	*84*	*117*	*33*	*0*	*4*
Labelling Only	**0**	**3**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**221**	**273**	**201**	**175**	**142**
Non Backlog	**100**	**110**	**124**	**174**	**137**
BACKLOG	**121**	**163**	**77**	**1**	**5**
% in Backlog	**55%**	**60%**	**38%**	**1%**	**4%**

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					
	2011-03-31	2012-03-31	2013-03-31	2014-03-31	2015-03-31
Chemistry & Manufacturing	**22**	**32**	**33**	**27**	**27**
Backlog	*14*	*11*	*9*	*0*	*0*
Clinical or Non-Clin Only	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**19**	**13**	**6**	**10**	**7**
Backlog	*11*	*8*	*2*	*0*	*0*
Labelling Only	**5**	**4**	**3**	**2**	**8**
Backlog	*1*	*0*	*0*	*0*	*0*
Total	**46**	**49**	**42**	**39**	**42**
Non Backlog	**20**	**30**	**31**	**39**	**42**
BACKLOG	**26**	**19**	**11**	**0**	**0**
% in Backlog	**57%**	**39%**	**26%**	**0%**	**0%**

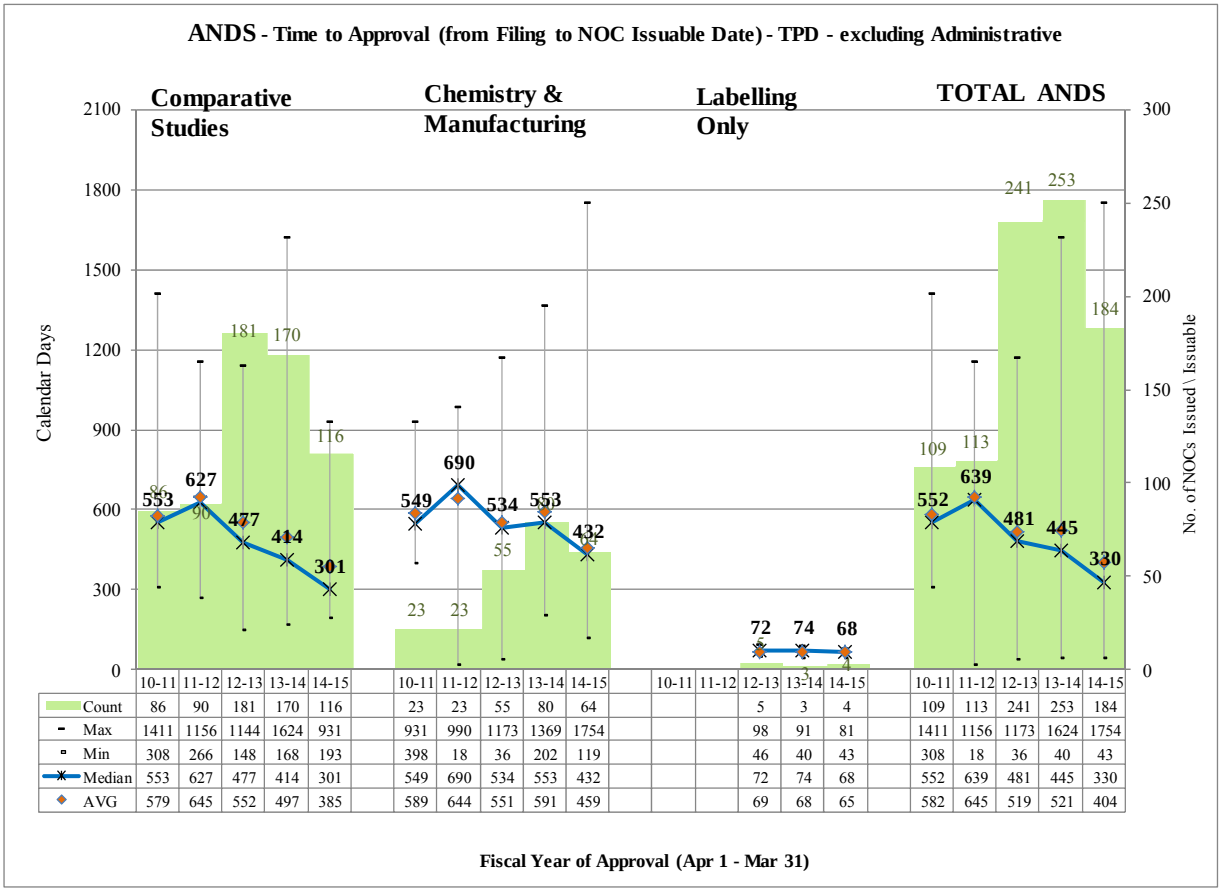
APPROVALS

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



	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
Labelling Only			5	3	4
Comparative Studies	86	90	181	170	116
Chemistry & Manufacturing	23	23	55	80	64
Total	109	113	241	253	184
Notice of Compliance	57	65	155	153	107
NOC on Hold (Patent)	51	48	86	100	76
NOC with Conditions	1				1

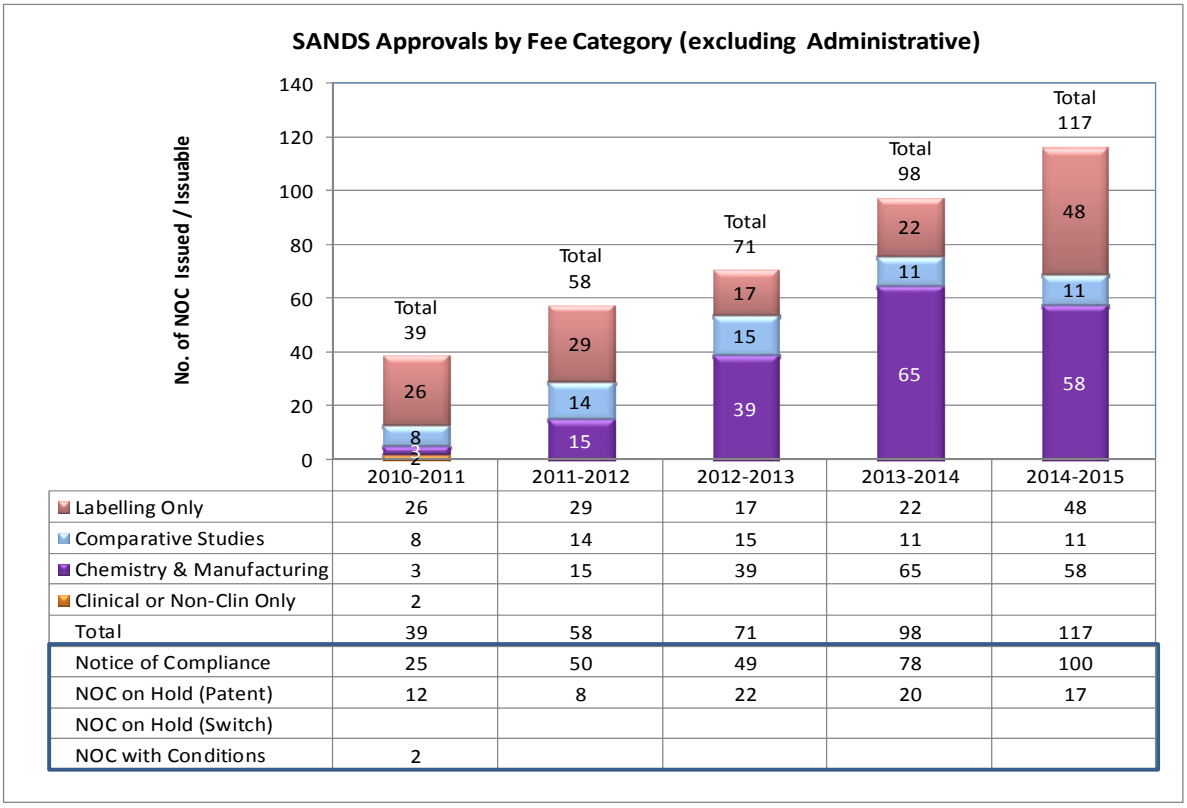
ANDS Approval Times



	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15
Count	86	90	181	170	116	23	23	55	80	64			5	3	4	109	113	241	253	184
Max	1411	1156	1144	1624	931	931	990	1173	1369	1754			98	91	81	1411	1156	1173	1624	1754
Min	308	266	148	168	193	398	18	36	202	119			46	40	43	308	18	36	40	43
Median	553	627	477	414	301	549	690	534	553	432			72	74	68	552	639	481	445	330
AVG	579	645	552	497	385	589	644	551	591	459			69	68	65	582	645	519	521	404

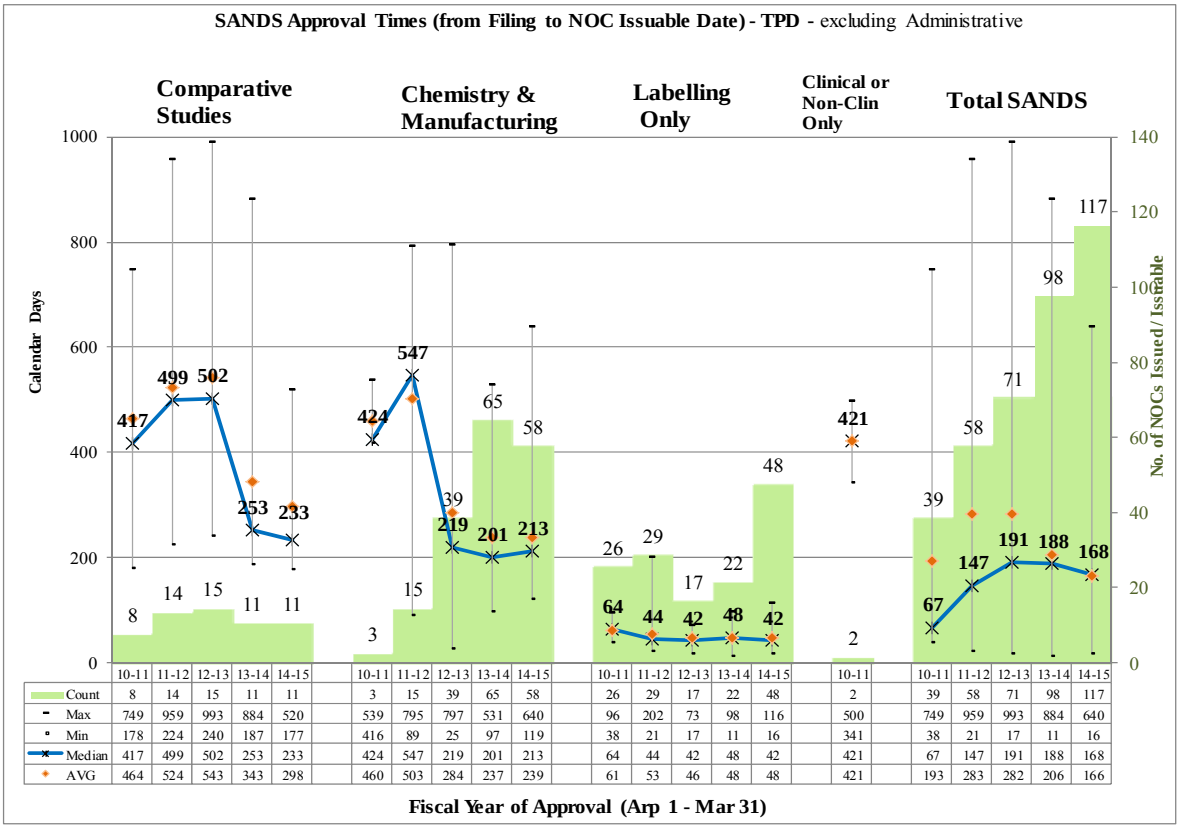
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

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



	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
Labelling Only	26	29	17	22	48
Comparative Studies	8	14	15	11	11
Chemistry & Manufacturing	3	15	39	65	58
Clinical or Non-Clin Only	2				
Total	39	58	71	98	117
Notice of Compliance	25	50	49	78	100
NOC on Hold (Patent)	12	8	22	20	17
NOC on Hold (Switch)					
NOC with Conditions	2				

SANDS Approval Times

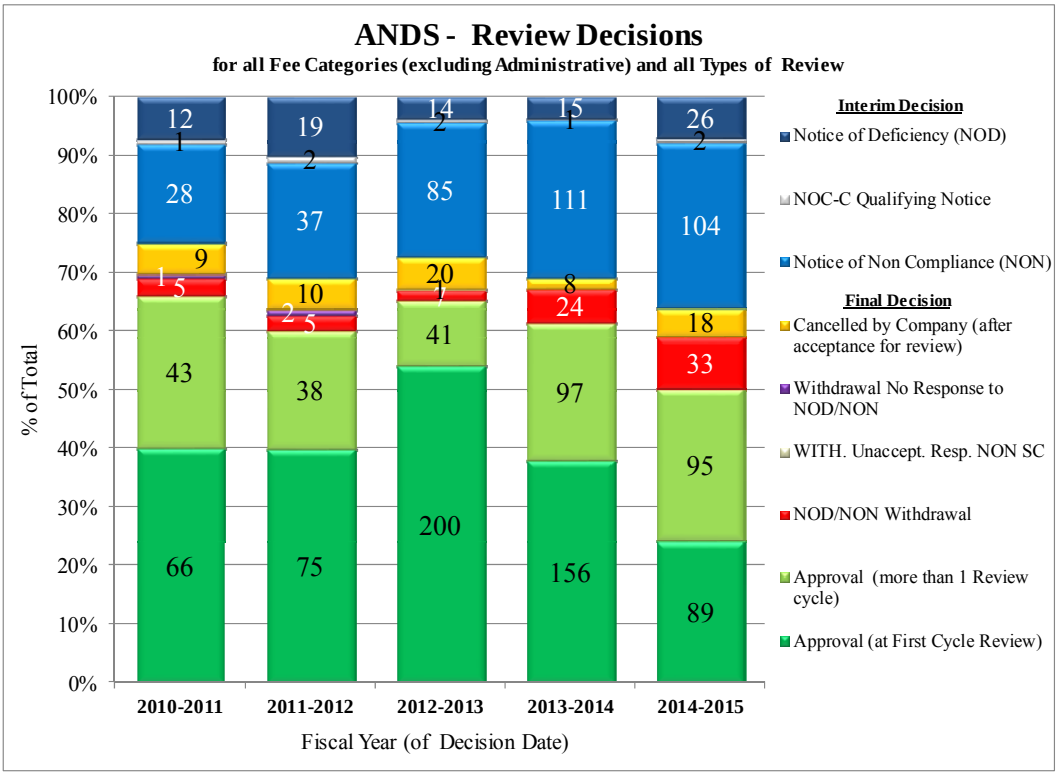


	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15	10-11	10-11	11-12	12-13	13-14	14-15
Count	8	14	15	11	11	3	15	39	65	58	26	29	17	22	48	2	39	58	71	98	117
Max	749	959	993	884	520	539	795	797	531	640	96	202	73	98	116	500	749	959	993	884	640
Min	178	224	240	187	177	416	89	25	97	119	38	21	17	11	16	341	38	21	17	11	16
Median	417	499	502	253	233	424	547	219	201	213	64	44	42	48	42	421	67	147	191	188	168
AVG	464	524	543	343	298	460	503	284	237	239	61	53	46	48	48	421	193	283	282	206	166

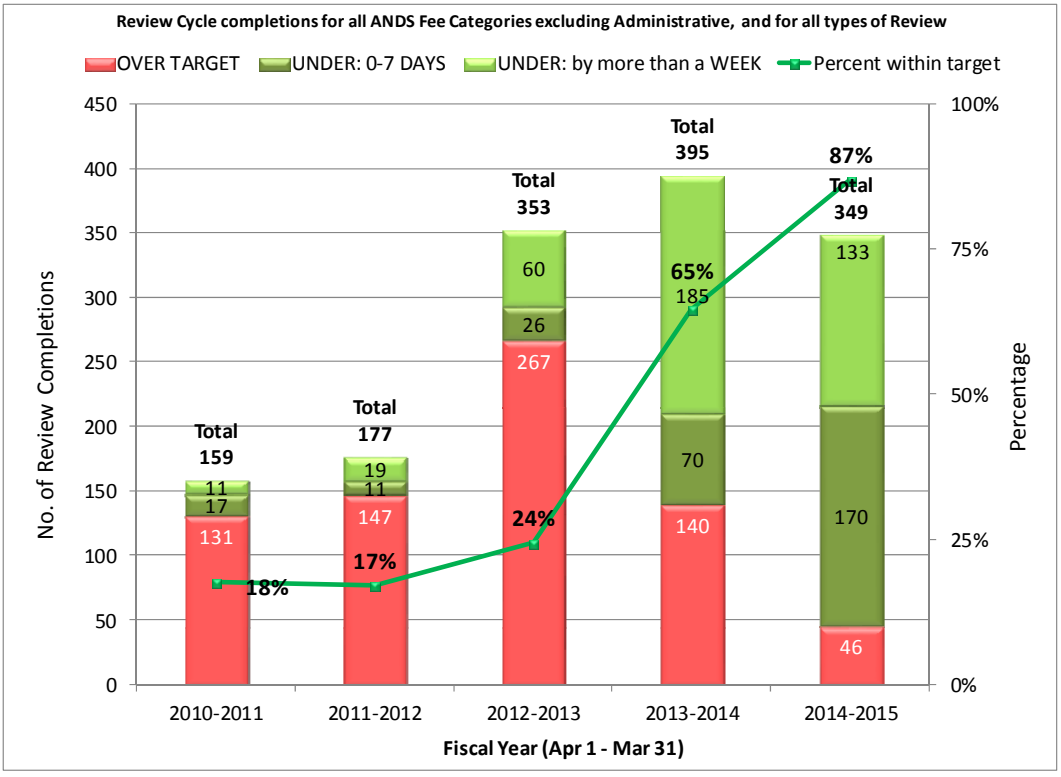
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

REVIEW CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Review Decisions

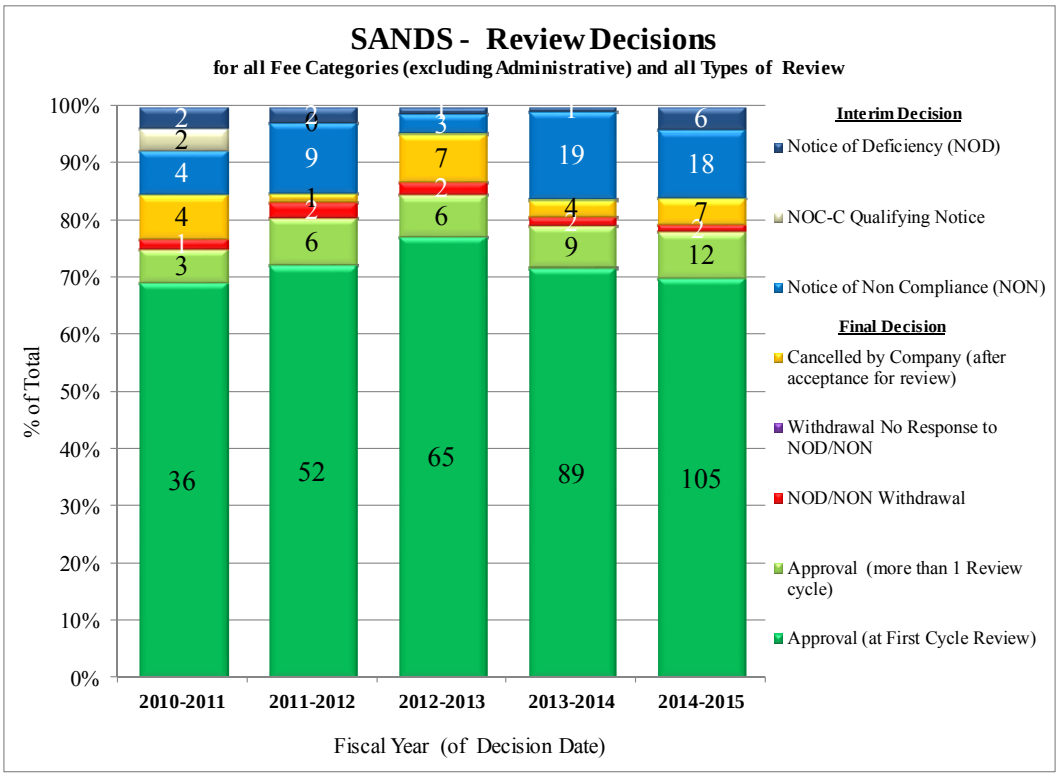


ANDS - Review Cycle Completions Showing Percentage Within Target

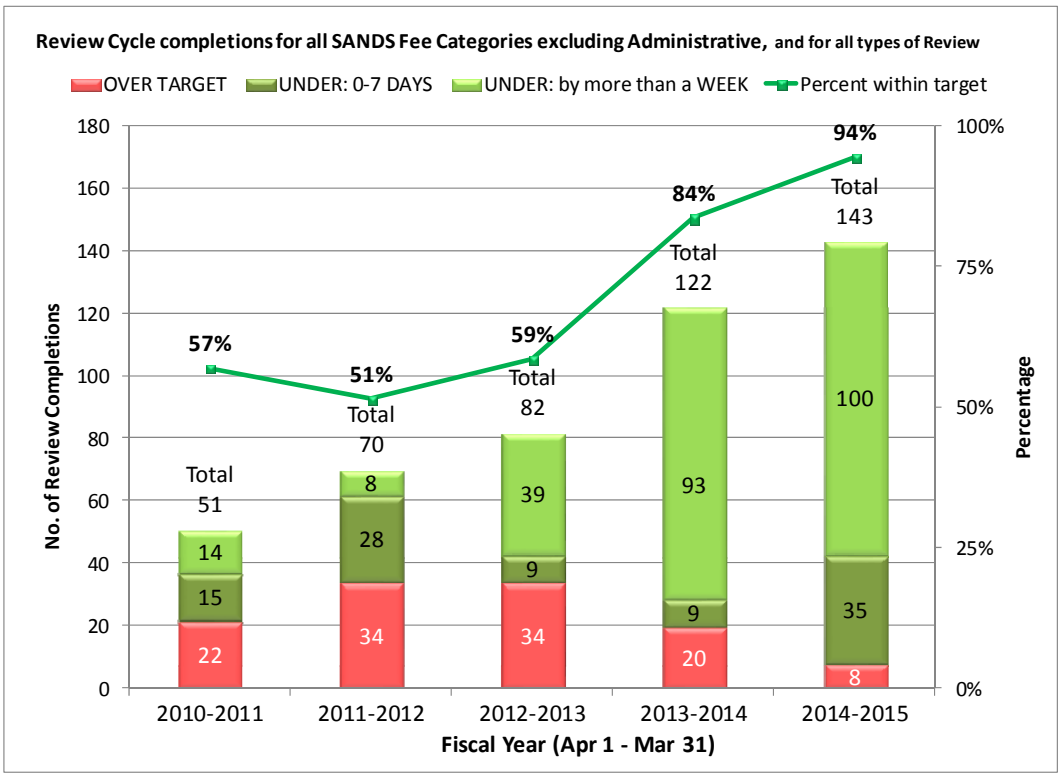


REVIEW CYCLE DECISIONS

Supplemental Abbreviated New Drug Submission (SANDS) Review Decisions

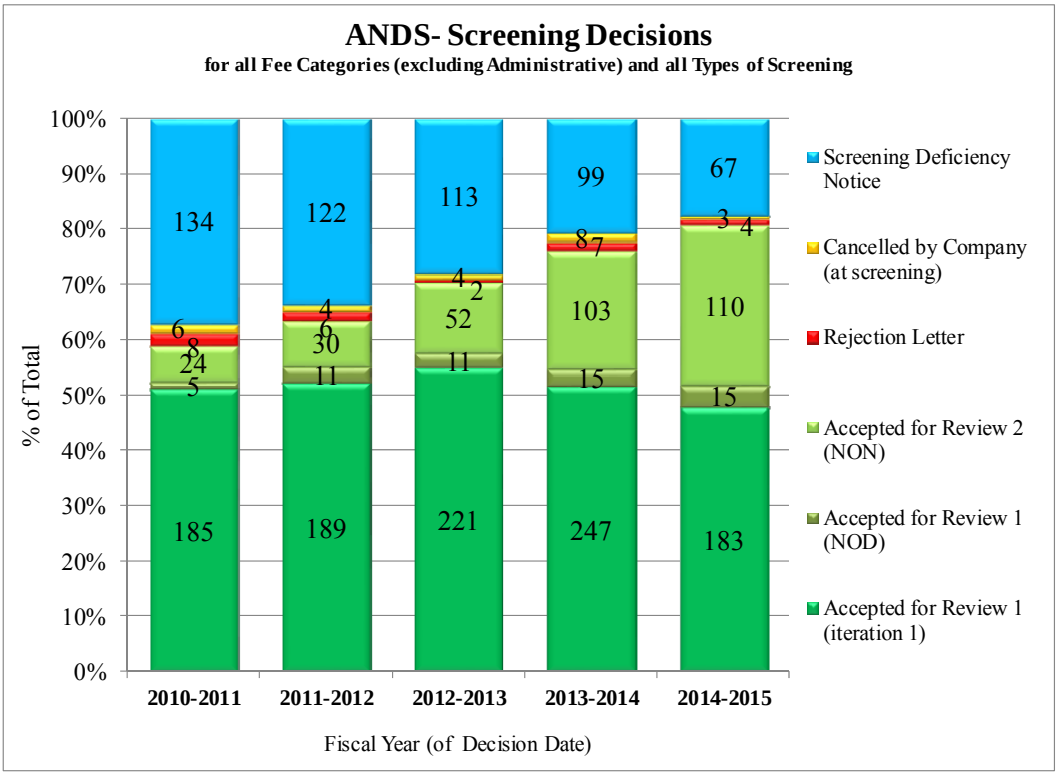


SANDS - Review Cycle Completions Showing Percentage Within Target

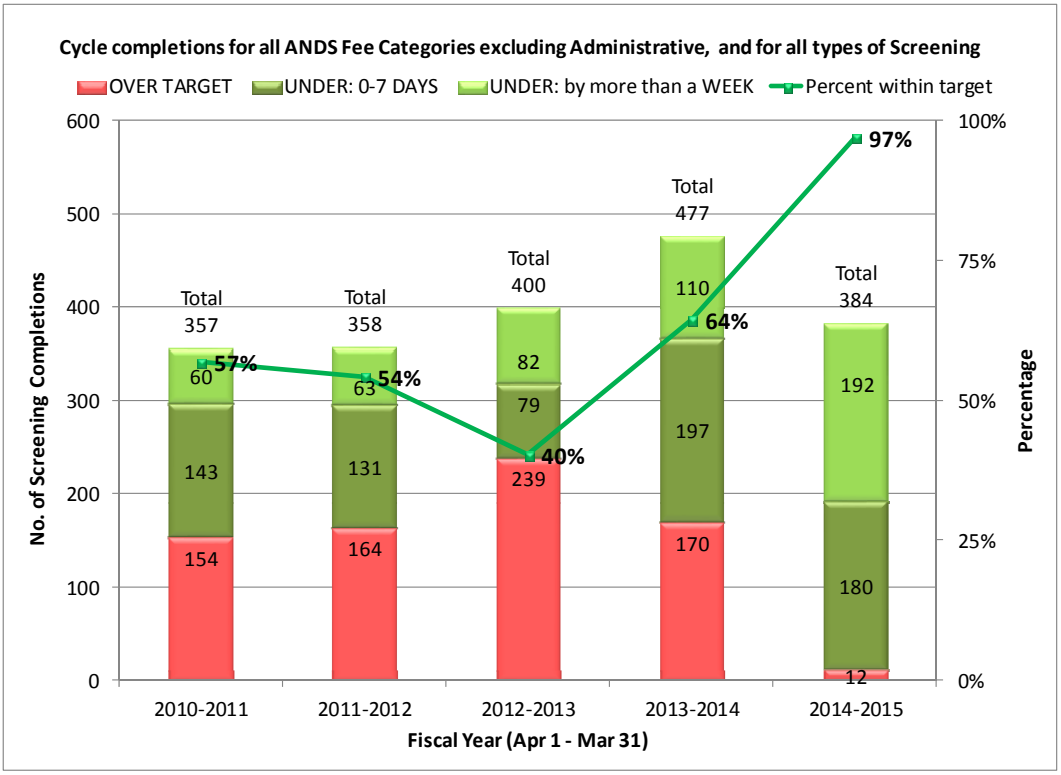


SCREENING CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Screening Decisions

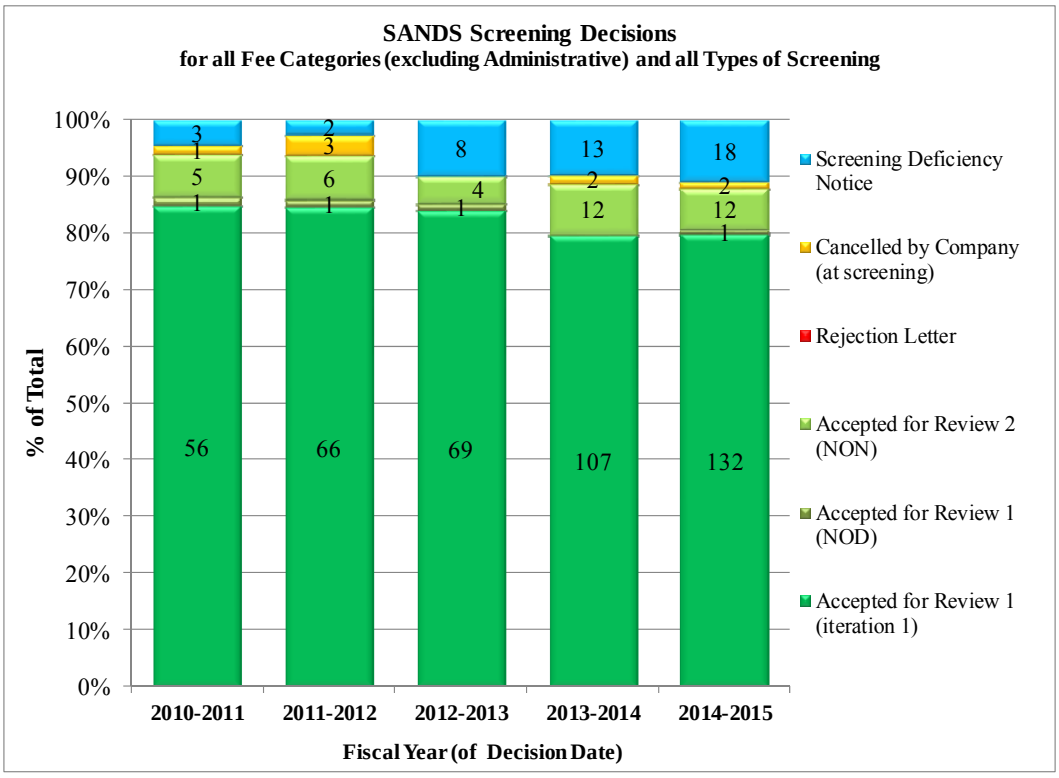


ANDS - Screening Cycle Completions Showing Percentage Within Target

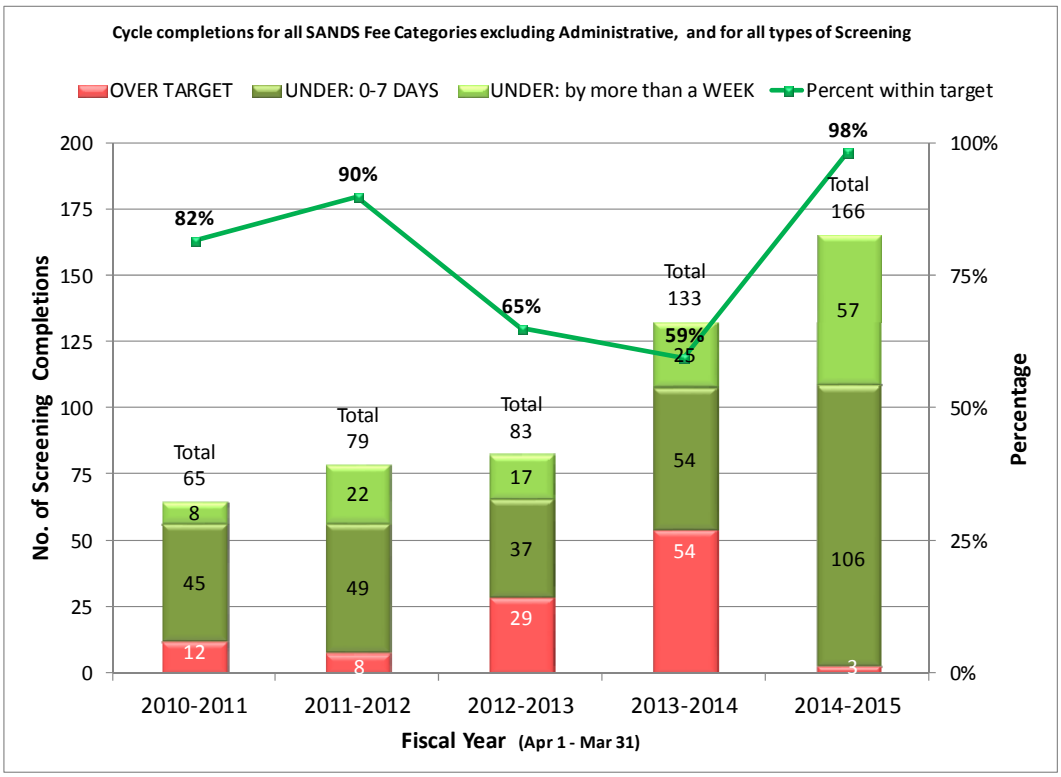


SCREENING CYCLE DECISIONS

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 (Arpil 1 - March 31)

Breakdown by Reconsideration Decision	10-11	11-12	12-13	13-14* revised	14-15	Final Decision in Dispute	ANDS's Status as of May 25 2015
TOTAL Received	**3**	**1**	**0**	**8**	**9**		
Total Pending	***0***	***0***	***0***	***0***	***1***		
Pending					1	NON-Withdrawal	Under Reconsideration
Total Granted	***1***	***0***	***0***	***1***	***3***		
Granted				1	3	NON-Withdrawal	Cleared
Granted	1					NOD-Withdrawal	Withdrawn
Total Denied	***2***	***1***	***0***	***3***	***0***		
Denied		1				Rejection at Screening	Cancelled by Company
Denied				2		NOD-Withdrawal	Withdrawn
Denied	2			1		NON-Withdrawal	Withdrawn
Total Cancelled	***0***	***0***	***0***	***4***	***5***		
Cancelled by Health Canada				1		NOD-Withdrawal	Review 1
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	Review1
Cancelled by Company				1	1	NON-Withdrawal	Withdrawn

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

SANDS - Reconsideration of Final Decisions Requests Received

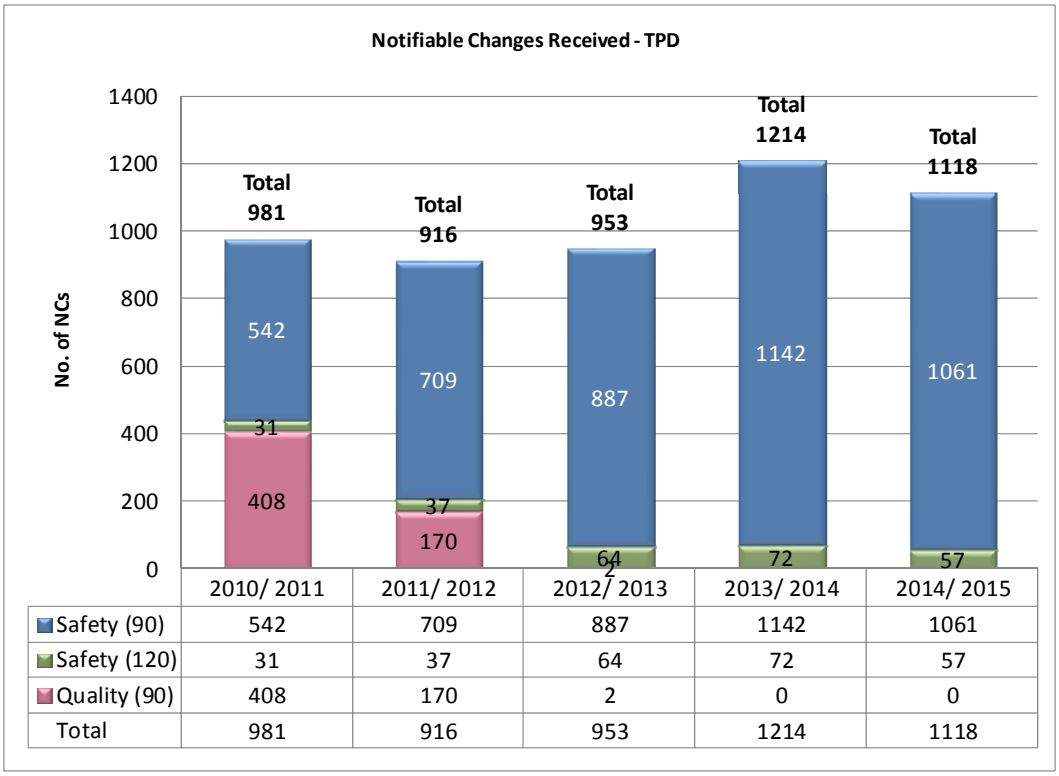
Fiscal Year of Request (Arp - Mar)

Breakdown by Reconsideration Decision	10-11	11-12 * revised	12-13	13-14	14-15	Final Decision in Dispute	SANDS Status as of May 25 2015
Total Received	**0**	**1**	**0**	**0**	**0**		
Total Granted	0	1	0	0	0	NON-Withdrawal	Cleared

NOTIFIABLE CHANGES (NC)

NOTIFIABLE CHANGES[7,8]

Number Received - Notifiable Changes (NC)



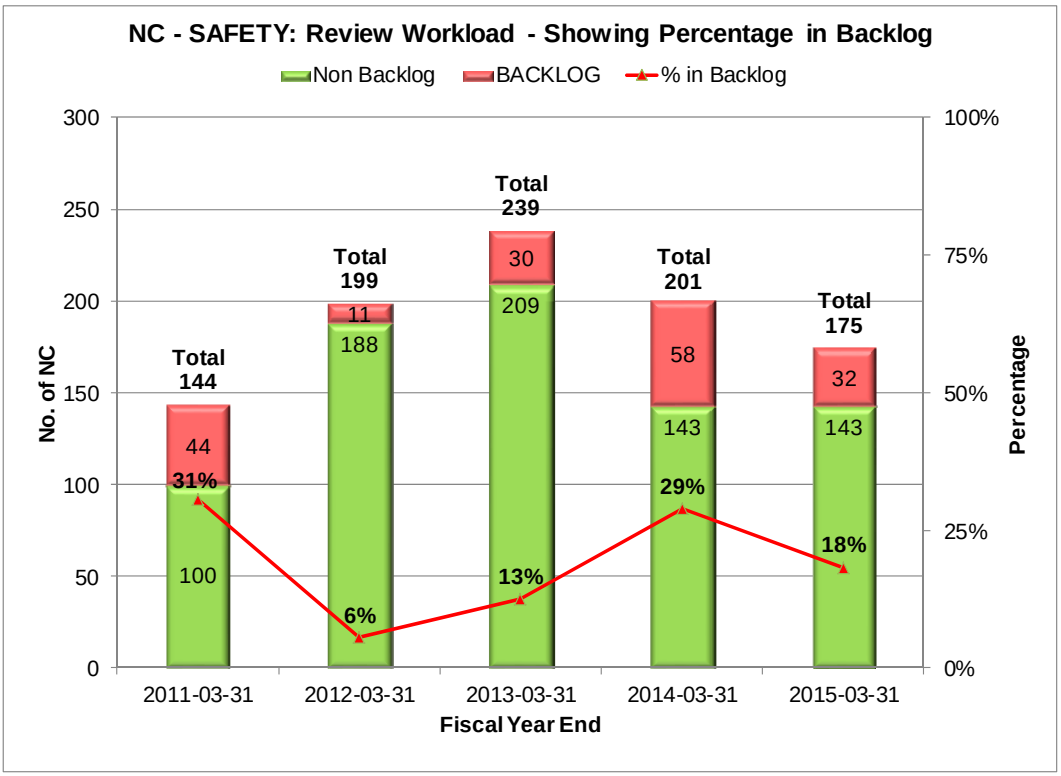
	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
Safety (90)	542	709	887	1142	1061
Safety (120)	31	37	64	72	57
Quality (90)	408	170	2	0	0
Total	981	916	953	1214	1118

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

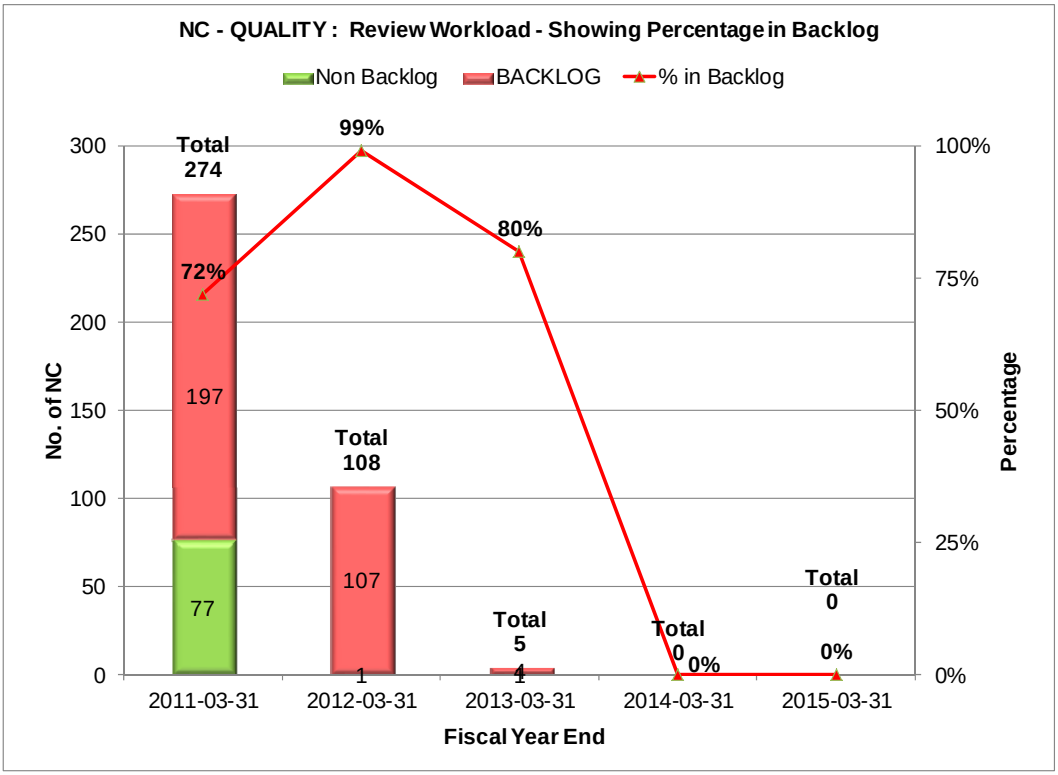
8 Post-Notice of Compliance (NOC) Changes - Quality Guidance Appendix 1 for Human Pharmaceuticals became effective October 17, 2011 and resulted in the elimination of Quality NCs for human pharmaceuticals.

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.
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/postnoc_change_apresac/noc_postnotice_ac_apresavis_change-eng.php
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. .

WORKLOAD

Notifiable Change (NC) SAFETY: Review Workload by Class

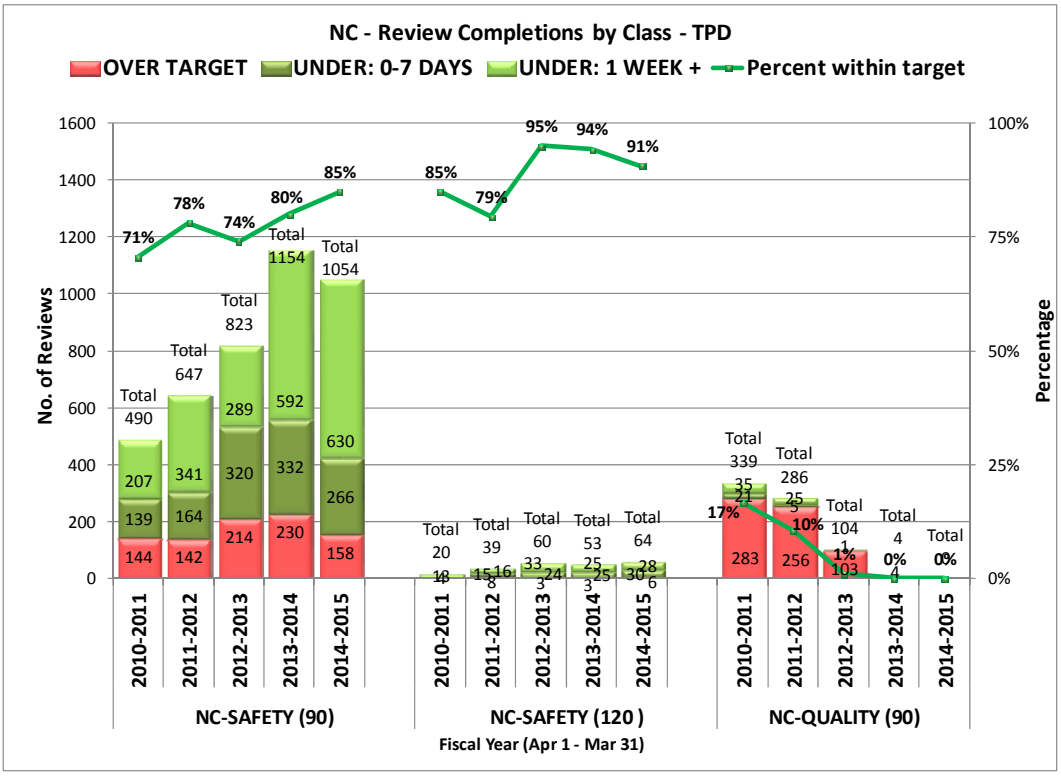
TPD NC- SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2011-03-31	2012-03-31	2013-03-31	2014-03-31	2015-03-31
SAFETY - 90 day	142	188	227	177	156
Backlog	*43*	*11*	*29*	*57*	*32*
SAFETY - 120 day	2	11	12	24	19
Backlog	*1*	*0*	*1*	*1*	*0*
Total	144	199	239	201	175
Non Backlog	100	188	209	143	143
BACKLOG	44	11	30	58	32
% in Backlog	31%	6%	13%	29%	18%

Notifiable Change (NC) QUALITY: Review Workload by Class

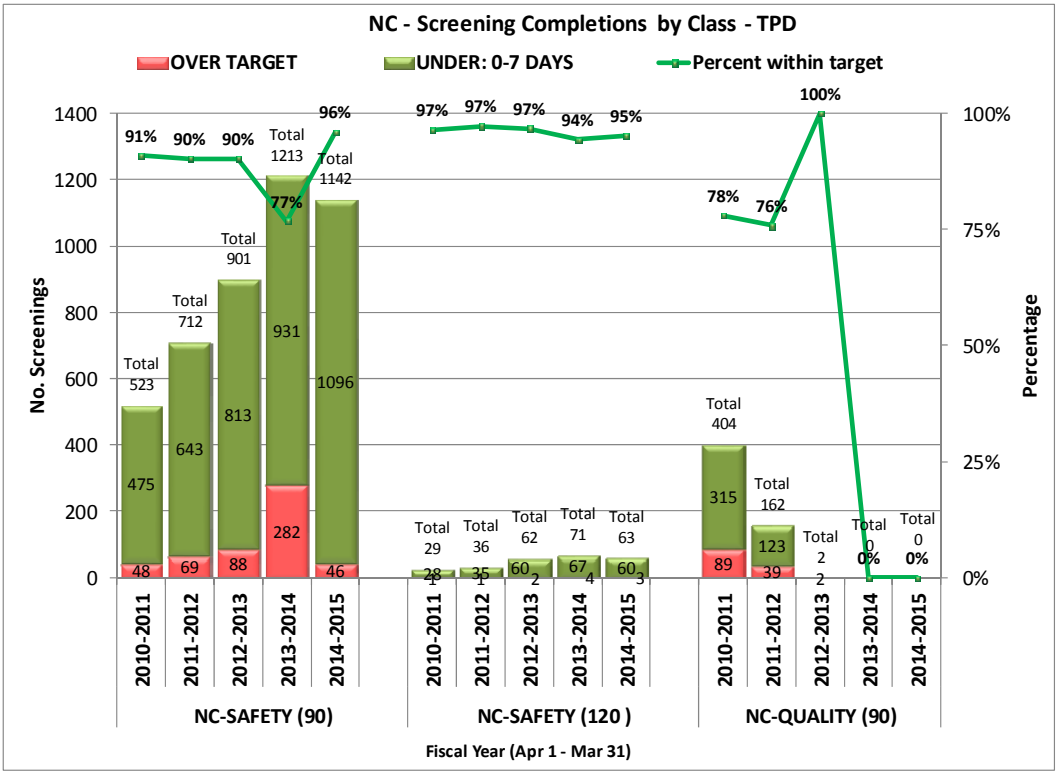
TPD NC- QUALITY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2011-03-31	2012-03-31	2013-03-31	2014-03-31	2015-03-31
QUALITY - 90 day	274	108	5	0	0
Backlog	*197*	*107*	*4*	*0*	*0*
Total	274	108	5	0	0
Non Backlog	77	1	1	0	0
BACKLOG	197	107	4	0	0
% in Backlog	72%	99%	80%	0%	0%

PERFORMANCE

REVIEW Completions by Class - Notifiable Changes (NC)



SCREENING Completions by Class - Notifiable Changes (NC)



DECISIONS[9]

Decision Documents by Class - Notifiable Change (NC)

NC - QUALITY (90)					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER	309	284	105	8	6
SCREEN. DEFICIENCY NOTICE	51	17			
CANCELLED BY COMPANY	27	87	6		
REJECTION LETTER (SCR)	19	5			
NC - HOLD (PATENT)	17	12			
NOT SATISFACTORY NOTICE	5	2	2		

NC - SAFETY (90)					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER	476	638	797	1098	1065
CANCELLED BY COMPANY	25	27	34	42	49
NC - HOLD (PATENT)	27	34	45	72	34
SCREEN. DEFICIENCY NOTICE	25	16	27	91	85
REJECTION LETTER (SCR)	5	2	1	5	6
NOT SATISFACTORY NOTICE	2	1	7	2	5

NC - SAFETY (120)					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER	18	38	60	49	63
NOT SATISFACTORY NOTICE	1			1	1
SCREENING DEFICIENCY NOTICE		2		1	3
CANCELLED BY COMPANY	2	3	1	7	1
REJECTION LETTER (SCR)				1	

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 (Arp - Mar)

Breakdown by Reconsideration Decision	10-11	11-12	12-13	13-14	14-15	Final Decision in Dispute	NC's Status as of May 25 2015
Total Received	**1**	**0**	**0**	**0**	**0**		
Total Granted	***1***	***0***	***0***	***0***	***0***	Not Satisfactory Notice	Refused
Total Denied	***0***	***0***	***0***	***0***	***0***		

[9] The No Objection Decisions for NC Quality 90 were for NCs received before October 17, 2011 for a product that was placed on Intellectual Property-HOLD that was issued a Notice of Compliance

This page is left blank intentionally.

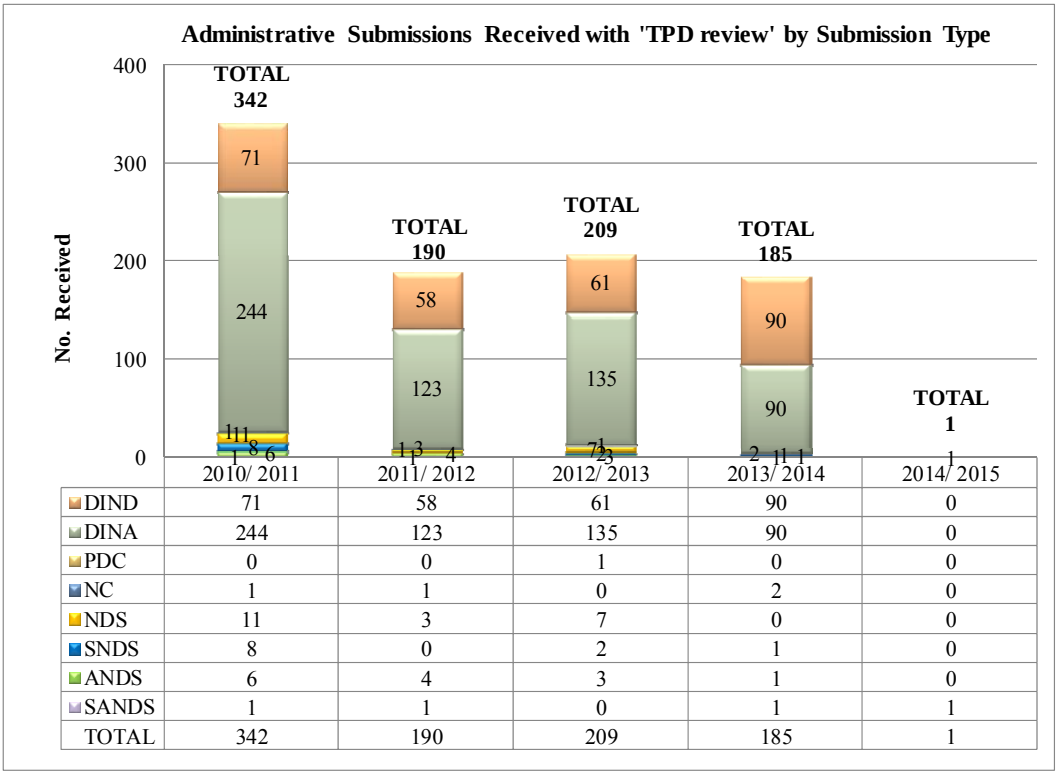
Administrative Submissions

Submissions in support of a manufacturer or product name change.

ADMINISTRATIVE SUBMISSIONS with TPD review

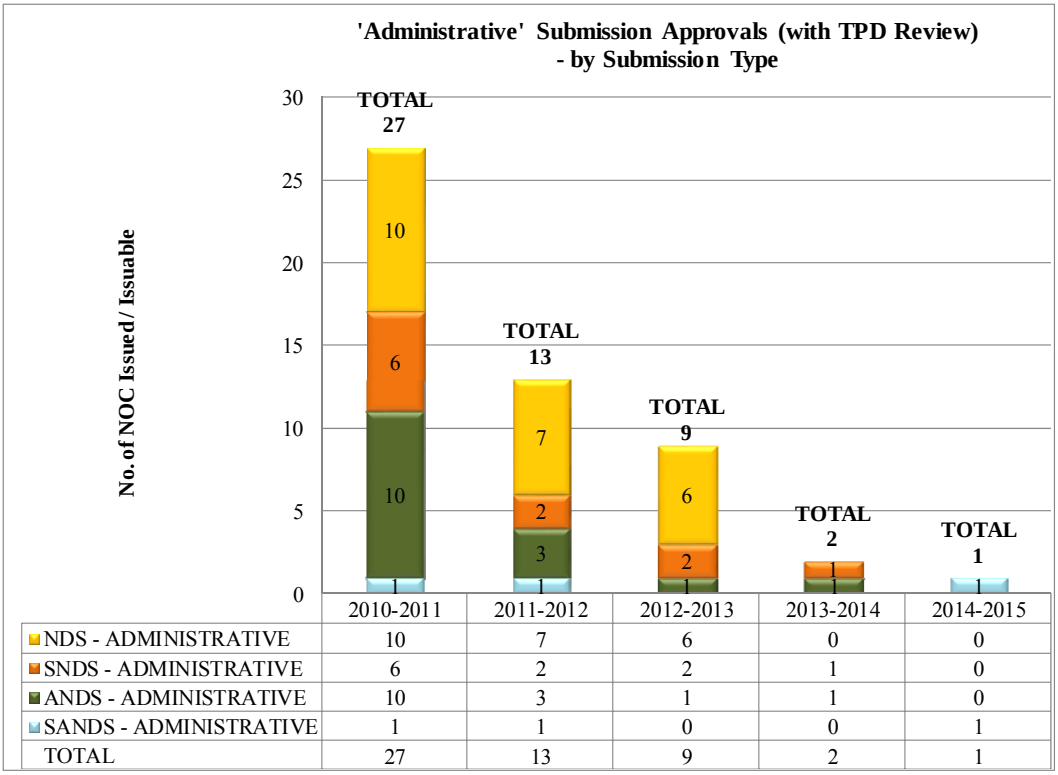
(such as product name change that requires a drug name review)

Administrative Submissions Received (with TPD review)



	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
DIND	71	58	61	90	0
DINA	244	123	135	90	0
PDC	0	0	1	0	0
NC	1	1	0	2	0
NDS	11	3	7	0	0
SNDS	8	0	2	1	0
ANDS	6	4	3	1	0
SANDS	1	1	0	1	1
TOTAL	342	190	209	185	1

Administrative Submission Approvals (with TPD Review)

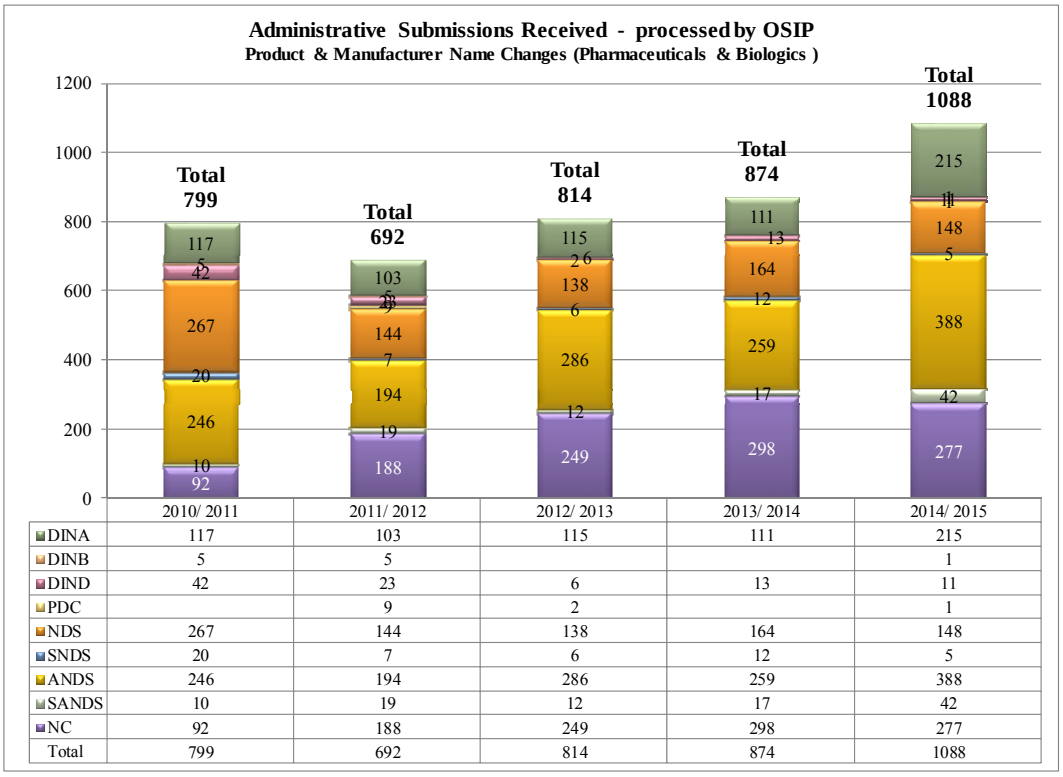


	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
NDS - ADMINISTRATIVE	10	7	6	0	0
SNDS - ADMINISTRATIVE	6	2	2	1	0
ANDS - ADMINISTRATIVE	10	3	1	1	0
SANDS - ADMINISTRATIVE	1	1	0	0	1
TOTAL	27	13	9	2	1

ADMINISTRATIVE SUBMISSIONS (Processed by OSIP)

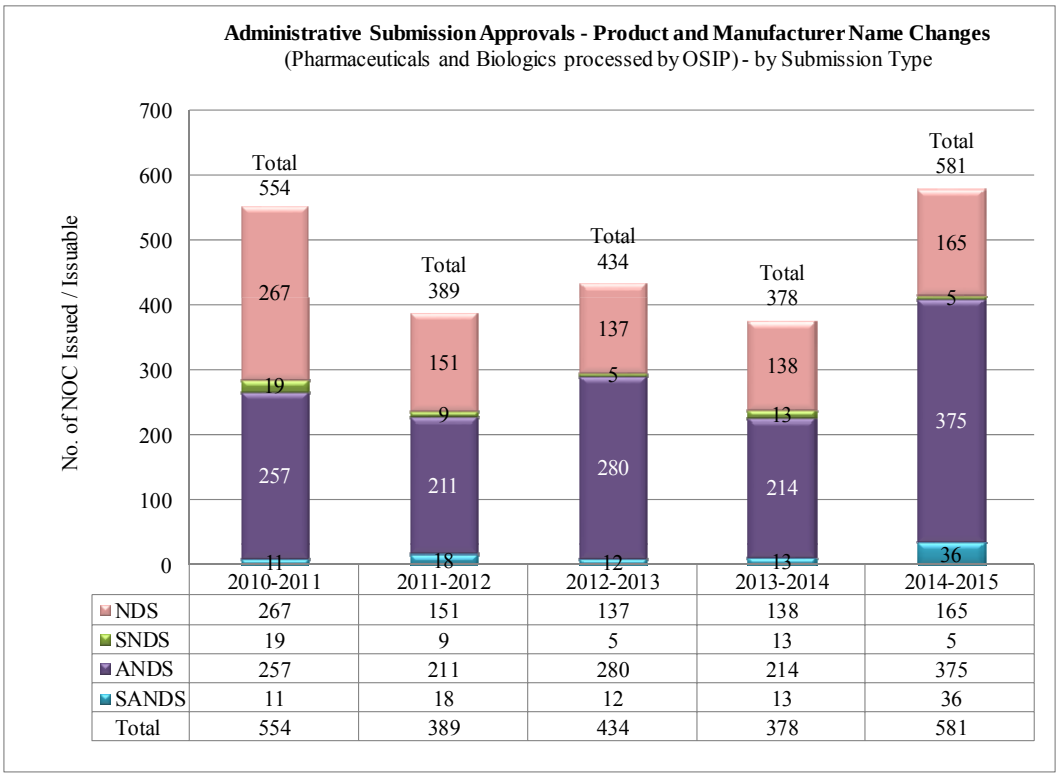
(Product & Manufacturer Name Changes)
(Admin Ncs are for cross-referenced changes)

Administrative Submissions Received by Submission Type (OSIP)



	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
DINA	117	103	115	111	215
DINB	5	5			1
DIND	42	23	6	13	11
PDC		9	2		1
NDS	267	144	138	164	148
SNDS	20	7	6	12	5
ANDS	246	194	286	259	388
SANDS	10	19	12	17	42
NC	92	188	249	298	277
Total	799	692	814	874	1088

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



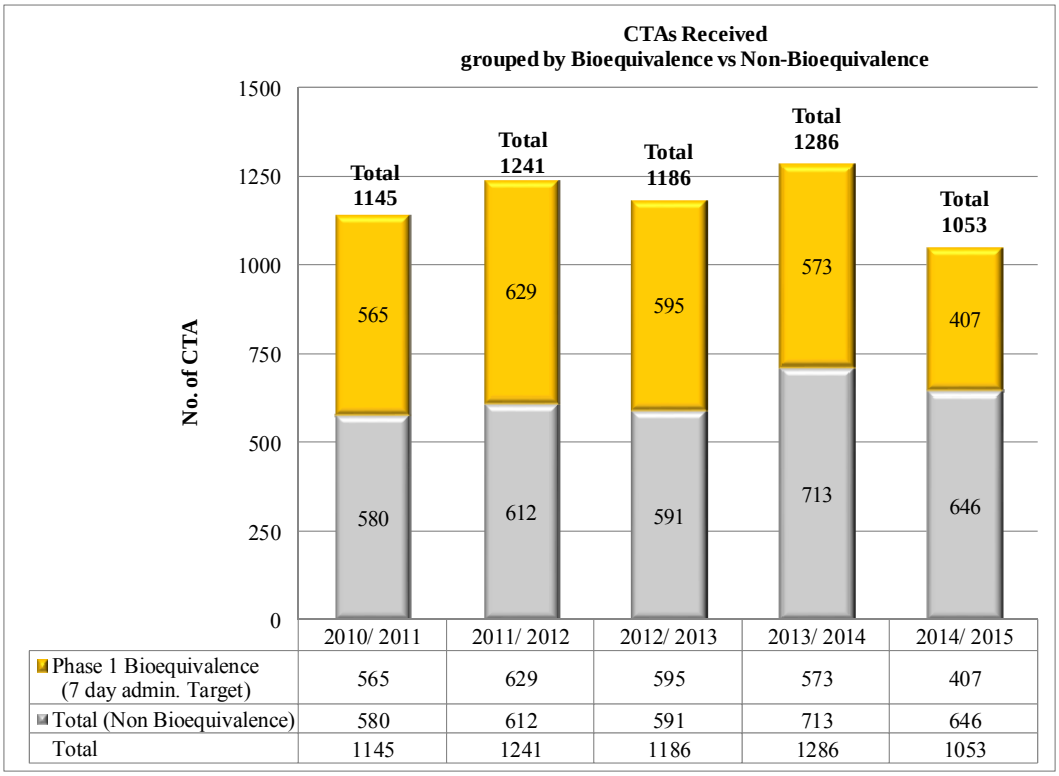
	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
NDS	267	151	137	138	165
SNDS	19	9	5	13	5
ANDS	257	211	280	214	375
SANDS	11	18	12	13	36
Total	554	389	434	378	581

Clinical Trial Applications and Amendments

(CTA & CTA-A)

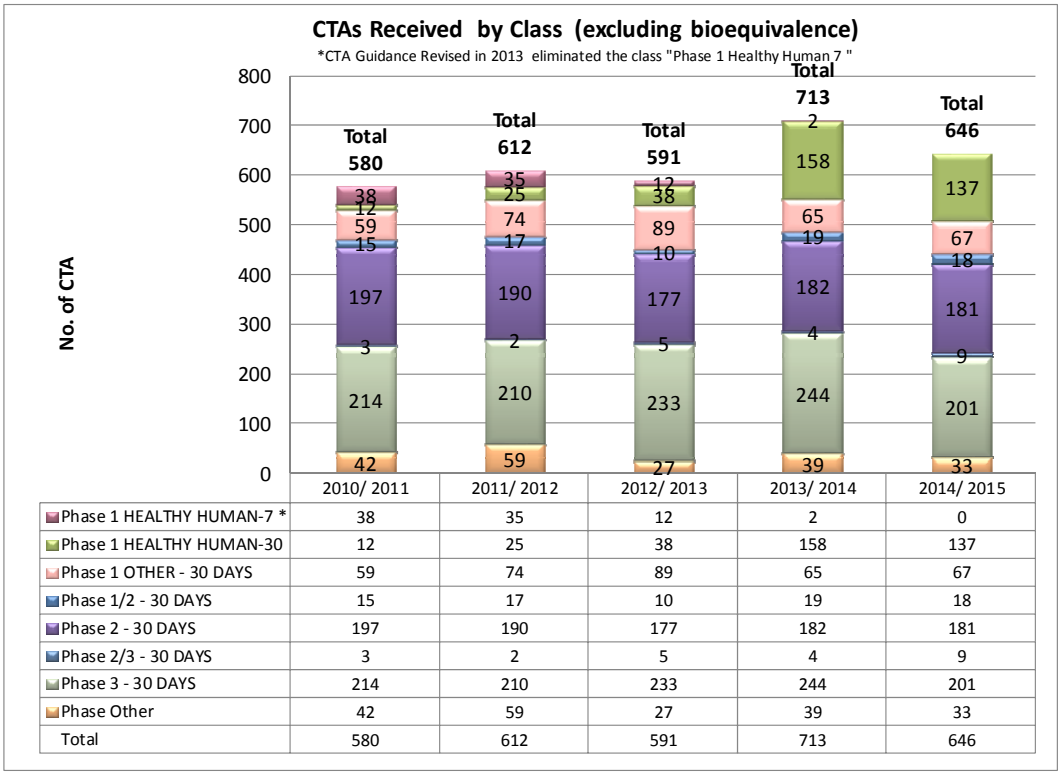
CLINICAL TRIAL APPLICATIONS

Number Received - Clinical Trial Application (CTA)



	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
Phase 1 Bioequivalence (7 day admin. Target)	565	629	595	573	407
Total (Non Bioequivalence)	580	612	591	713	646
Total	1145	1241	1186	1286	1053

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



	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
Phase 1 HEALTHY HUMAN-7 *	38	35	12	2	0
Phase 1 HEALTHY HUMAN-30	12	25	38	158	137
Phase 1 OTHER - 30 DAYS	59	74	89	65	67
Phase 1/2 - 30 DAYS	15	17	10	19	18
Phase 2 - 30 DAYS	197	190	177	182	181
Phase 2/3 - 30 DAYS	3	2	5	4	9
Phase 3 - 30 DAYS	214	210	233	244	201
Phase Other	42	59	27	39	33
Total	580	612	591	713	646

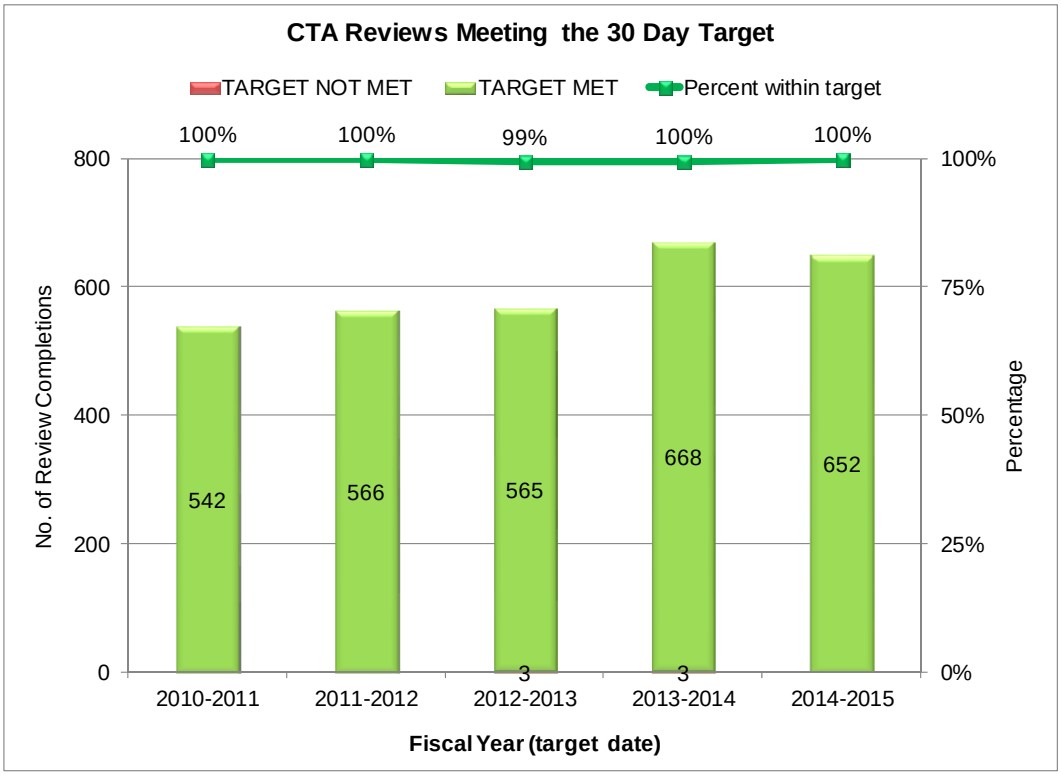
DECISION DOCUMENTS

Decision Documents - Clinical Trial Application (CTA)

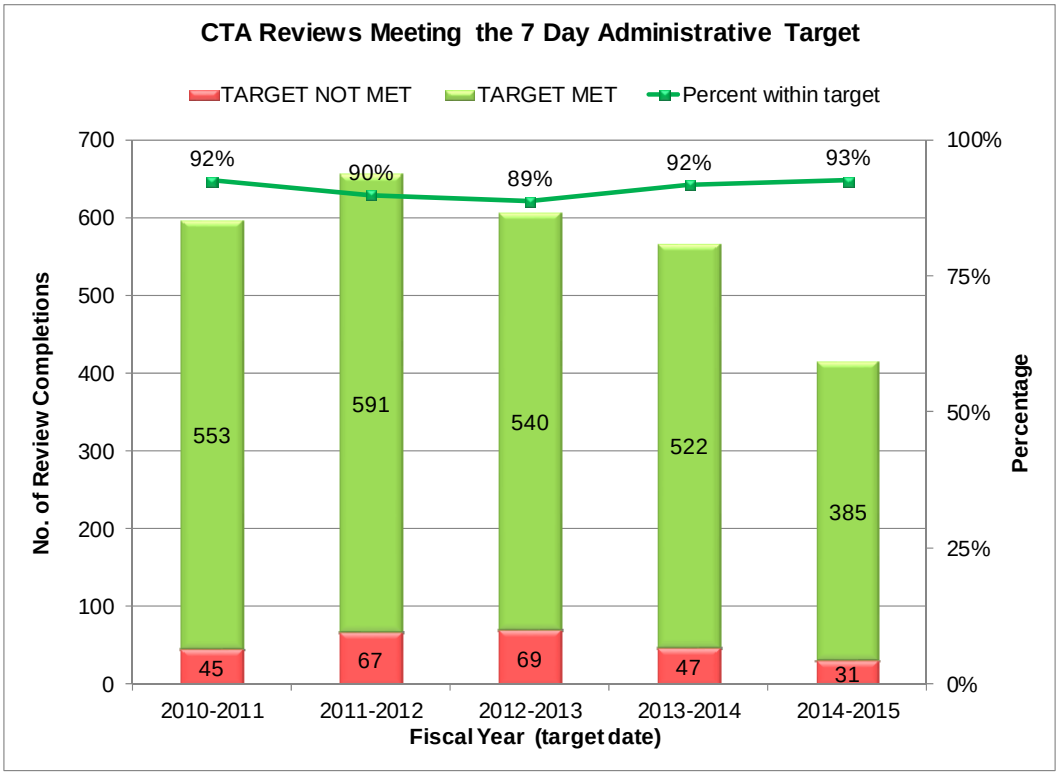
CTA (Total)					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER	1099	1199	1139	1186	1021
CANCELLED BY COMPANY DURING REVIEW	29	28	39	54	48
CANCELLED BY COMPANY AT PROCESSING	3	10	0	17	7
CTA (7 day administrative target)					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER	584	649	596	553	410
CANCELLED BY COMPANY DURING REVIEW	8	10	13	16	6
CANCELLED BY COMPANY AT PROCESSING	0	5	0	2	0
CTA (30 day target)					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER	515	550	543	633	611
CANCELLED BY COMPANY DURING REVIEW	21	18	26	38	42
CANCELLED BY COMPANY AT PROCESSING	3	5	0	15	7

PERFORMANCE

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

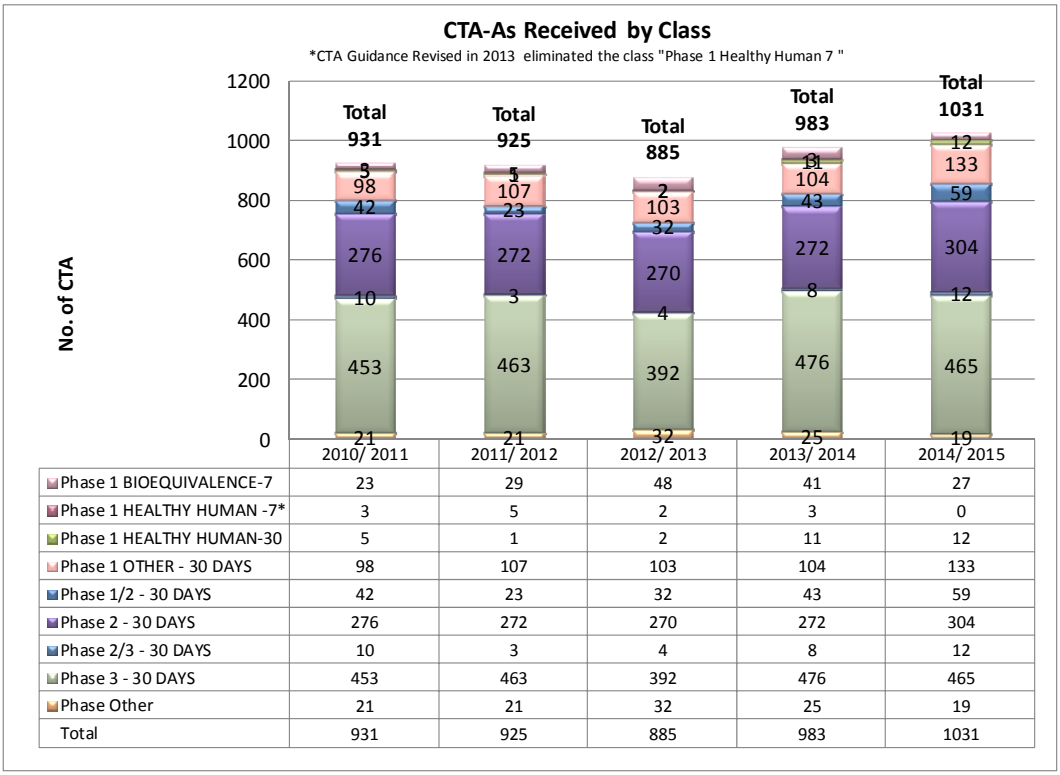


Performance – CTA Reviews Meeting the 7 Day Administrative Target



CLINICAL TRIAL APPLICATION-AMENDMENTS

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



	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
Phase 1 BIOEQUIVALENCE-7	23	29	48	41	27
Phase 1 HEALTHY HUMAN -7*	3	5	2	3	0
Phase 1 HEALTHY HUMAN-30	5	1	2	11	12
Phase 1 OTHER - 30 DAYS	98	107	103	104	133
Phase 1/2 - 30 DAYS	42	23	32	43	59
Phase 2 - 30 DAYS	276	272	270	272	304
Phase 2/3 - 30 DAYS	10	3	4	8	12
Phase 3 - 30 DAYS	453	463	392	476	465
Phase Other	21	21	32	25	19
Total	931	925	885	983	1031

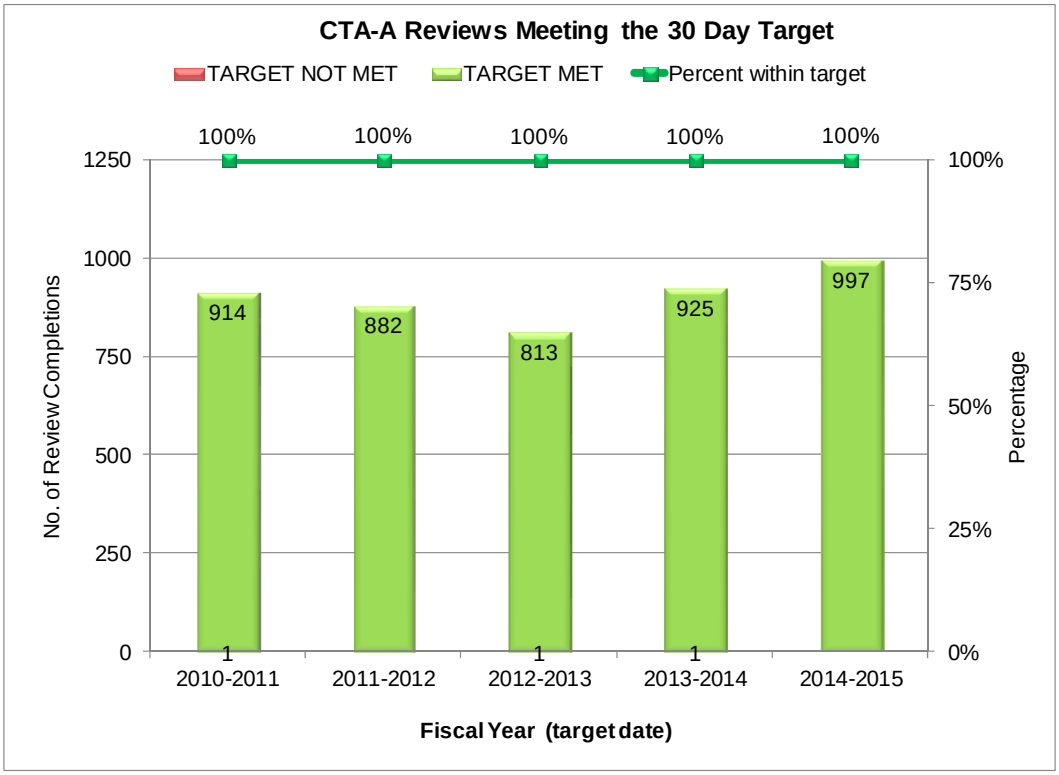
DECISION DOCUMENTS

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

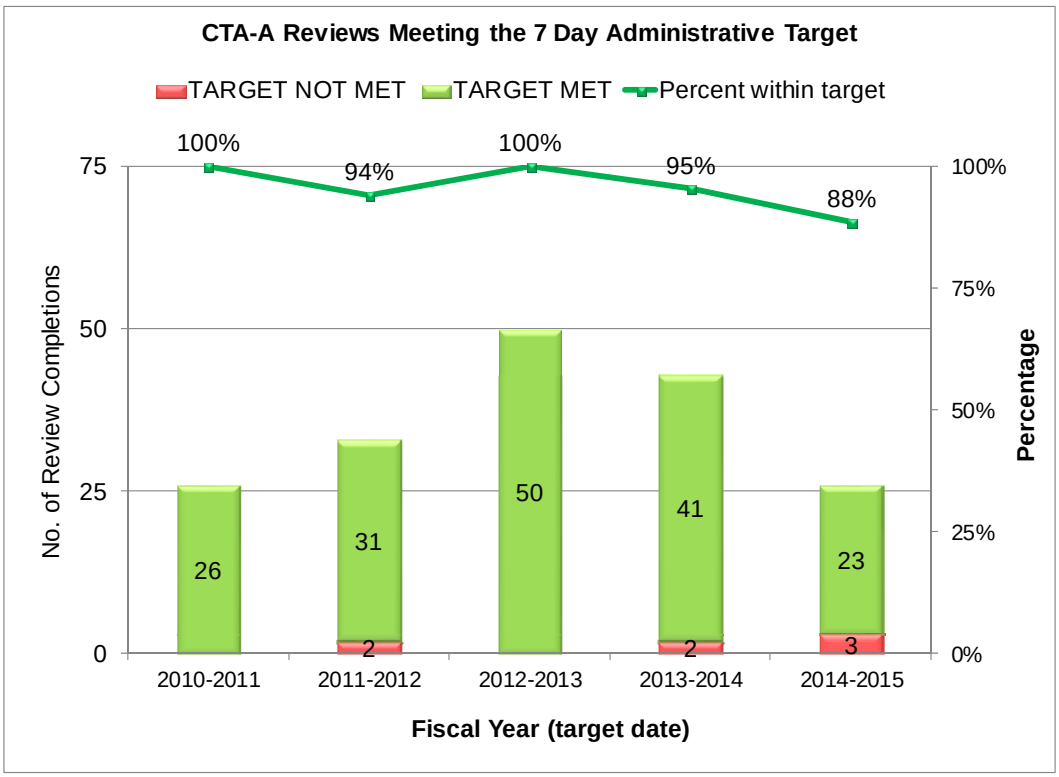
CTA-A (Total)					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER	931	905	859	963	1013
CANCELLED BY COMPANY DURING REVIEW	5	9	5	8	11
CANCELLED BY COMPANY AT PROCESSING	0	2	5	0	4
CTA-A (7 day administrative target)					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER	25	32	49	43	26
CANCELLED BY COMPANY DURING REVIEW	0	1	1	0	0
CANCELLED BY COMPANY AT PROCESSING	0	0	0	0	0
CTA-A (30 day target)					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER	906	873	810	920	987
CANCELLED BY COMPANY DURING REVIEW	5	8	4	8	11
CANCELLED BY COMPANY AT PROCESSING	0	3	5	0	4

PERFORMANCE

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



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

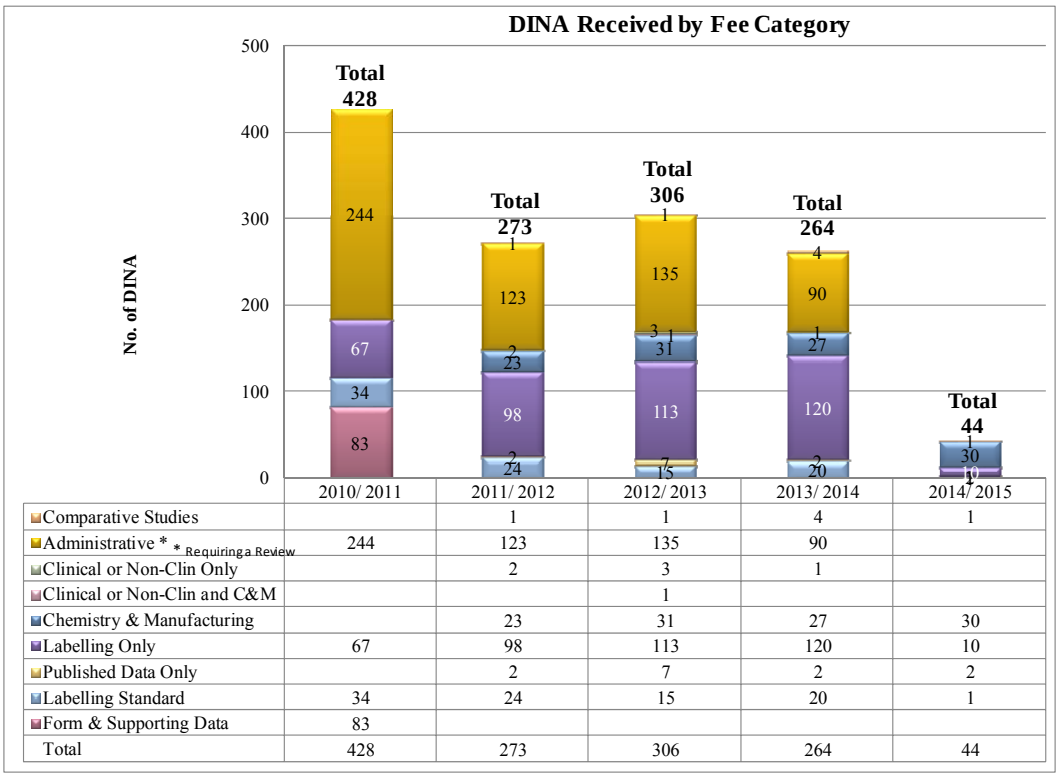


DINA, DIND & DINF

Application for a Drug Identification Number

DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER[10]

Number Received - DINA

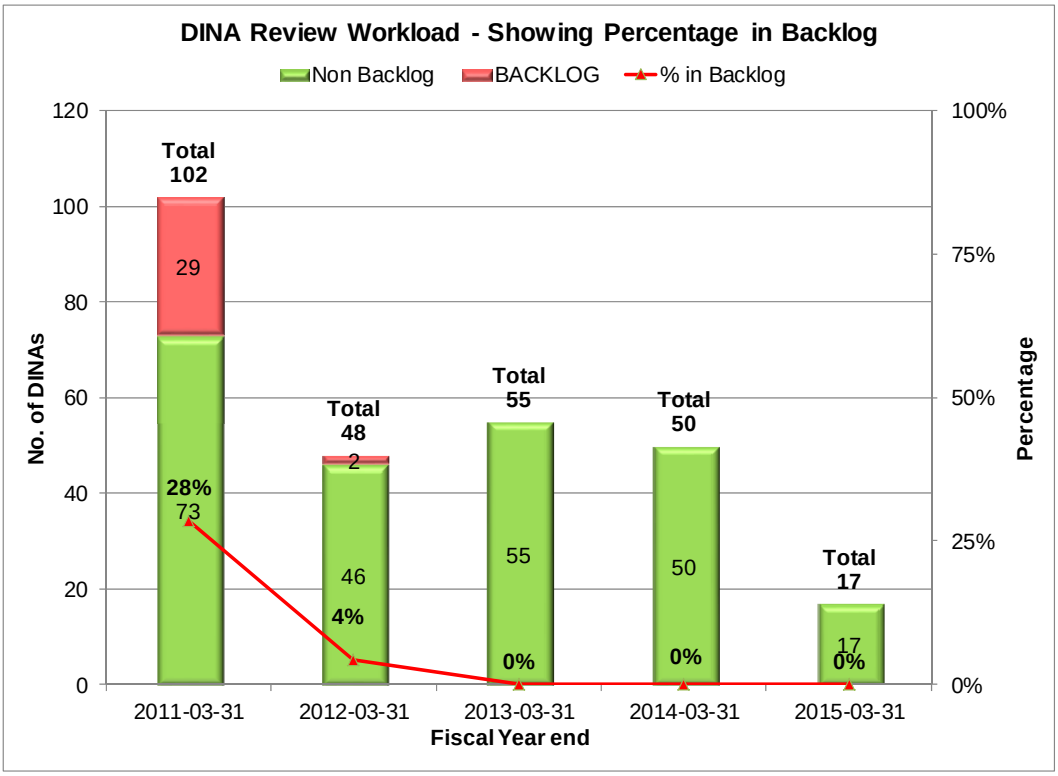


	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
Comparative Studies		1	1	4	1
Administrative * * Requiring a Review	244	123	135	90	
Clinical or Non-Clin Only		2	3	1	
Clinical or Non-Clin and C&M			1		
Chemistry & Manufacturing		23	31	27	30
Labelling Only	67	98	113	120	10
Published Data Only		2	7	2	2
Labelling Standard	34	24	15	20	1
Form & Supporting Data	83				
Total	428	273	306	264	44

[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 being reported separately in the **Appendix B: Non-Prescription and Disinfectant Drugs**.

REVIEW WORKLOAD

Review Workload / Backlog - Showing Percentage in Backlog - DINA

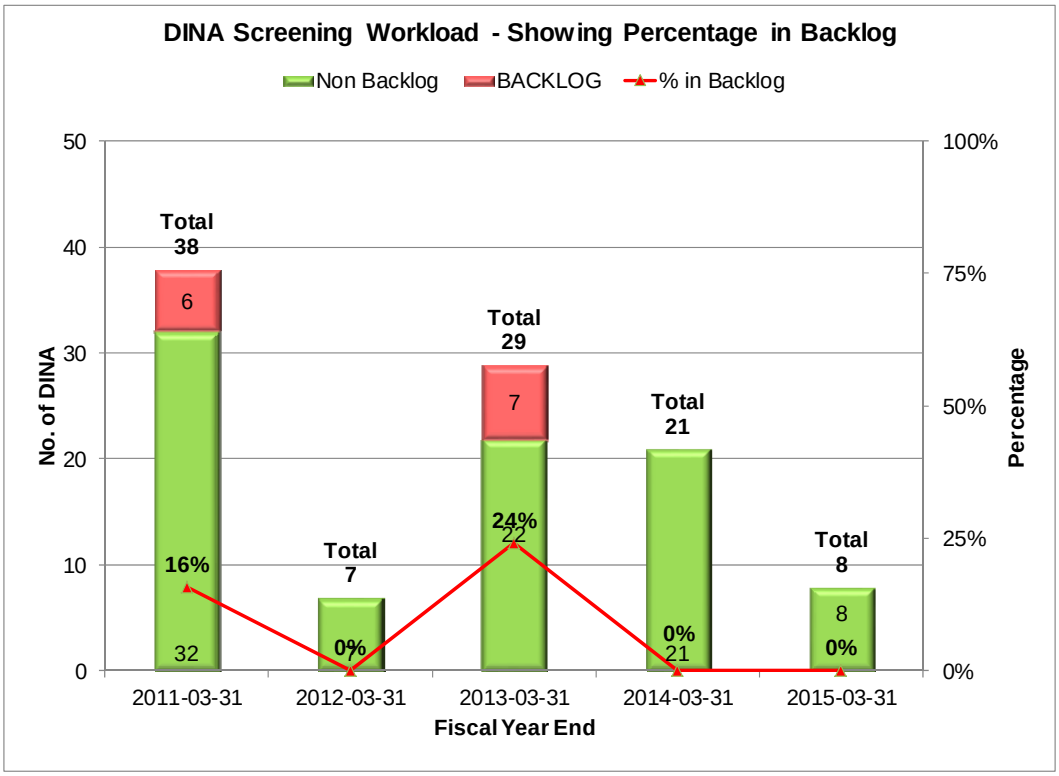


Review Workload by Class - DINA

TPD DINA All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2011-03-31	2012-03-31	2013-03-31	2014-03-31	2015-03-31
Labelling Only (Form)	**25**	**31**	**44**	**32**	**2**
Backlog	*4*	*0*	*0*	*0*	*0*
Form and Supporting Data	**77**	**5**	**0**	**0**	**0**
Backlog	*25*	*2*	*0*	*0*	*0*
Clinical or Non-Clin Only	**0**	**1**	**2**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**0**	**0**	**1**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**0**	**8**	**4**	**15**	**14**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	**0**	**2**	**4**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**0**	**1**	**0**	**2**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**102**	**48**	**55**	**50**	**17**
Non Backlog	**73**	**46**	**55**	**50**	**17**
BACKLOG	**29**	**2**	**0**	**0**	**0**
% in Backlog	**28%**	**4%**	**0%**	**0%**	**0%**

SCREENING WORKLOAD

Screening Workload / Backlog - Showing Percentage in Backlog - DINA



Screening Workload by Class - DINA

TPD DINA All SCREENING WORKLOAD by User Fee Category (excluding administrative) and Fiscal Year End					
CLASS	**2011-03-31**	**2012-03-31**	**2013-03-31**	**2014-03-31**	**2015-03-31**
Labelling Only (Form)	**12**	**4**	**15**	**13**	**3**
Backlog	*4*	*0*	*1*	*0*	*0*
Form & Supporting Data	**13**	**0**	**1**	**0**	**0**
Backlog	*1*	*0*	*0*	*0*	*0*
Labelling Standard	**13**	**0**	**1**	**4**	**0**
Backlog	*1*	*0*	*1*	*0*	*0*
Chemistry & Manufacturing	**0**	**3**	**10**	**3**	**3**
Backlog	*0*	*0*	*5*	*0*	*0*
Clinical or Non-Clinical Only	**0**	**0**	**1**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data Only	**0**	**0**	**2**	**0**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**0**	**0**	**0**	**1**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**38**	**7**	**29**	**21**	**8**
Non Backlog	**32**	**7**	**22**	**21**	**8**
BACKLOG	**6**	**0**	**7**	**0**	**0**
% in Backlog	**16%**	**0%**	**24%**	**0%**	**0%**

DECISION DOCUMENTS

Decision Documents – DINA by Class

DINA - LABELLING ONLY					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NOTIFICATION FORM/DIN ISSUED	14	27	54	92	4
NO OBJECTION LETTER	4	1	11	21	6
CANCELLED BY COMPANY	2		16	10	
DIN INCORR SUBTYPE-CLASS	5	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	3	1	30	17	4
SPONSOR SUB CHANGE ACCEPT	5	13	12	10	

DINA - ADMINISTRATIVE					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NOTIFICATION FORM/DIN ISSUED	25	18	90	87	
NO OBJECTION LETTER			1	1	
REJECTION LETTER (SCREENING)	21	8	31	10	
SCREENING DEFICIENCY NOTICE	3		6	6	
CANCELLED BY COMPANY	1	1	3	2	

DINA - LABELLING STANDARD					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NOTIFICATION FORM/DIN ISSUED	8	4	10	16	
NO OBJECTION LETTER			1		
NEW DRUG LETTER SCREEN			1	1	
REJECTION LETTER (SCREENING)	1	2			
SCREENING DEFICIENCY NOTICE	4	1	1	1	1
SPONSOR SUB CHANGE ACCEPT		1			
DIN INCORR SUBTYPE-CLASS	2	1			
CANCELLED BY COMPANY		1	2	1	1

DINA - PUBLISHED DATA ONLY					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER			2		
NOTICE OF DEFICIENCY			1		
REJECTION LETTER (SCREENING)					1
SCREENING DEFICIENCY NOTICE		1	2		
CANCELLED BY COMPANY				2	

DINA - CHEMISTRY & MANUFACTURING					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NOTIFICATION FORM/DIN ISSUED			19	8	17
NOD WITHDRAWAL LETTER			1		
NOTICE OF DEFICIENCY			1		3
REJECTION LETTER (SCREENING)			4	3	
SCREENING DEFICIENCY NOTICE			5	15	11
CANCELLED BY COMPANY			1	5	
NO OBJECTION LETTER			6	3	8
NEW DRUG LETTER SCREEN				1	
NOTICE OF NON-COMPLIANCE				6	3

DINA - CLINICAL OR NON-CLINICAL DATA					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NOTIFICATION FORM/DIN ISSUED			1	1	
NOTICE OF DEFICIENCY			1		
NO OBJECTION LETTER				3	

DINA - COMPARATIVE STUDIES					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NOTIFICATION FORM/DIN ISSUED			2	1	2
NO OBJECTION LETTER				1	
NOTICE OF DEFICIENCY				1	1

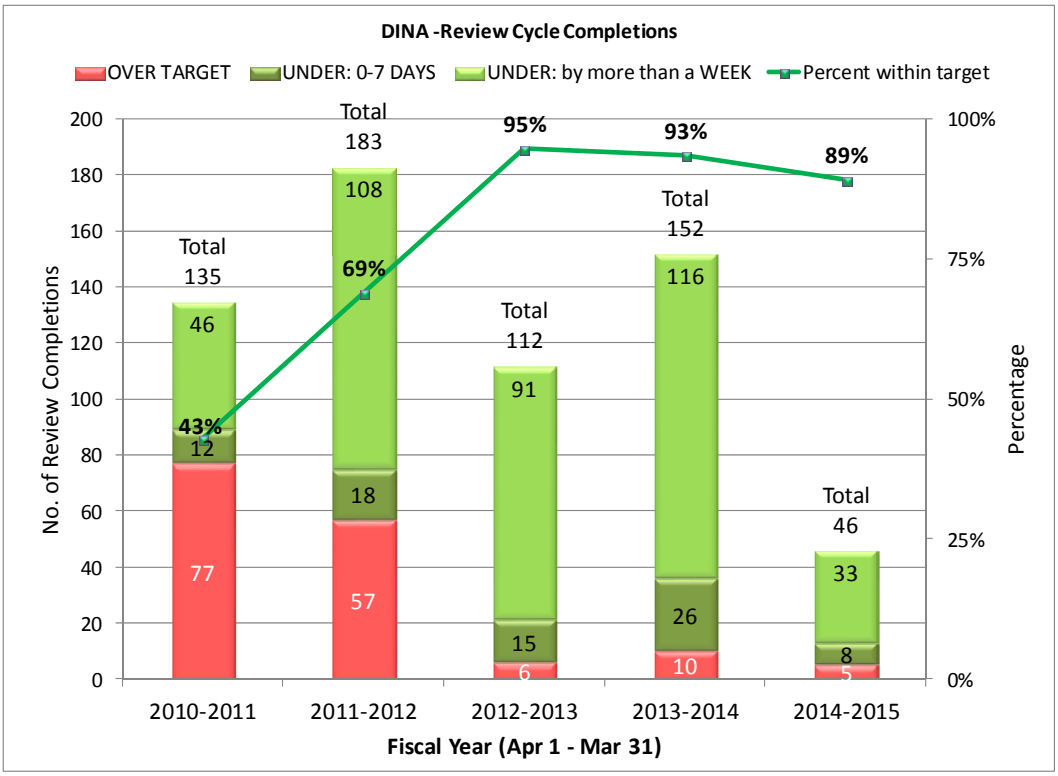
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – DINA

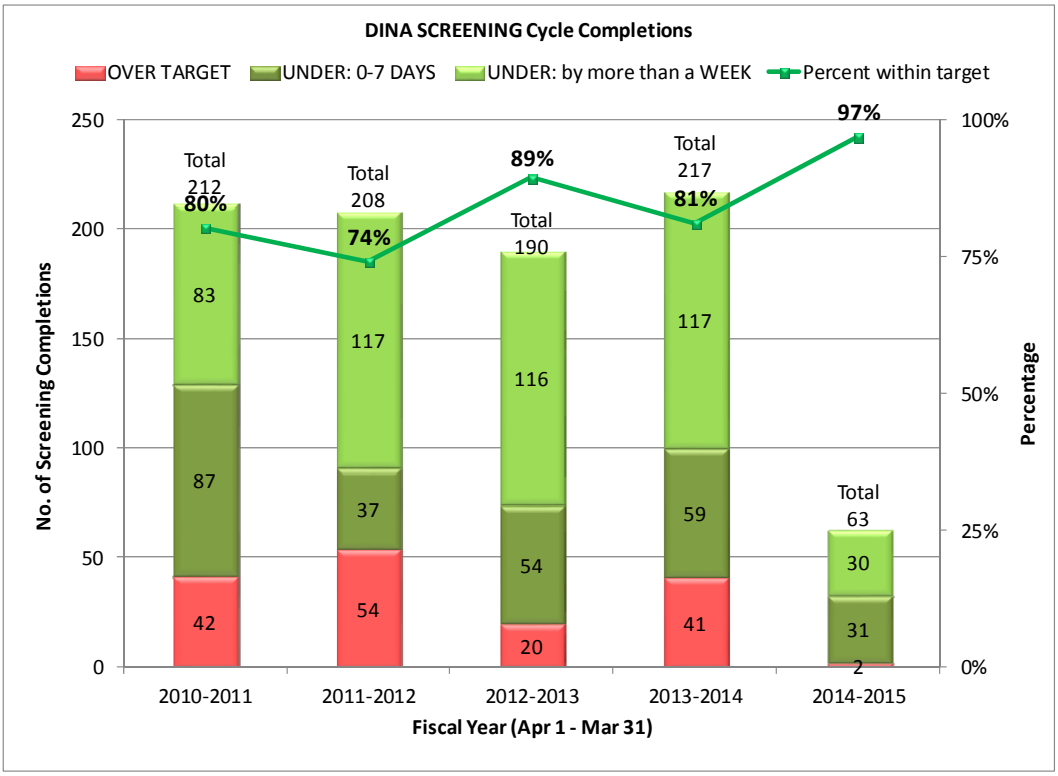
DINA - Reconsideration of Final Decisions by Year Requested Fiscal Year of Request (Arp - Mar)							
Breakdown by Reconsideration Decision	**10-11**	**11-12**	**12-13**	**13-14**	**14-15**	**Final Decision in Dispute**	**Submission Status as May 25 2015**
Total Received	**0**	**2**	**0**	**0**	**1**		
Total Pending	**0**	**0**	**0**	**0**	**1**		
	0	0	0	0	1	New Drug Letter	Under Reconsideration
Total Denied	***0***	***2***	***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

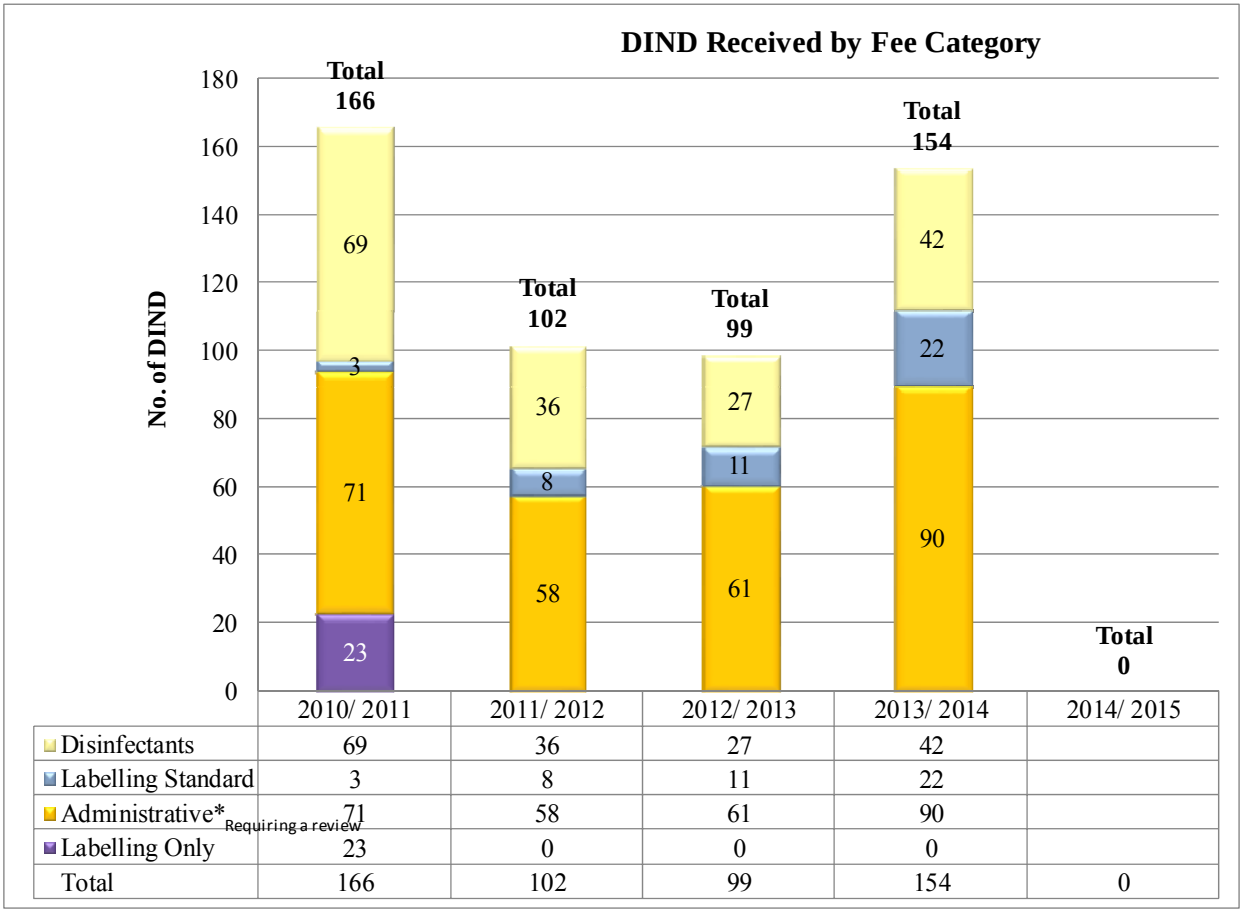


Screening Cycle Completions - DINA



DIND: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - DISINFECTANT PRODUCT[11]

Number Received - DIND

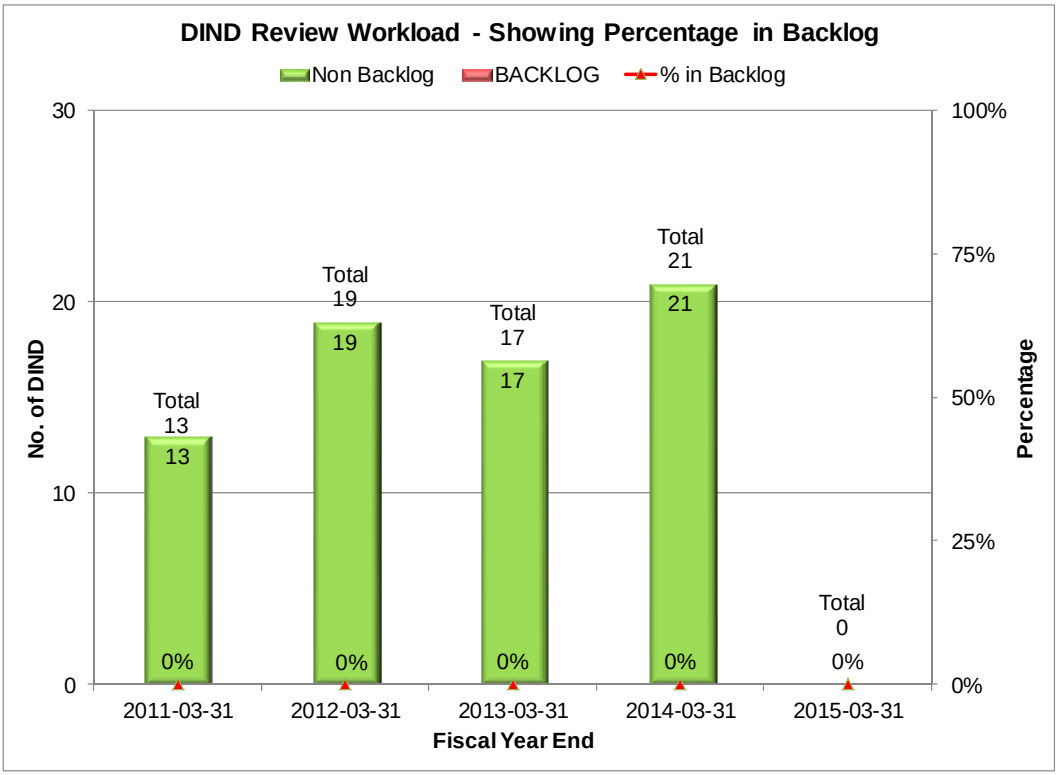


	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
Disinfectants	69	36	27	42	
Labelling Standard	3	8	11	22	
Administrative* Requiring a review	71	58	61	90	
Labelling Only	23	0	0	0	
Total	166	102	99	154	0

[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 **Appendix B: Non-Prescription and Disinfectant Drugs**.

REVIEW WORKLOAD

Review Workload / Backlog - Showing Percentage in Backlog - DIND

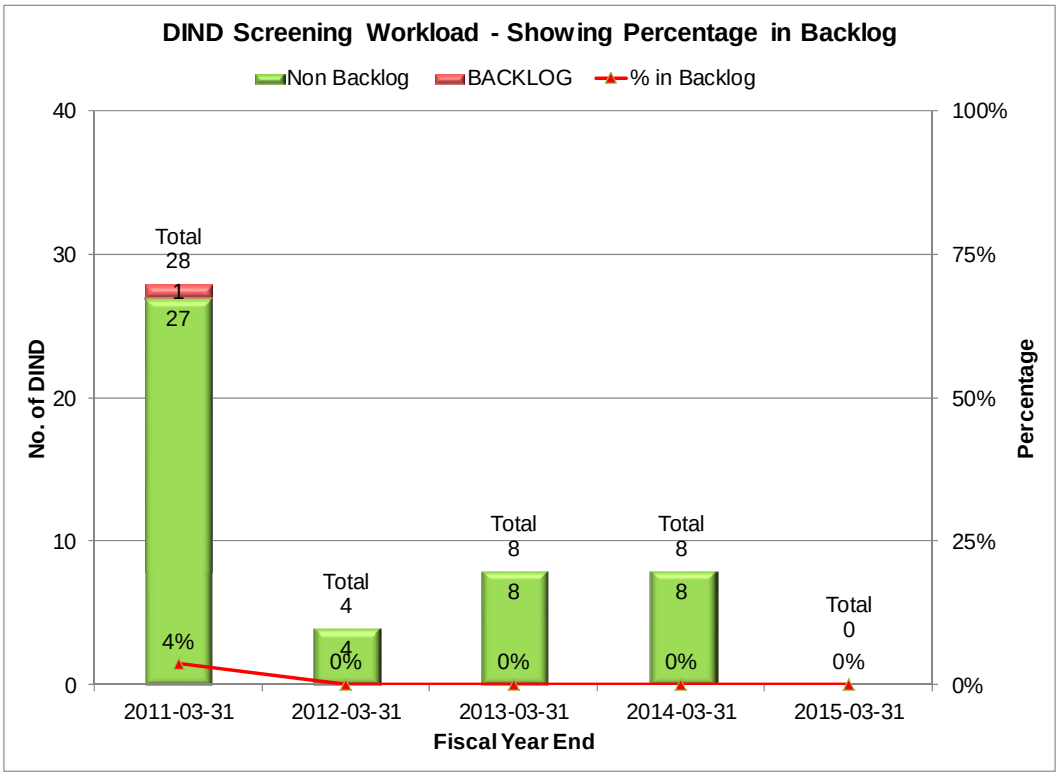


Review Workload by User Fee Category - DIND

TPD DIND All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2011-03-31	2012-03-31	2013-03-31	2014-03-31	2015-03-31
Labelling Only (Form)	**8**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Disinfectant (Form and Supporting Data)	**5**	**19**	**17**	**21**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**13**	**19**	**17**	**21**	**0**
Non Backlog	**13**	**19**	**17**	**21**	*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	**2011-03-31**	**2012-03-31**	**2013-03-31**	**2014-03-31**	**2015-03-31**
Labelling Only (Form)	**2**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Disinfectant (Form & Support	**26**	**3**	**3**	**7**	**0**
Backlog	*1*	*0*	*0*	*0*	*0*
Labelling Standard	**0**	**1**	**5**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**28**	**4**	**8**	**8**	**0**
Non Backlog	**27**	**4**	**8**	**8**	**0**
BACKLOG	**1**	**0**	**0**	**0**	**0**
% in Backlog	**4%**	**0%**	**0%**	**0%**	**0%**

DECISION DOCUMENTS

Decision Documents – DIND by Class

DIND - LABELLING ONLY					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NOTIFICATION FORM/DIN ISSUED	16	10			-
NO OBJECTION LETTER	5	3			-
CANCELLED BY COMPANY					-
NEW DRUG LETTER SCREEN	1				-
NON WITHDRAWAL LETTER					-
NOTICE OF NON-COMPLIANCE	1				-
REJECTION LETTER (SCREENING)	1				-
SCREENING DEFICIENCY NOTICE	3				-

DIND - Form and Supporting Data					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NOTIFICATION FORM/DIN ISSUED	47	8			-
NO OBJECTION LETTER	27	21			-
CANCELLED BY COMPANY	2				-
NEW DRUG LETTER REVIEW	2				-
NEW DRUG LETTER SCREEN	4				-
NOTICE OF NON-COMPLIANCE	8	7			-
NOTICE OF DEFICIENCY	3				-
NON WITHDRAWAL LETTER		1			-
REJECTION LETTER (SCREENING)	1				-
SCREENING DEFICIENCY NOTICE	13	2			-
WITHDRAWAL NO RESP TO NON		3			-
WITHDRAWAL NO RESP TO NOD					-
WITH.UNACCEPT.RESP.NON SC		1			-

DIND - ADMINISTRATIVE					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NOTIFICATION FORM/DIN ISSUED	65	58	62	75	-
NO OBJECTION LETTER	5	2	3	1	-
CANCELLED BY COMPANY					-
REJECTION LETTER (SCREENING)	4	3	1		-
SCREENING DEFICIENCY NOTICE	39	19	21	18	-

DIND - LABELLING STANDARD					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NOTIFICATION FORM/DIN ISSUED	1	3	6	25	-
REJECTION LETTER (SCREENING)	3				-
SCREENING DEFICIENCY NOTICE	1	4	5	17	-
CANCELLED BY COMPANY		1	1		-
REJECTION LETTER (SCREENING)	3				-
NEW DRUG LETTER SCREEN			1	1	-

DIND - DIS NONCLIN/CLINICAL					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
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	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
SCREENING DEFICIENCY NOTICE		1			-

DIND - DISINFECT LABEL ONLY					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
SCREENING DEFICIENCY NOTICE			1	2	-
CANCELLED BY COMPANY			3		-

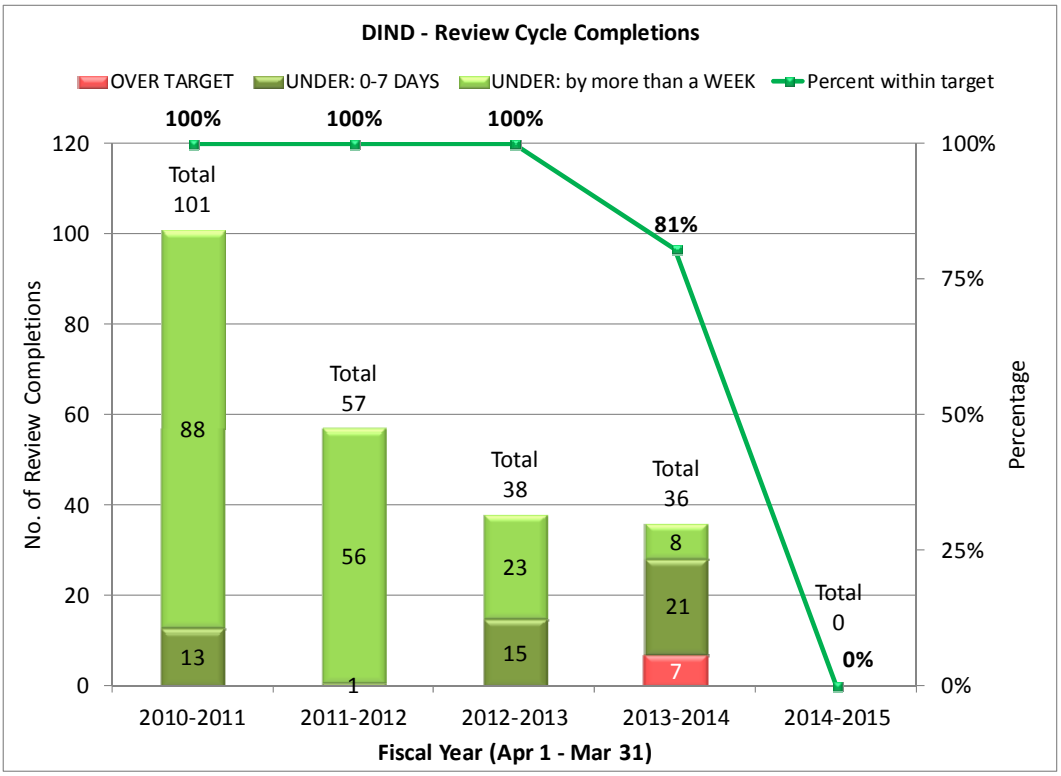
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – DIND

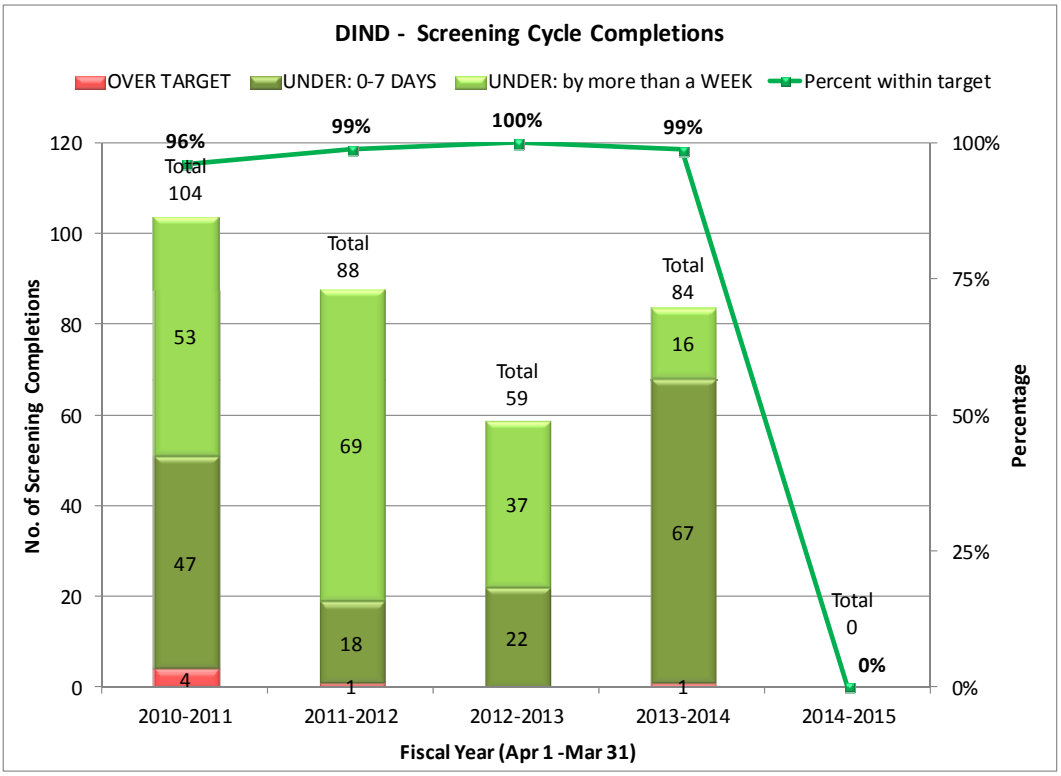
DIND - Reconsideration of Final Decisions by Year Requested Fiscal Year of Request (Arp - Mar)							
Breakdown by Reconsideration Decision	**10-11**	**11-12**	**12-13**	**13-14**	**14-15**	**Final Decision in Dispute**	**Submission Status as May 25 2015**
Total Received	**0**	**1**	**0**	**0**	**0**		
Total Denied	***0***	***1***	***0***	***0***	***0***		
Denied		1				New Drug Letter	Rejected

PERFORMANCE

Review Cycle Completions - DIND

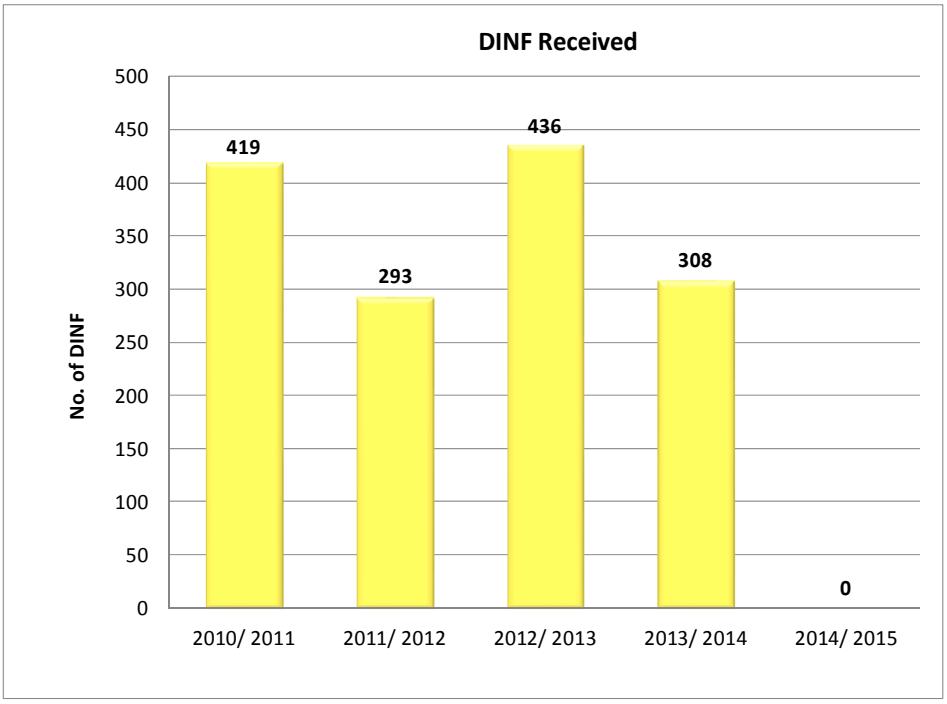


Screening Cycle Completions - DIND

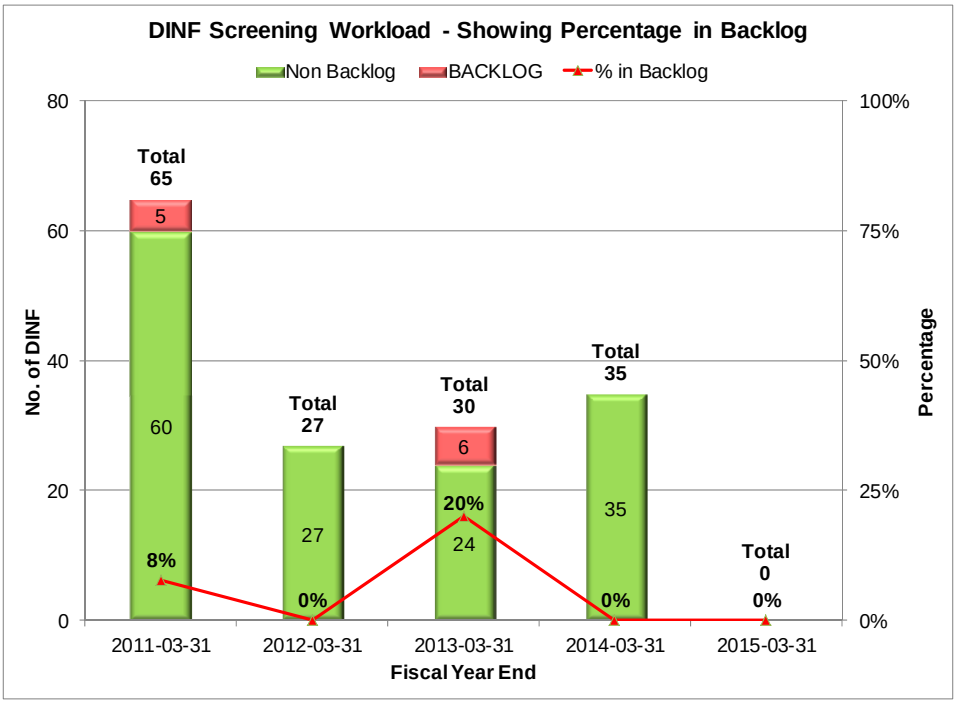


DINF: CATEGORY IV PRODUCT - (LABELLING STANDARD)[12]

Number Received - DINF



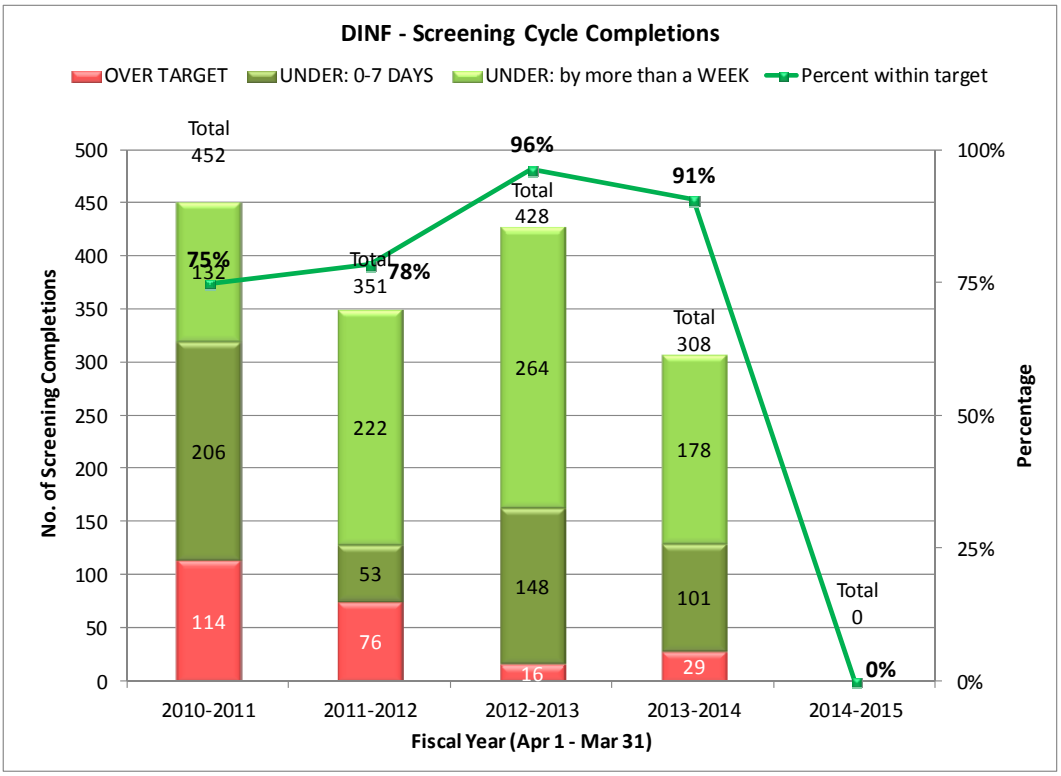
Screening Workload / Backlog – Showing Percentage in Backlog – DINF



[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 **Appendix B: Non-Prescription and Disinfectant Drugs**.

PERFORMANCE

Screening Cycle Completions - DINF



DECISION DOCUMENTS

Decision Documents – DINF - Labelling Standard

DINF - LABELLING STANDARD					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NOTIFICATION FORM/DIN ISSUED	294	176	325	286	-
NO OBJECTION LETTER		2	4	1	-
CANCELLED BY COMPANY	12	16	74	11	-
DIN INCORR SUBTYPE-CLASS	6	6	5	1	-
NEW DRUG LETTER SCREEN	4	1	1		-
NOT SATISFACTORY NOTICE					-
REJECTION LETTER (SCREENING)	97	69	32	8	-
SCREENING DEFICIENCY NOTICE	59	25	45	12	-
SPONSOR SUB CHANGE ACCEPT				1	-

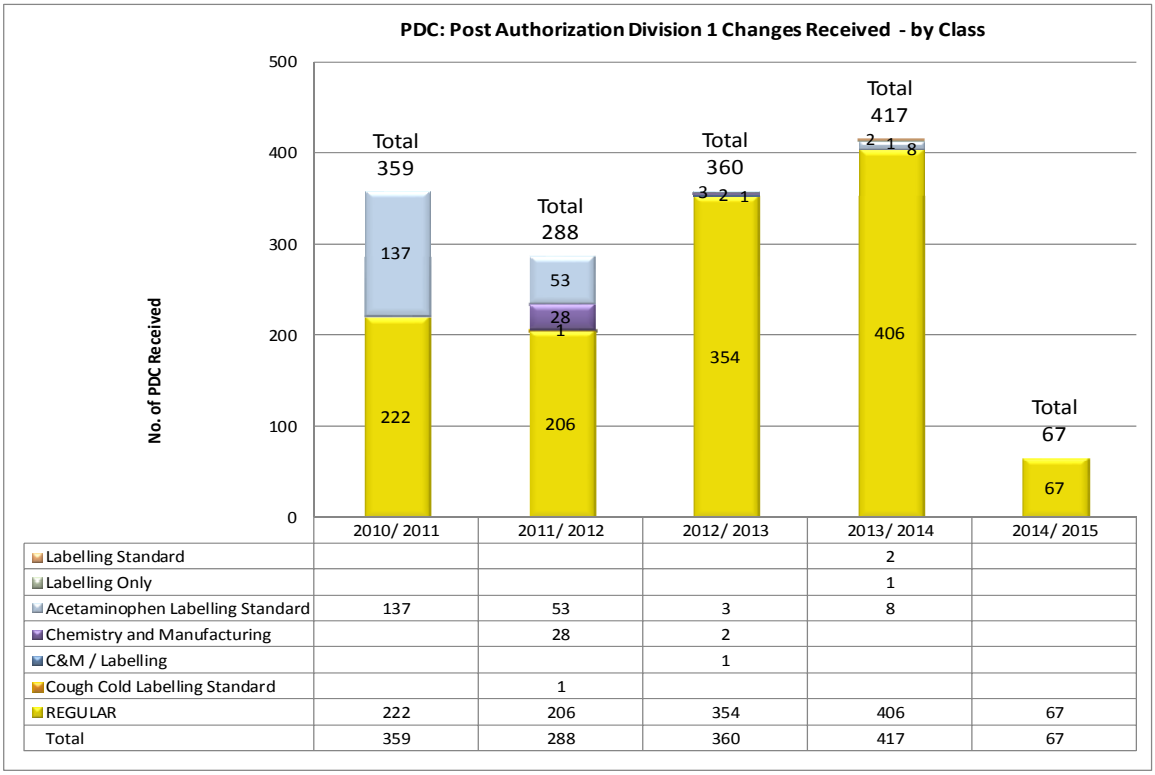
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – DINF

DINF - Reconsideration of Final Decisions by Year Requested Fiscal Year of Request (Arp - Mar)							
Breakdown by Reconsideration Decision	**10-11**	**11-12 * revised**	**12-13**	**13-14**	**14-15**	**Final Decision in Dispute**	**Submission Status as May 25 2015**
Total Received	**2**	**1**	**2**	**0**	**0**		
Total Granted	***2***	***0***	***0***	***0***	***0***		
Granted						New Drug Letter	Rejected
Granted	1					New Drug Letter	Cleared
Granted	1					Rejection at Screening	Cleared
Total Denied	0	1	1	0	0	Rejection at Screening	Rejected
Total Cancelled by Company	0	0	1	0	0	Rejection at Screening	Rejected

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

Post-Authorization Division 1 Changes (PDC) Received



	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
Labelling Standard				2	
Labelling Only				1	
Acetaminophen Labelling Standard	137	53	3	8	
Chemistry and Manufacturing		28	2		
C&M / Labelling			1		
Cough Cold Labelling Standard		1			
REGULAR	222	206	354	406	67
Total	359	288	360	417	67

[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 **Appendix B: Non-Prescription and Disinfectant Drugs**.

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

PDC					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
COUGH COLD LABELLING STANDARD					
NO OBJECTION LETTER	3	1			
NOT SATISFACTORY NOTICE	1				
ACETAMINOPHEN LS					
CANCELLED BY COMPANY	2	1			
NO OBJECTION LETTER	97	69	1	10	
NOT SATISFACTORY NOTICE	31	10			
REGULAR					
CANCELLED BY COMPANY		8	17	16	7
NO OBJECTION LETTER	177	174	251	362	67
NOT SATISFACTORY NOTICE	46	16	51	15	
NOTIFICATION FORM/DIN ISSUED	5	1			
REJECTION LETTER (SCREENING)	1	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 (Arp - Mar)

Breakdown by Reconsideration Decision	10-11	11-12	12-13* revised	13-14	14-15	Final Decision in Dispute	Submission Status as May 25 2015
Total Received	**0**	**1**	**0**	**2**	**0**		
Total Cancelled by Company				2		Not Satisfactory Notice	Rejected
Total DENIED		1	*			Not Satisfactory Notice	Rejected

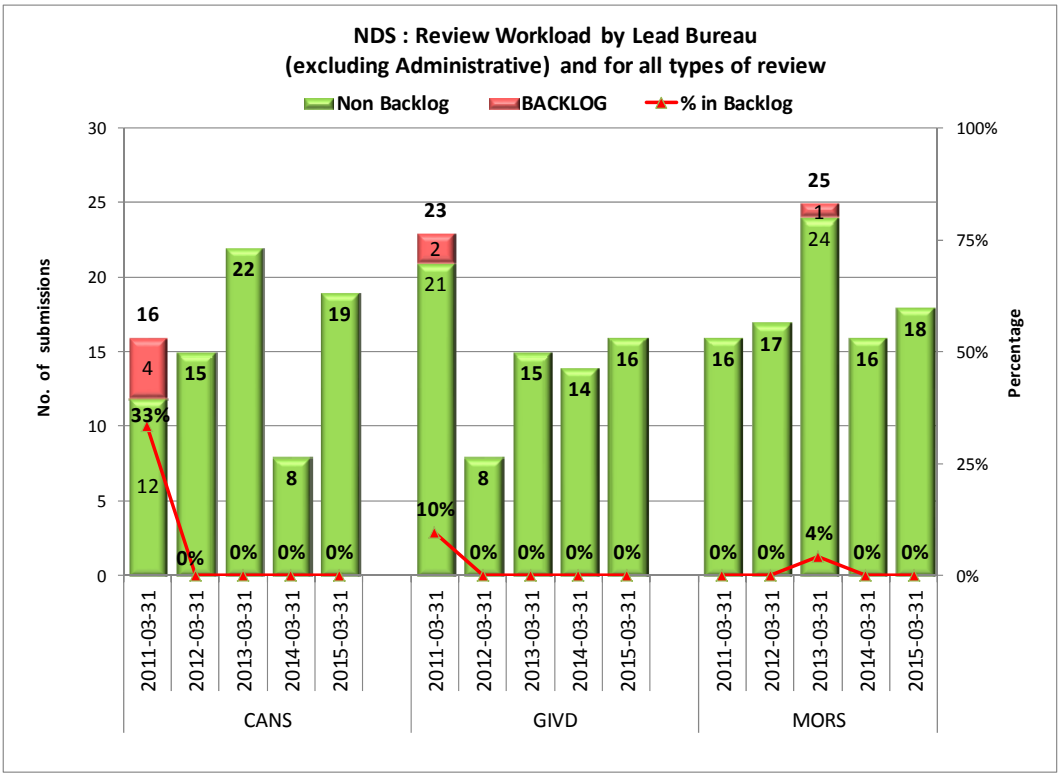
This page is left blank intentionally

APPENDIX A - Lead Bureau Summaries

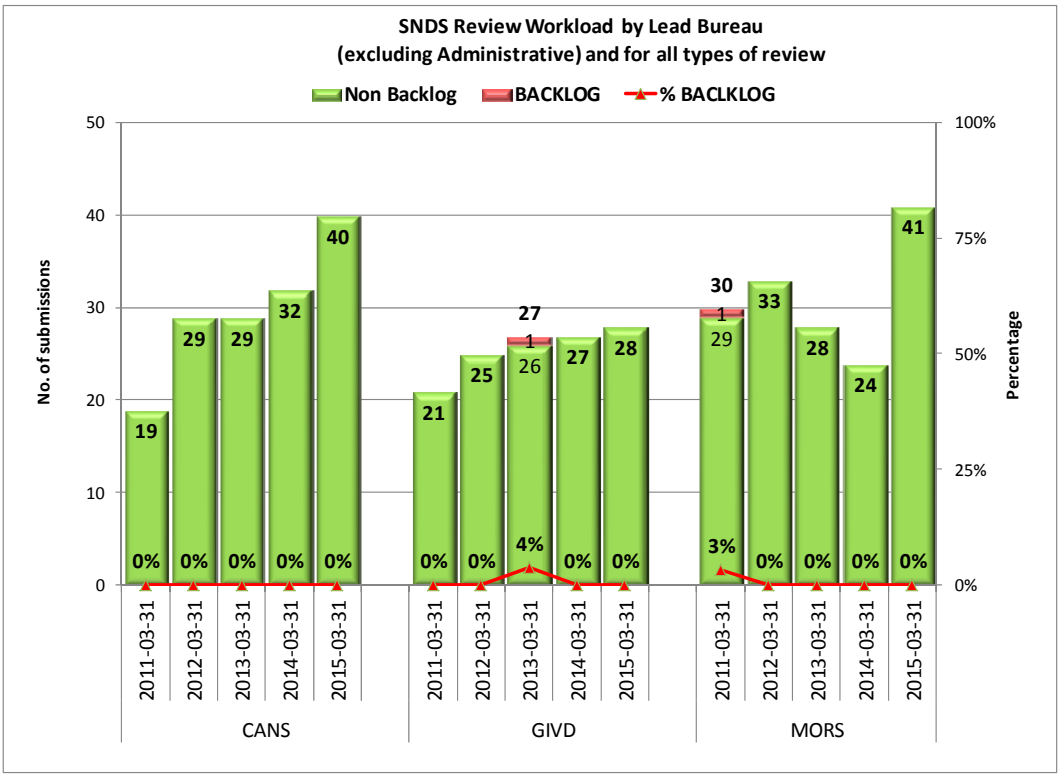
NDS & SNDS

WORKLOAD by Lead Bureau

NDS Review Workload by Lead Bureau

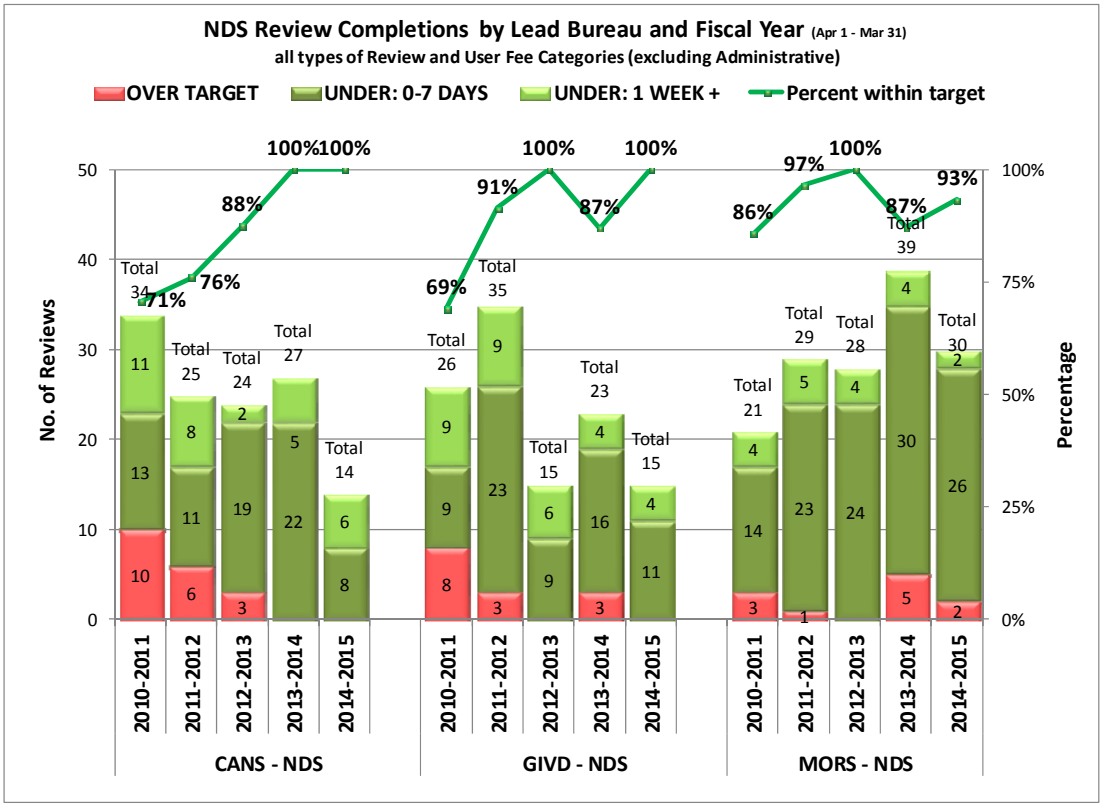


SNDS Review Workload by Lead Bureau

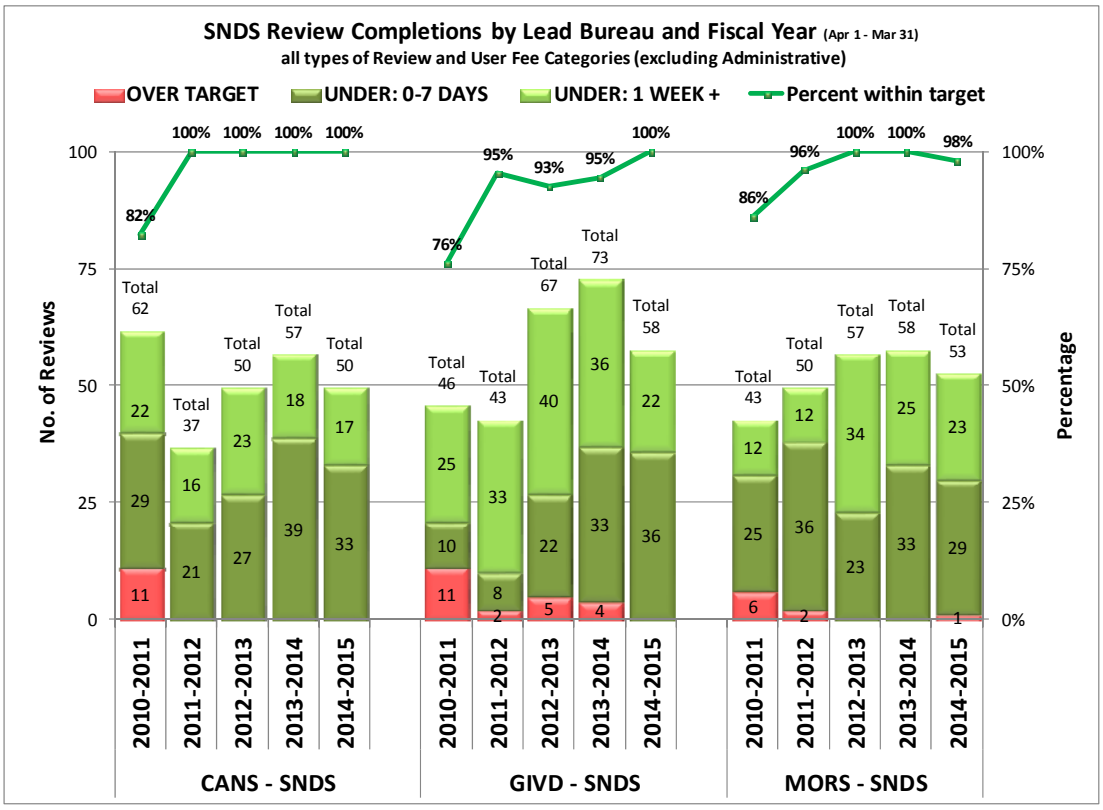


PERFORMANCE by Lead Bureau

NDS Review Performance by Lead Bureau

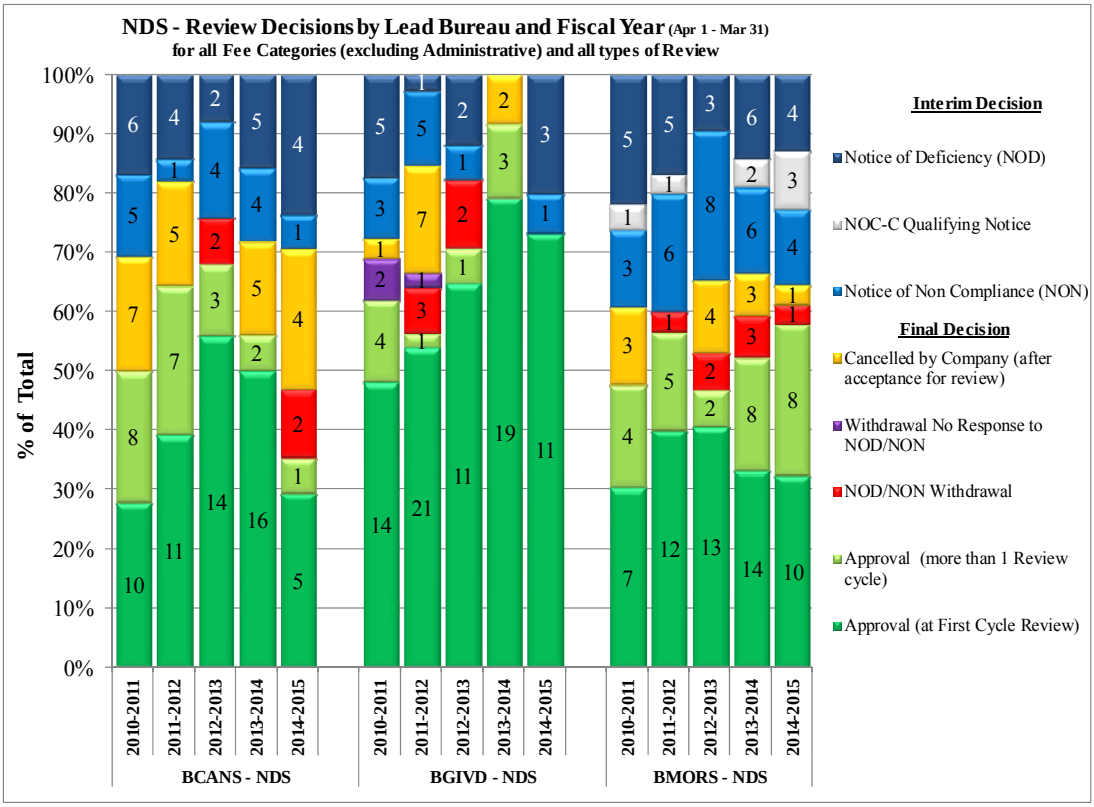


SNDS Review Performance by Lead Bureau

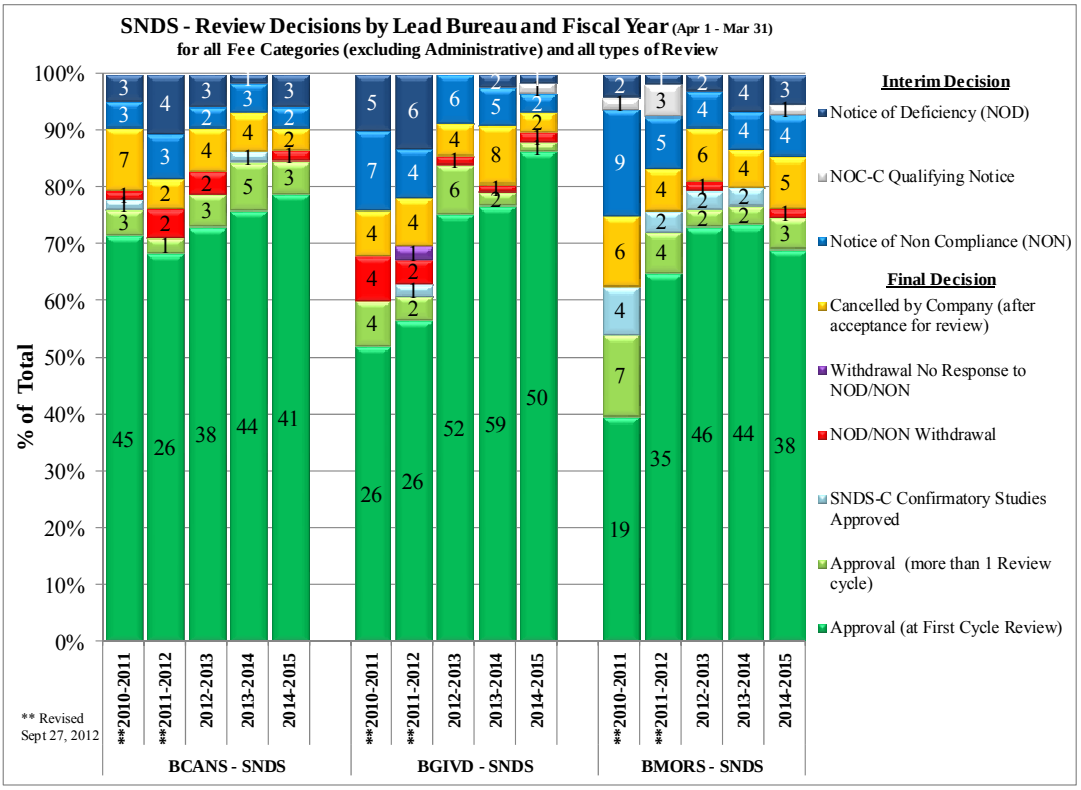


REVIEW DECISIONS by Lead Bureau

NDS Review Decisions by Lead Bureau

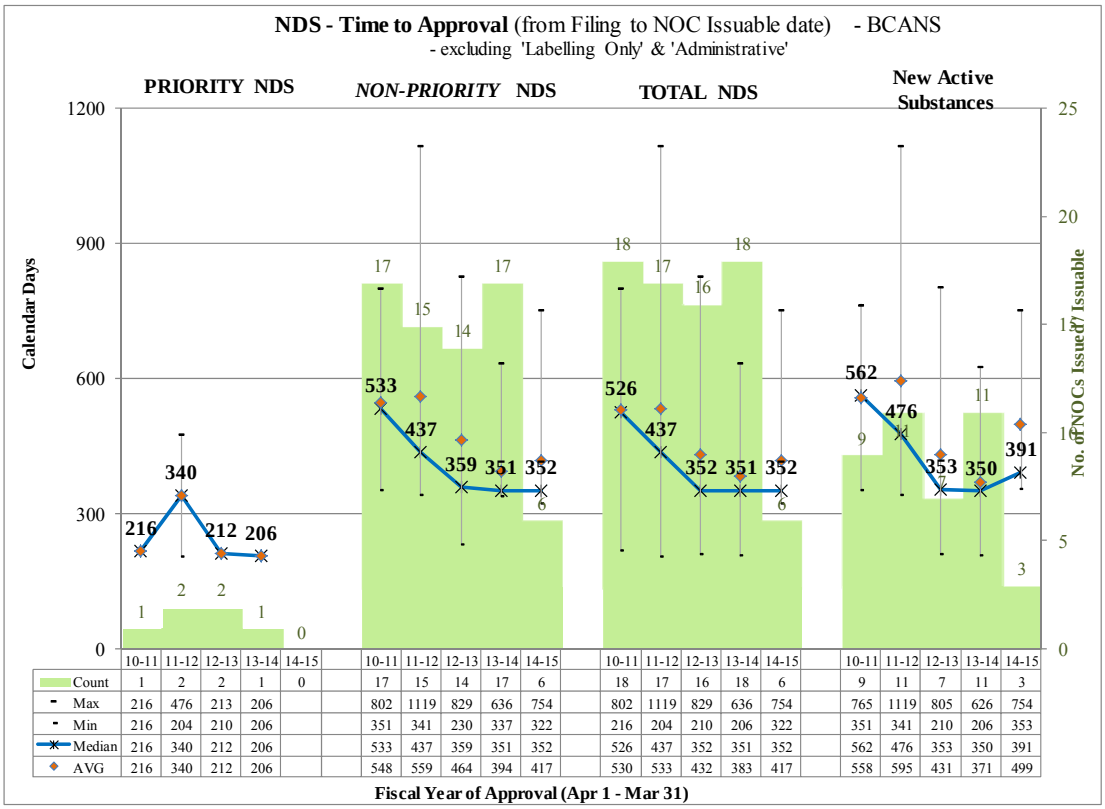


SNDS Review Decisions by Lead Bureau



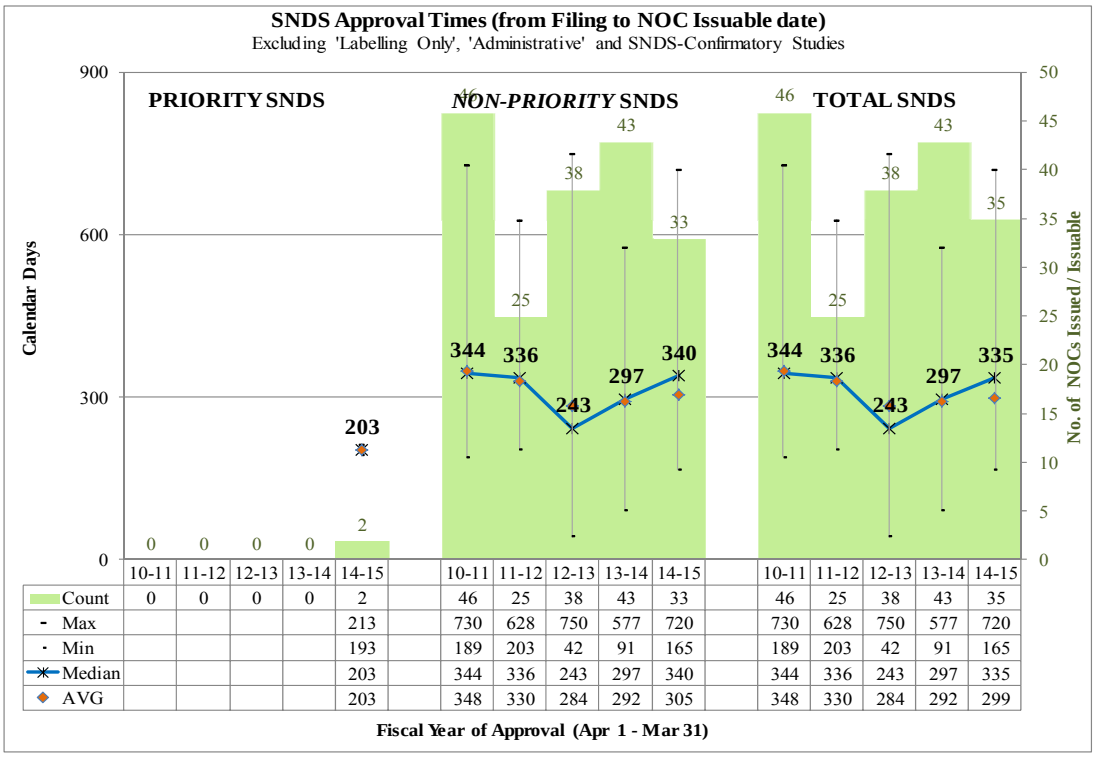
APPROVALS by Lead Bureau

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



	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15
Count	1	2	2	1	0	17	15	14	17	6	18	17	16	18	6	9	11	7	11	3
Max	216	476	213	206		802	1119	829	636	754	802	1119	829	636	754	765	1119	805	626	754
Min	216	204	210	206		351	341	230	337	322	216	204	210	206	322	351	341	210	206	353
Median	216	340	212	206		533	437	359	351	352	526	437	352	351	352	562	476	353	350	391
AVG	216	340	212	206		548	559	464	394	417	530	533	432	383	417	558	595	431	371	499

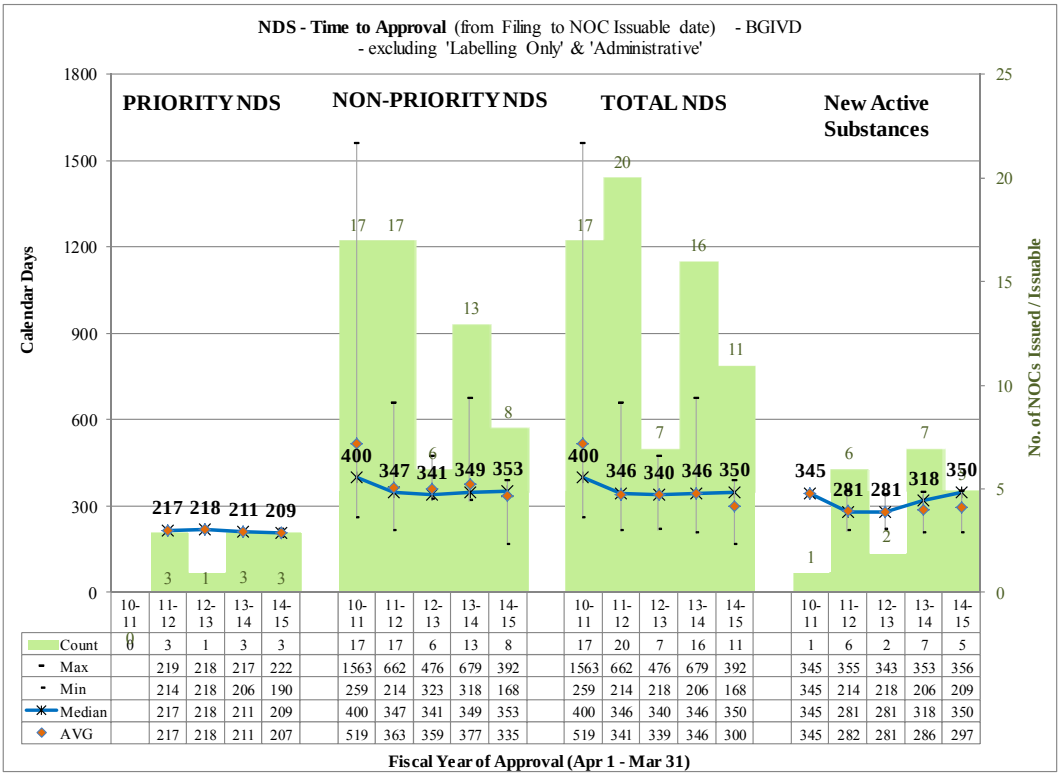
SNDS Approvals – Bureau of Cardiology, Allergy and Neurological Sciences (BCANS)



	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15
Count	0	0	0	0	2	46	25	38	43	33	46	25	38	43	35
Max					213	730	628	750	577	720	730	628	750	577	720
Min					193	189	203	42	91	165	189	203	42	91	165
Median					203	344	336	243	297	340	344	336	243	297	335
AVG					203	348	330	284	292	305	348	330	284	292	299

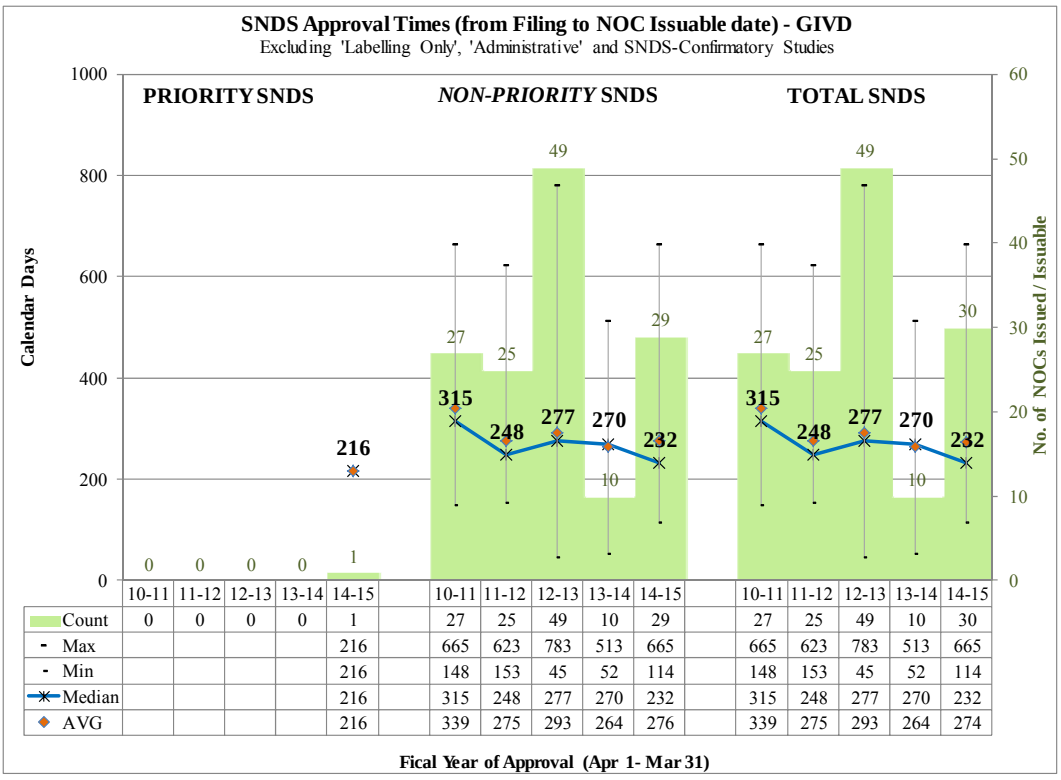
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

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



	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15
Count	0	3	1	3	3	17	17	6	13	8	17	20	7	16	11	1	6	2	7	5
Max		219	218	217	222	1563	662	476	679	392	1563	662	476	679	392	345	355	343	353	356
Min		214	218	206	190	259	214	323	318	168	259	214	218	206	168	345	214	218	206	209
Median		217	218	211	209	400	347	341	349	353	400	346	340	346	350	345	281	281	318	350
AVG		217	218	211	207	519	363	359	377	335	519	341	339	346	300	345	282	281	286	297

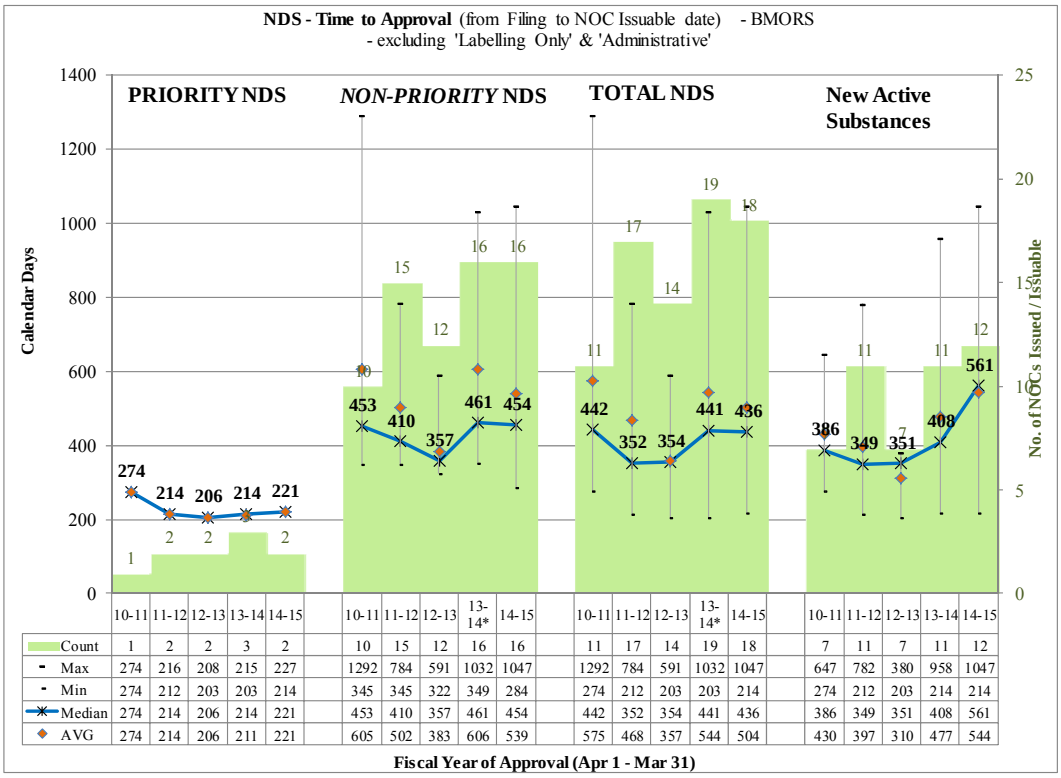
SNDS Approvals – Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD)



	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15
Count	0	0	0	0	1	27	25	49	10	29	27	25	49	10	30
Max					216	665	623	783	513	665	665	623	783	513	665
Min					216	148	153	45	52	114	148	153	45	52	114
Median					216	315	248	277	270	232	315	248	277	270	232
AVG					216	339	275	293	264	276	339	275	293	264	274

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

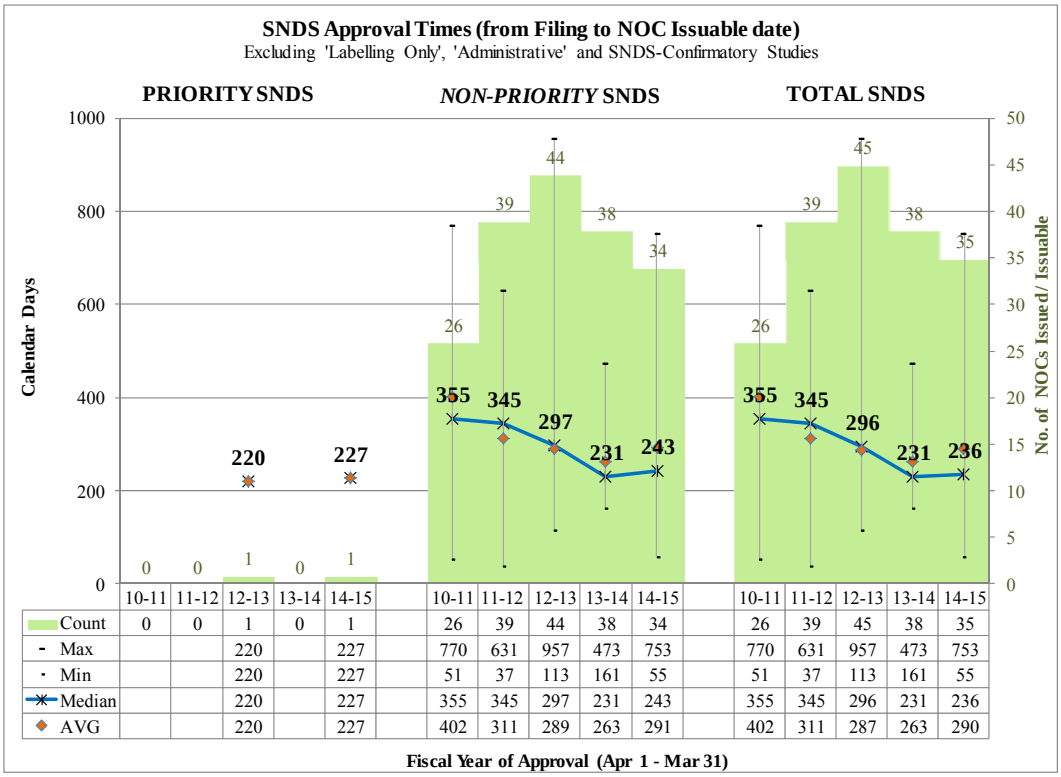
NDS Approvals – Bureau of Metabolism, Oncology & Reproductive Sciences (BMORS)



	PRIORITY NDS					NON-PRIORITY NDS					TOTAL NDS					New Active Substances				
	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14*	14-15	10-11	11-12	12-13	13-14*	14-15	10-11	11-12	12-13	13-14	14-15
Count	1	2	2	3	2	10	15	12	16	16	11	17	14	19	18	7	11	7	11	12
Max	274	216	208	215	227	1292	784	591	1032	1047	1292	784	591	1032	1047	647	782	380	958	1047
Min	274	212	203	203	214	345	345	322	349	284	274	212	203	203	214	274	212	203	214	214
Median	274	214	206	214	221	453	410	357	461	454	442	352	354	441	436	386	349	351	408	561
AVG	274	214	206	211	221	605	502	383	606	539	575	468	357	544	504	430	397	310	477	544

*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)



	PRIORITY SNDS					NON-PRIORITY SNDS					TOTAL SNDS				
	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15
Count	0	0	1	0	1	26	39	44	38	34	26	39	45	38	35
Max			220		227	770	631	957	473	753	770	631	957	473	753
Min			220		227	51	37	113	161	55	51	37	113	161	55
Median			220		227	355	345	297	231	243	355	345	296	231	236
AVG			220		227	402	311	289	263	291	402	311	287	263	290

Appendix B

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

Non-Prescription Drugs: Submission Types Received

Division 1 Related	
SUBMISSION TYPE - USER FEE CATEGORY	**2014/2015**
DIN APPLICATION (DINA)	
DINA - ADMINISTRATIVE SUBMISSION	100
DINA - CHEMISTRY AND MANUFACTURING	4
DINA - CLINICAL OR NON CLINICAL-DATA	3
DINA - LABELLING ONLY	54
DINA - LABELLING STANDARD	33
DINA - PUBLISHED DATA ONLY	2
DINA Total	***196***
DIN APPLICATION - CATEGORY FOUR (DINF)	
DINF - LABELLING STANDARD	195
POST-AUTHORIZATION DIVISION 1 CHANGE (PDC)	
PDC - REGULAR	254
Division 8 Related	
SUBMISSION TYPE - USER FEE CATEGORY	**2014/2015**
NEW DRUG SUBMISSION (NDS)	
NDS - CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	4
NDS - LABELLING ONLY	7
NDS - PRESCRIPTION TO NON-PRESCRIPTION SWITCH	1
NDS Total	***12***
SUPPLEMENTAL NEW DRUG SUBMISSION (SNDS)	
SNDS - CHEMISTRY AND MANUFACTURING	1
SNDS - LABELLING ONLY	7
SNDS Total	***8***
NOTIFIABLE CHANGE - NEW DRUG (NC)	
NC - SAFETY 90	15

Non-Prescription Drugs: Submission Workload/ Backlog

DIVISION 1 Related		Workload on March 31, 2015		
Cycle Type	SUBMISSION TYPE - USER FEE CATEGORY	Non-Backlog	In Backlog	*Total*
	DIN APPLICATION (DINA)			
Admin Screening	DINA - ADMINISTRATIVE SUBMISSION	4	0	**4**
REVIEW	DINA - CHEMISTRY AND MANUFACTURING	1	0	**1**
	DINA - CLINICAL OR NON-CLINICAL DATA	2	0	**2**
	DINA - LABELLING ONLY	24	0	**24**
	DINA - PUBLISHED DATA ONLY	2	0	**2**
	DINA in Review Total	*29*	*0*	***29***
SCREENING	DINA - LABELLING ONLY	6	0	**6**
	DINA - LABELLING STANDARD	2	0	**2**
	DINA in Screening Total	*8*	*0*	***8***
SCREENING	**DIN APPLICATION - CATEGORY FOUR (DINF)**			
	DINF - LABELLING STANDARD	5	1	**6**
SCREENING	**POST-AUTHORIZATION DIVISION 1 CHANGE (PDC)**			
	PDC - REGULAR	7	0	**7**

DIVISION 8 Related		Workload on March 31, 2015		
Cycle Type	SUBMISSION TYPE - USER FEE CATEGORY	Non-Backlog	In Backlog	*Total*
REVIEW	**NEW DRUG SUBMISSION (NDS)**			
	NDS - CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	4	0	**4**
	NDS - LABELLING ONLY	2	0	**2**
	NDS in Review Total	*6*	*0*	***6***
REVIEW	**SUPPLEMENTAL NEW DRUG SUBMISSION (SNDS)**			
	SNDS - LABELLING ONLY	2	0	**2**
	SNDS - CHEMIDTRY AND MANUFACTURING	1	0	**1**
	SNDS in Review Total	*3*	*0*	***3***
REVIEW	**NOTIFIABLE CHANGE - NEW DRUG (NC)**			
	NC - SAFETY 90	2	0	**2**
SCREENING	**NEW DRUG SUBMISSION (NDS)**			
	NDS - PRESCRIPTION TO NON-PRESCRIPTION SWITCH	1	0	***1***
	NDS in Review Total	*1*	*0*	***1***

Non-Prescription Drugs: Performance

DIVISION 1 Related				Performed 2014/2015		
Cycle Type	Submission Type - User Fee Category	Status- Iteration	*Perf. Std days*	Within Target	Over Target	Total
	DINA: DIN APPLICATION					
Admin Screening	DINA - ADMINISTRATIVE SUBMISSION	ADMIN-SCREENING - 1	*45*	93	7	**100**
		ADMIN-SCREENING - 2	*45*	2	0	**2**
	DINA Administrative Screening Total			*95*	*7*	***102***
REVIEW	DINA - CHEMISTRY AND MANUFACTURING	REVIEW 1 - 1	*210*	6	0	**6**
		REVIEW 1 - 2	*210*	1	0	**1**
	DINA - COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	REVIEW 1 - 1	*210*	1	0	**1**
	DINA - CLINICAL OR NON-CLINICAL DATA	REVIEW 1 - 1	*210*	2	0	**2**
	DINA - LABELLING ONLY	REVIEW 1 - 1	*180*	63	0	**63**
		REVIEW 2 - 1	*120*	0	8	**8**
	DINA Review Total			*73*	*8*	***81***
SCREENING	DINA - CHEMISTRY AND MANUFACTURING	SCREENING 1 - 1	*45*	4	0	**4**
		SCREENING 1 - 2	*45*	1	0	**1**
	DINA - CLINICAL OR NON-CLINICAL DATA	SCREENING 1 - 1	*45*	3	0	**3**
		SCREENING 1 - 2	*45*	1	0	**1**
	DINA - COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	SCREENING 1 - 1	*45*	1	0	**1**
	DINA - LABELLING ONLY	SCREENING 1 - 1	*45*	56	0	**56**
		SCREENING 1 - 2	*45*	22	0	**22**
		SCREENING 2 - 1	*45*	8	0	**8**
	DINA - LABELLING STANDARD	SCREENING 1 - 1	*45*	29	0	**29**
		SCREENING 1 - 2	*45*	8	0	**8**
	DINA - PUBLISHED DATA ONLY	SCREENING 1 - 1	*45*	2	0	**2**
		SCREENING 1 -2	*45*	1	0	**1**
	DINA Screening Total			*136*	*0*	***136***
SCREENING	**DINF: DIN APPLICATION - CATEGORY FOUR**					
	DINF - LABELLING STANDARD	SCREENING 1 - 1	*45*	226	4	**230**
		SCREENING 1 - 2	*45*	11	0	**11**
	DINF Screening Total			*237*	*4*	**241**
SCREENING	**PDC: POST-AUTHORIZATION DIVISION 1 CHANGE**					
	PDC - REGULAR	SCREENING 1 - 1	*30*	219	37	**256**

DIVISION 8 Related				Performed 2014/2015		
Cycle Type	Submission Type - User Fee Category	Status- Iteration	*Perf. Std days*	Within Target	Over Target	Total
REVIEW	**ANDS: ABBREVIATED NEW DRUG SUBMISSION**					
	ANDS - LABELLING ONLY	REVIEW RECONSID - 1	*115*	1	0	**1**
REVIEW	**NDS: NEW DRUG SUBMISSION**					
	NDS - COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	REVIEW 1 - 1	*180*	2	0	**2**
	NDS - PRESCRIPTION TO NON-PRESCRIPTION SWITCH	REVIEW 1 - 1	*180*	1	0	**1**
	NDS - LABELLING ONLY	REVIEW 1 - 1	*60*	5	0	**5**
	NDS Review Total			*8*	*0*	**8**
REVIEW	**SNDS: SUPPLEMENTAL NEW DRUG SUBMISSION**					
	SNDS - CLINICAL OR NON-CLINICAL DATA	REVIEW 1 - 1	*300*	3	0	**3**
	SNDS - COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	REVIEW 1 - 1	*180*	1	0	**1**
		REVIEW 1 - 2	*180*	0	1	**1**
	SNDS - LABELLING ONLY	REVIEW 1 - 1	*60*	5	0	**5**
	SNDS - PUBLISHED DATA ONLY	REVIEW 1 - 1	*300*	1	0	**1**
	SNDS Review Total			*10*	*1*	***11***
REVIEW	**NC: NOTIFIABLE CHANGE - NEW DRUG**					
	NC - SAFETY 90	REVIEW 1 - 1	*90*	17	0	**17**
SCREENING	**NDS: NEW DRUG SUBMISSION**					
	NDS - COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	SCREENING 1 - 1	*45*	1	0	**1**
	NDS - CLINICAL OR NON-CLINICAL DATA	SCREENING 1 - 1	*45*	4	0	**4**
		SCREENING 1 - 2	*45*	3	0	**3**
	NDS - LABELLING ONLY	SCREENING 1 - 1	*45*	7	0	**7**
		SCREENING 1 - 2	*45*	0	1	**1**
	NDS Screening Total			*15*	*1*	***16***
SCREENING	**SNDS: SUPPLEMENTAL NEW DRUG SUBMISSION**					
	SNDS - COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	SCREENING 1 - 2	*45*	1	0	**1**
	SNDS - LABELLING ONLY	SCREENING 1 - 1	*7*	7	0	**7**
		SCREENING 1 - 2	*7*	0	1	**1**
	SNDS - CHEMISTRY AND MANUFACTURING	SCREENING 1 - 1	*45*	1	0	**1**
	SNDS Screening Total			*9*	*1*	***10***
SCREENING	**NC: NOTIFIABLE CHANGE - NEW DRUG**					
	NC - SAFETY 90	SCREENING 1 - 1	*7*	16	0	**16**

Non-Prescription Drugs: Decisions

Division 1 Related

Subm Type Code	Submission Type	User Fee Category	Decision	2014/2015
DINA	DIN APPLICATION	ADMINISTRATIVE SUBMISSION	CANCELLATION LETTER	6
			NOTIFICATION FORM DIN SUB	86
			REJECTION LETTER (SCR)	11
			SCREENING DEFICIENCY NOTICE	6
		CHEMISTRY AND MANUFACTURING	NOTICE OF DEFICIENCY	1
			NOTIFICATION FORM DIN SUB	5
			NO OBJECTION LETTER	1
		CLINICAL OR NON-CLINICAL DATA	NOTIFICATION FORM DIN SUB	2
			SCREENING DEFICIENCY NOTICE	1
		COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTIFICATION FORM DIN SUB	1
		LABELLING ONLY	CANCELLATION LETTER	5
			DIN INCORR SUBTYPE-CLASS	11
			NO OBJECTION LETTER	2
			NOTICE OF NON-COMPLIANCE	3
			NOTIFICATION FORM DIN SUB	63
			REJECTION LETTER (SCR)	1
			SCREENING DEFICIENCY NOTICE	11
		LABELLING STANDARD	CANCELLATION LETTER	2
			NOTIFICATION FORM DIN SUB	25
			REJECTION LETTER (SCR)	2
			SCREENING DEFICIENCY NOTICE	9
		PUBLISHED DATA	SCREENING DEFICIENCY NOTICE	1
DINF	DIN APPLICATION - CATEGORY FOUR	LABELLING STANDARD	CANCELLATION LETTER	6
			DIN INCORR SUBTYPE-CLASS	4
			NEW DRUG LETTER SCREEN	4
			NOTIFICATION FORM DIN SUB	218
			REJECTION LETTER (SCR)	3
			SCREENING DEFICIENCY NOTICE	11
PDC	POST-AUTHORIZATION DIVISION 1 CHANGE	REGULAR	CANCELLATION LETTER	8
			NO OBJECTION LETTER	241
			NOT SATISFACTORY NOTICE	7
			NOTIFICATION FORM DIN SUB	1

Division 8 Related Decisions:

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

Subm Type Code	Submission Type	User Fee Category	Decision	2014/2015
ANDS	ABBREVIATED NEW DRUG SUBMISSION	LABELLING ONLY	NOTICE OF COMPLIANCE*	1
NDS	NEW DRUG SUBMISSION	CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	3
		COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOC ON HOLD (SWITCH)*	2
		LABELLING ONLY	NOTICE OF COMPLIANCE*	5
			SCREENING DEFICIENCY NOTICE	1
		PRESCRIPTION TO NON-PRESCRIPTION SWITCH	NOC ON HOLD (SWITCH)*	1
SNDS	SUPPLEMENTAL NEW DRUG SUBMISSION	CLINICAL OR NON-CLINICAL DATA	NOC ON HOLD (SWITCH)*	1
			NOTICE OF COMPLIANCE*	2
		COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	2
		LABELLING ONLY	NOC ON HOLD (SWITCH)*	1
			NOTICE OF COMPLIANCE*	4
			SCREENING DEFICIENCY NOTICE	1
			CANCELLATION LETTER	1
		PRESCRIPTION TO NON-PRESCRIPTION SWITCH	NOC ON HOLD (SWITCH)*	0
		PUBLISHED DATA ONLY	CANCELLATION LETTER	1
NC	NOTIFIABLE CHANGE - NEW DRUG	SAFETY 90	NO OBJECTION LETTER	18
			NC-HOLD (SWITCH)	1

Appendix B

Part 2: DISINFECTANTS

Disinfectants - Submissions and DIN applications Received

Division 1 Related	
SUBMISSION TYPE - USER FEE CATEGORY	**2014/2015**
DIN DISINFECTANTS (DIND)	
DIND - ADMINISTRATIVE SUBMISSION	81
DIND - DISINFECTANTS	41
DIND - LABELLING STANDARD	17
DIND Total	***139***
POST-AUTHORIZATION DIVISION 1 CHANGE (PDC)	
PDC - RRGULAR	90
Division 8 Related	
SUBMISSION TYPE - USER FEE CATEGORY	**2014/2015**
PRE - NDS MEETING (MPNDS)	
MPNDS - CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	1
NOTIFIABLE CHANGE - NEW DRUG (NC)	
NC - SAFETY 90	4
NDS-D - NEW DRUG SUBMISSION-DISINFECTANTS	
DISINFECTANTS	1

Disinfectants: Submission Workload/ Backlog

DIVISION 1 Related		Workload on March 31, 2015		
Cycle Type	SUBMISSION TYPE - USER FEE CATEGORY	Non-Backlog	In Backlog	*Total*
	DIND - DIN DISINFECTANTS			
Admin Screening	DIND - ADMINISTRATIVE SUBMISSION	1	0	**1**
REVIEW	DIND - DISINFECTANTS	21	0	**21**
SCREENING	DIND - DISINFECTANTS	4	0	**4**
	DIND in Screening Total	*4*	*0*	**4**
	POST-AUTHORIZATION DIVISION 1 CHANGE (PDC)			
SCREENING	PDC - REGULAR	1	0	**1**

DIVISION 8 Related		Workload on March 31, 2015		
Cycle Type	SUBMISSION TYPE - USER FEE CATEGORY	Non-Backlog	In Backlog	*Total*
	NOTIFIABLE CHANGE - NEW DRUG (NC)			
REVIEW	NC - SAFETY 90	1	0	**1**
	NEW DRUG SUBMISSION (NDS)			
REVIEW	NDS - DISINFECTANTS	1	0	**1**

Disinfectants: Performance

DIVISION 1 Related				Performed 2014/2015		
Cycle Type	USER FEE CATEGORY DESCRIPTION	Status- Iteration	*Perf. Std days*	Within Target	Over Target	**Total**
Admin Screening	**DIN DISINFECTANTS (DIND)**					
	DIND - ADMINISTRATIVE SUBMISSION	ADMIN-SCREENING - 1	*45*	82	8	**90**
		ADMIN-SCREENING - 2	*45*	17	0	**17**
		ADMIN-SCREENING - 3	*45*	1	0	**1**
	DIND Admin-Screening Total			*100*	*8*	**108**
REVIEW	**DIN DISINFECTANTS (DIND)**					
	DIND - DISINFECTANTS	REVIEW 1 - 1	*210*	41	2	**43**
		REVIEW 2 - 1	*150*	3	0	**3**
	DIND Review Total			*44*	*2*	**46**
SCREENING	**DIN DISINFECTANTS (DIND)**					
	DIND - DISINFECTANTS	SCREENING 1 - 1	*45*	41	0	**41**
		SCREENING 1 - 2	*45*	2	2	**4**
		SCREENING 2 - 1	*45*	6	0	**6**
	DIND - LABELLING STANDARD	SCREENING 1 - 1	*45*	17	1	**18**
		SCREENING 1 - 2	*45*	8	0	**8**
	DIND Screening Total			*74*	*3*	**77**
SCREENING	**POST-AUTHORIZATION DIVISION 1 CHANGE (PDC)**					
	PDC - REGULAR	SCREENING 1 - 1	*30*	72	38	**110**

DIVISION 8 Related				Performed 2014/2015		
Cycle Type	**Submission Type - User Fee Category**	Status- Iteration	*Perf. Std days*	Within Target	Over Target	**Total**
REVIEW	**NEW DRUG SUBMISSION (NDS)**					
	NDS - DISINFECTANTS	REVIEW 1 - 1	*300*	3	0	**3**
		REVIEW 2 - 1	*150*	3	0	**3**
	NDS Review Total			6	0	**6**
REVIEW	**NOTIFIABLE CHANGE - NEW DRUG (NC)**					
	NC - SAFETY 90	REVIEW 1 - 1	*90*	2	0	**2**
SCREENING	**NEW DRUG SUBMISSION (NDS)**					
	NDS - DISINFECTANTS	SCREENING 1 - 1	*45*	1	0	**1**
		SCREENING 2 -1	*45*	3	0	**3**
	NDS Screening Total			4	0	**4**
SCREENING	**NOTIFIABLE CHANGE - NEW DRUG (NC)**					
	NC - SAFETY 90	SCREENING 1 - 1	*7*	3	0	**3**

Disinfectants: Decisions

Division 1 Related Decisions

Subm Type Code	Submission Type	User Fee Category	Decision	2014/2015
DIND	DIN DISINFECTANTS	ADMINISTRATIVE SUBMISSION	CANCELLATION LETTER	2
			NO OBJECTION LETTER	1
			DIN INCORR SUBTYPE-CLASS	1
			NOTIFICATION FORM DIN SUB	90
			REJECTION LETTER (SCR)	3
			SCREENING DEFICIENCY NOTICE	14
		DISINFECTANTS	DIN INCORR SUBTYPE-CLASS	2
			NO OBJECTION LETTER	14
			CANCELLATION LETTER	2
			NON WITHDRAWAL LETTER	1
			NOTICE OF NON-COMPLIANCE	8
			NOTIFICATION FORM DIN SUB	25
			SCREENING DEFICIENCY NOTICE	3
			REJECTION LETTER (SCR)	1
			WITH.UNACCEPT.RESP.NON SC	1
		LABELLING STANDARD	NOTIFICATION FORM DIN SUB	18
			SCREENING DEFICIENCY NOTICE	8
			REJECTION LETTER (SCR)	1
PDC	POST-AUTHORIZATION DIVISION 1 CHANGE	REGULAR	CANCELLATION LETTER	2
			NO OBJECTION LETTER	83
			NOT SATISFACTORY NOTICE	24
			REJECTION LETTER (SCR)	1

Division 8 Related Decisions:

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

Subm Type Code	Submission Type	User Fee Category	Decision	2014/2015
NC	NOTIFIABLE CHANGE - NEW DRUG	SAFETY 90	NO OBJECTION LETTER	2
			CANCELLATION LETTER	1
NDS-D	NDS DISINFECTANT	DISINFECTANTS	NOTICE OF NON-COMPLIANCE	3
			NOTICE OF COMPLIANCE*	3

APPENDIX C – Regulatory Activities in eCTD Format

Regulatory Activities in eCTD Format

Overview

This section of the Annual Drug Submission Performance Report for fiscal year 2014/15 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-prescription Health Products Directorate (NNHPD-NDED). The time period for which data is displayed in this report ranges from April 1st, 2010 to March 31st, 2015. 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 has completed the transition to the acceptance of regulatory activities in stand-alone eCTD format and now accepts regulatory activities in eCTD electronic-only filling format that are filed in compliance with the ICH eCTD specification and the posted *"Guidance Document: Preparation of Drug Regulatory Activities in Electronic Common Technical Document (eCTD)".*

Health Canada has started to receive regulatory transactions in eCTD format via the Common Electronic Submission Gateway (CESG). The pilot phase started with a selected number of companies on November 01, 2013. The Gateway has been opened to all industry since January 31, 2014. Health Canada is currently receiving certain regulatory transactions such as Responses to Clarification Requests, Pristine Product Monographs, and Drug Notification Forms, for all regulatory activity types received in eCTD format. The scope of the gateway is outlined in the *Frequently Asked Questions – CESG*.
The transactions are received for TPD, BGTD, MHPD, and NNHPD.

GLOSSARY OF TERMS

eCTD: Electronic Common Technical Document

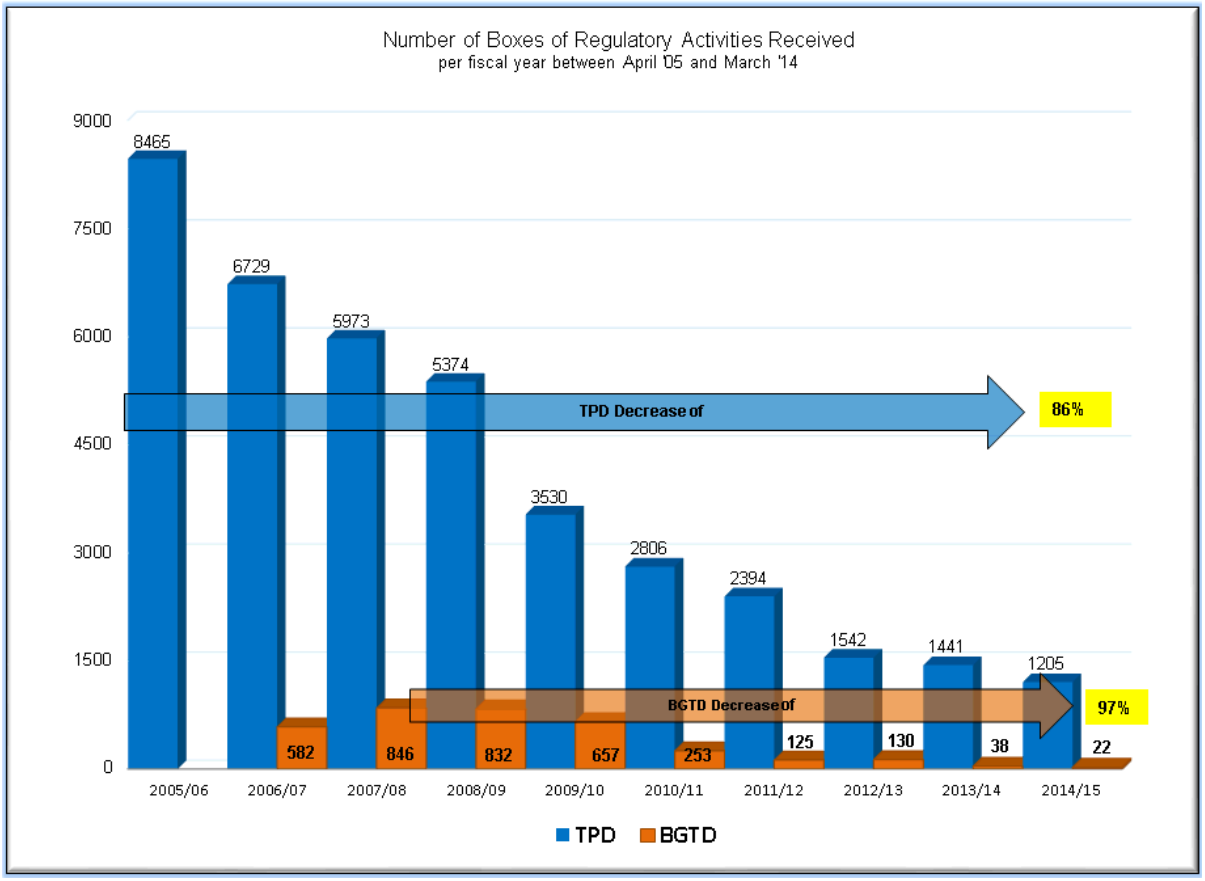
Dossier: A collection of all Regulatory Activities throughout the life cycle of a product (e.g. human drug, veterinary drug, medical device, food).

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, etc.

Regulatory Transaction: Any information package sent by the sponsor as part of a Regulatory Activity such as Initial data, Unsolicited and Solicited data (e.g. response to a clarification request. NON, NOD, pristine PM, DNF, etc.).

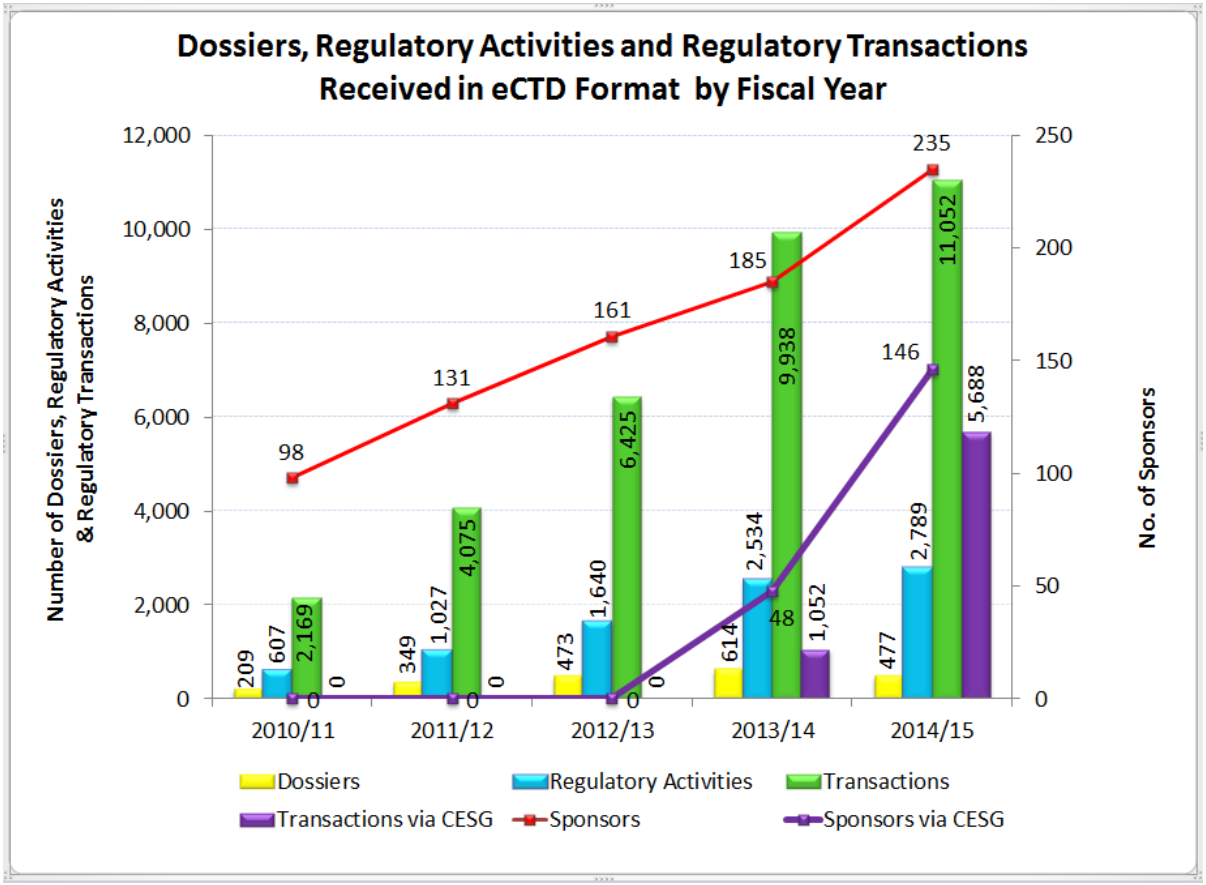
Pharmacovigilance Data (PV Data):
- **PSUR-C:** Periodic Safety Update Reports – Confirmatory
- **PBRER-C:** Periodic Benefit-Risk Evaluation Reports - Confirmatory
- **PSUR-PV:** Periodic Safety Update Reports - Pharmacovigilance
- **PBRER-PV:** Periodic Benefit-Risk Evaluation Reports - Pharmacovigilance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

Number of Boxes of Regulatory Activities Received



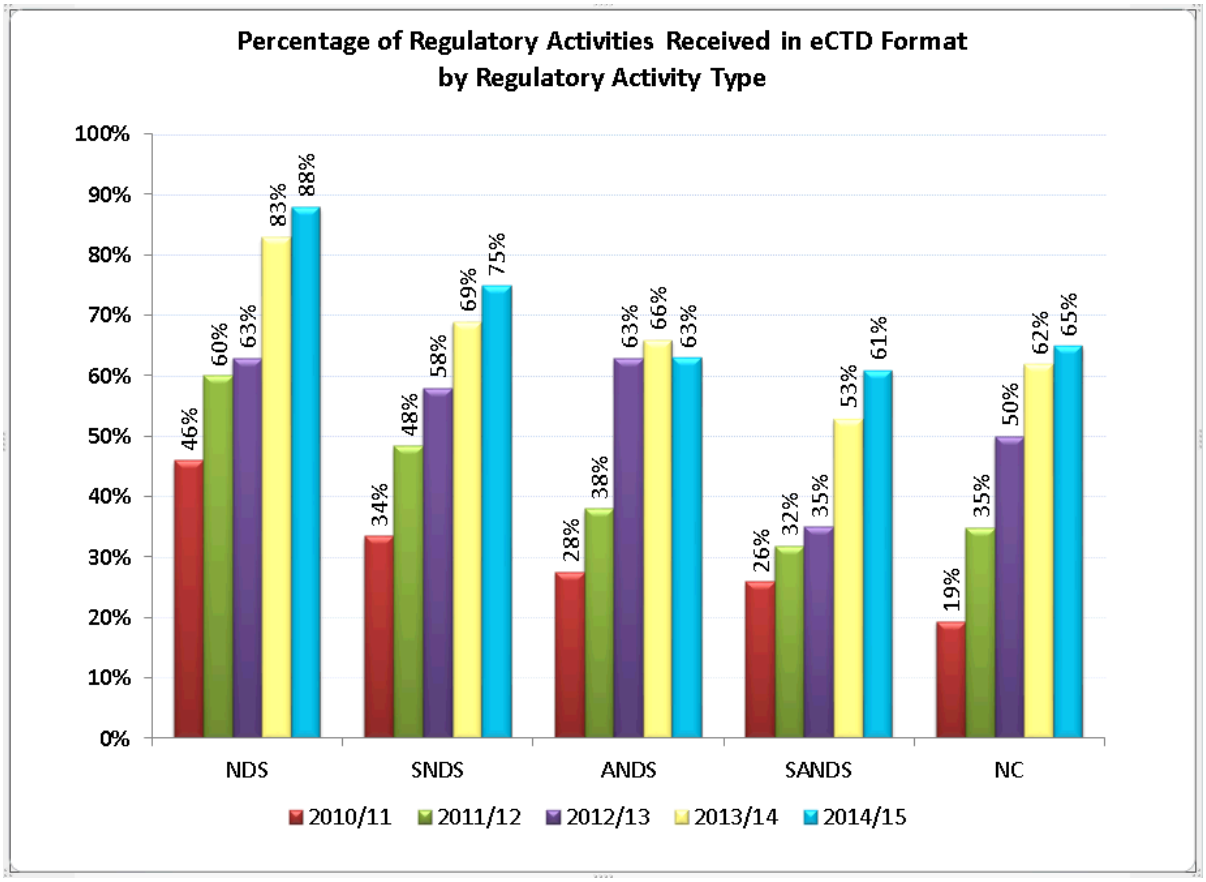
The above chart displays the reduction in boxes of paper Health Canada has received as a result of accepting regulatory activities electronically, both in CTD and eCTD formats.

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



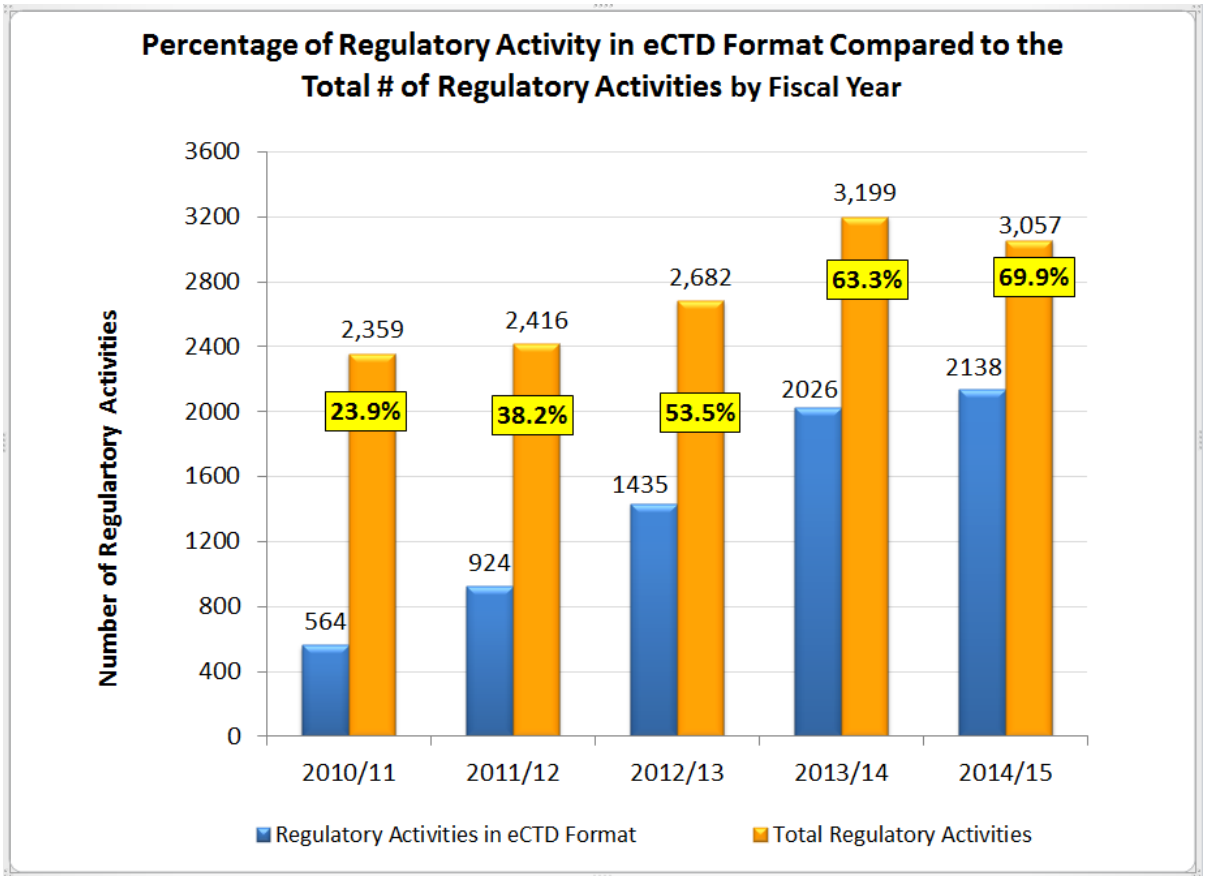
Number of Regulatory Activities Received in eCTD Format by Regulatory Activity Type

Year Filed	NDS	SNDS*	ANDS	SANDS	NC	Total
2014/15	81	251	110	78	1,072	**1,592**
2013/14	67	189	163	62	1,045	**1,526**
2012/13	71	152	129	25	709	**1,086**
2011/12	46	109	94	22	482	**753**
2010/11	41	74	54	15	279	**463**
Total	**306**	**775**	**550**	**202**	**3,587**	**5,420**

* 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.