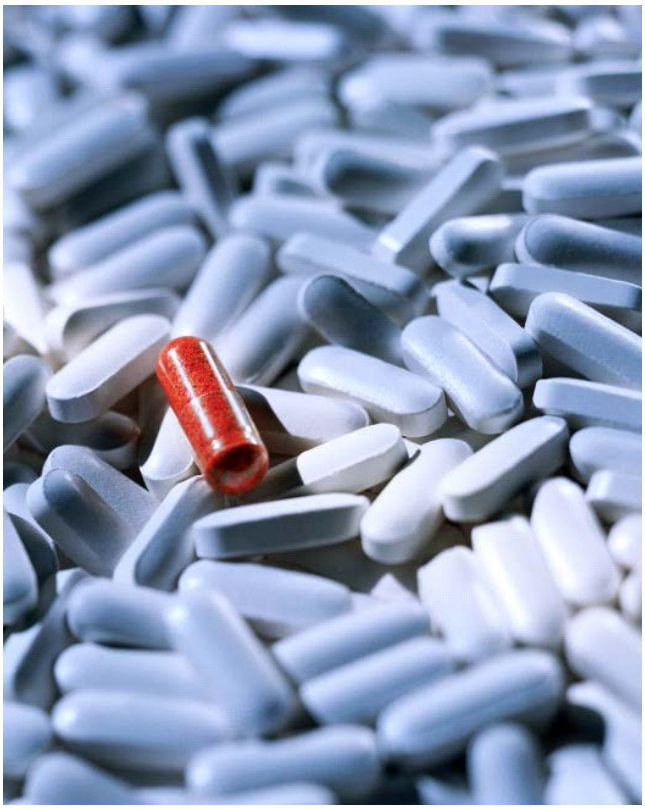
Biologics and Genetic Therapies Directorate
Drug Submission Performance Annual Report

Fiscal Year
2014 – 2015

Apr 1 2014 – Mar 31 2015



Canada

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OVERVIEW

The Biologics and Genetic Therapies Directorate's (BGTD) Annual Drug Submission Performance Report reflects biologic and radiopharmaceutical 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 lists details of Priority Submissions and New Active Substances approved during the fiscal year Apr 1 2014 to March 31 2015.

What's New

The numbers of **Subsequent Entry Biologic NDS**s received and approved have been added to the report.

Clinical Trials: The Clinical Trial Applications and Amendments are now broken down by class.

The numbers of **Post –Authorization Division 1 Changes – Biologic (PDC-B)** received have been added to the report.

General Information

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

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

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

Submissions Received are counts of submissions received during the year using the filing date, which is the date the submission is considered administratively complete by Health Canada.

Workload is the number of submissions "under active review" on a given day.

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

"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 the 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, Biologics and Genetic Therapies 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

CTA	-	Clinical Trial Application
CTA-A	-	Clinical Trial Application-Amendment
DINB	-	Application for a DIN – Biological Product
NDS	-	New Drug Submission
NC	-	Notifiable Change – New Drug
PDC-B		Post-Authorization Division 1 Changes - Biologics
PRNDS	-	Request for Priority Review Status: New Drug Submission
PRSNDS	-	Request for Priority Review Status: Supplemental New Drug Submission
SNDS	-	Supplemental New Drug Submission
SNDS-C	-	Supplemental New Drug Submission – CONFIRMATORY
YBPR	-	Yearly Biologic Product Report

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] Disinfectant and non-prescription (or over the counter) drug review functions were moved from the Therapeutics Products Directorate (TPD) to the Natural and Non-Prescription Health Products Directorate (NNHPD) on July 1 2013.

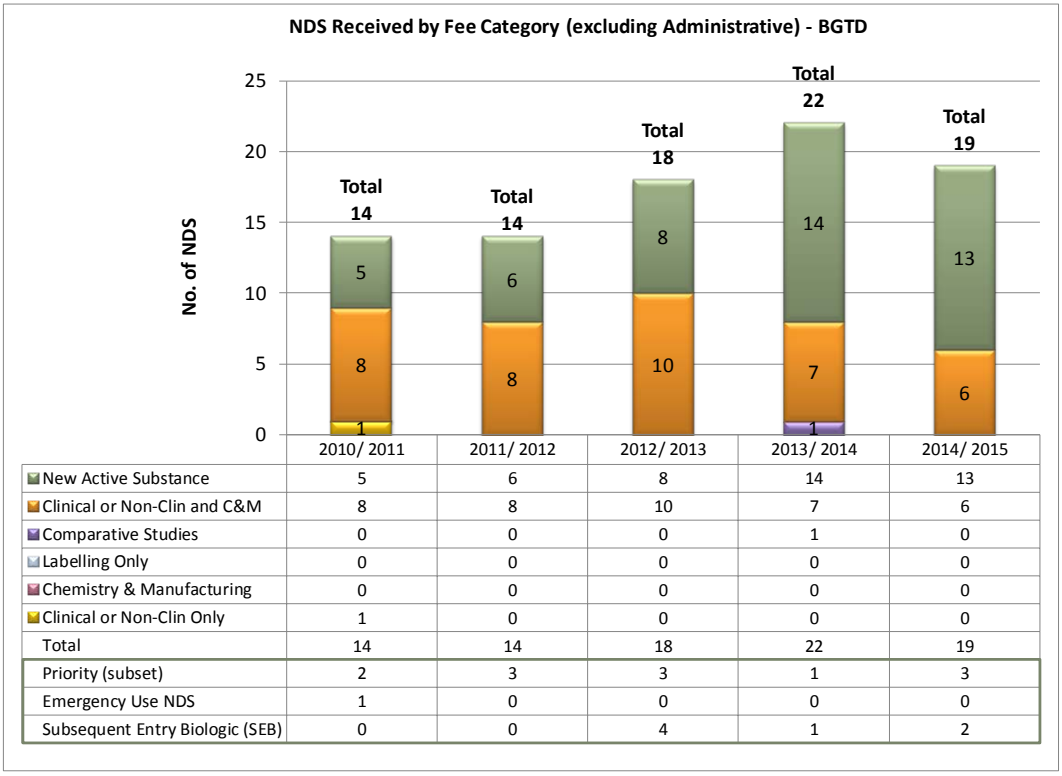
New Drug Submission (NDS)

&

Supplemental New Drug Submission (SNDS)

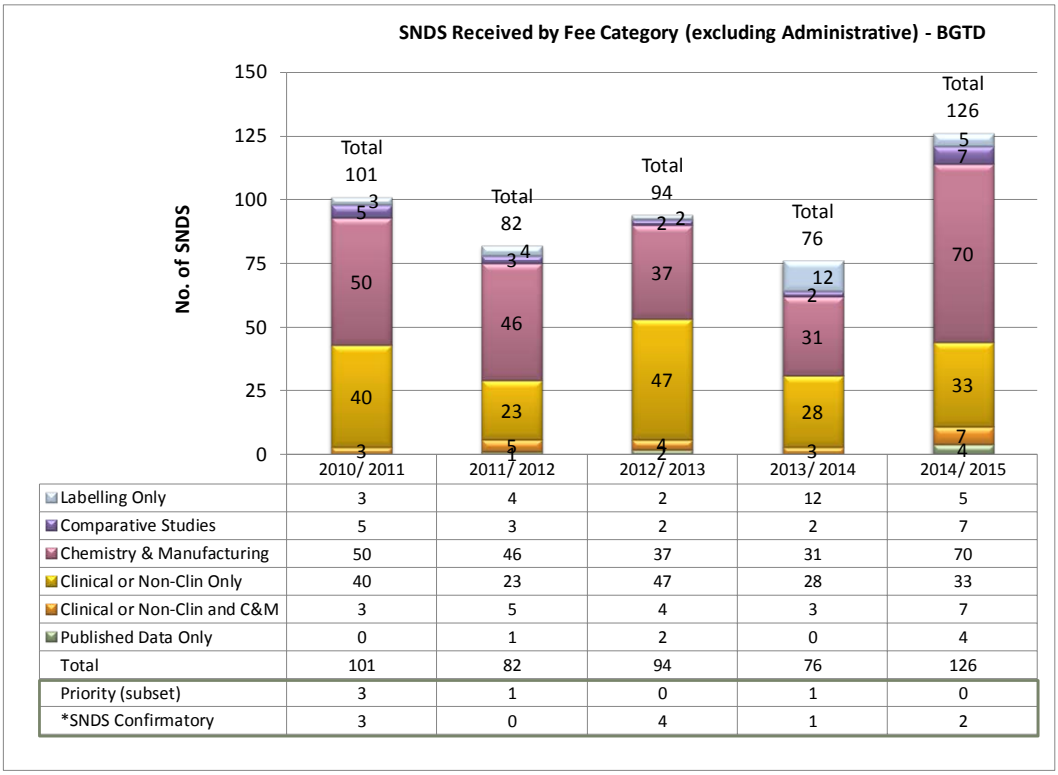
SUBMISSIONS RECEIVED

New Drug Submissions (NDS) Received by Fee Category



	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
New Active Substance	5	6	8	14	13
Clinical or Non-Clin and C&M	8	8	10	7	6
Comparative Studies	0	0	0	1	0
Labelling Only	0	0	0	0	0
Chemistry & Manufacturing	0	0	0	0	0
Clinical or Non-Clin Only	1	0	0	0	0
Total	14	14	18	22	19
Priority (subset)	2	3	3	1	3
Emergency Use NDS	1	0	0	0	0
Subsequent Entry Biologic (SEB)	0	0	4	1	2

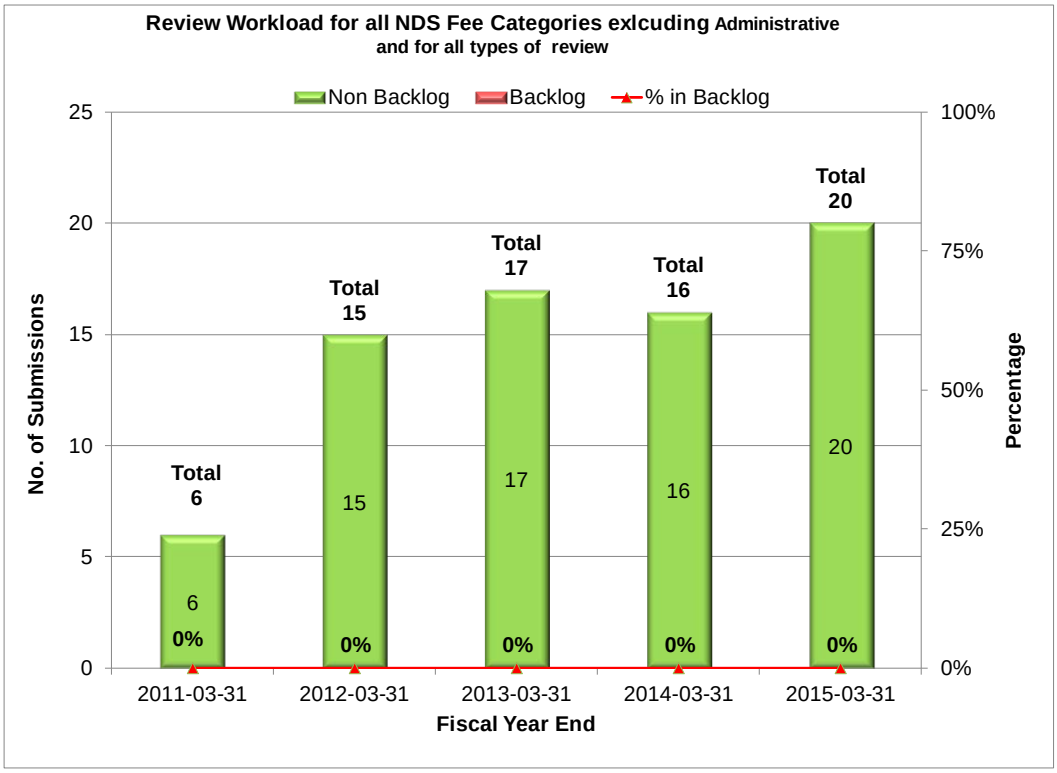
Supplemental New Drug Submissions (SNDS) Received by Fee Category



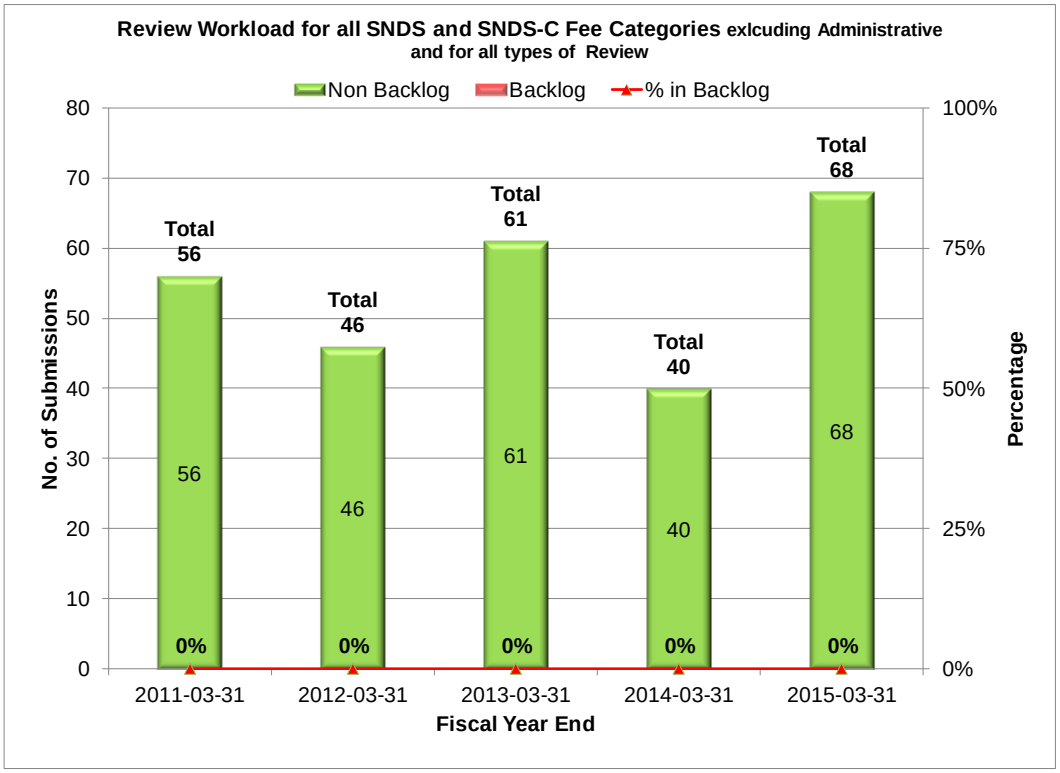
	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
Labelling Only	3	4	2	12	5
Comparative Studies	5	3	2	2	7
Chemistry & Manufacturing	50	46	37	31	70
Clinical or Non-Clin Only	40	23	47	28	33
Clinical or Non-Clin and C&M	3	5	4	3	7
Published Data Only	0	1	2	0	4
Total	101	82	94	76	126
Priority (subset)	3	1	0	1	0
*SNDS Confirmatory	3	0	4	1	2

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

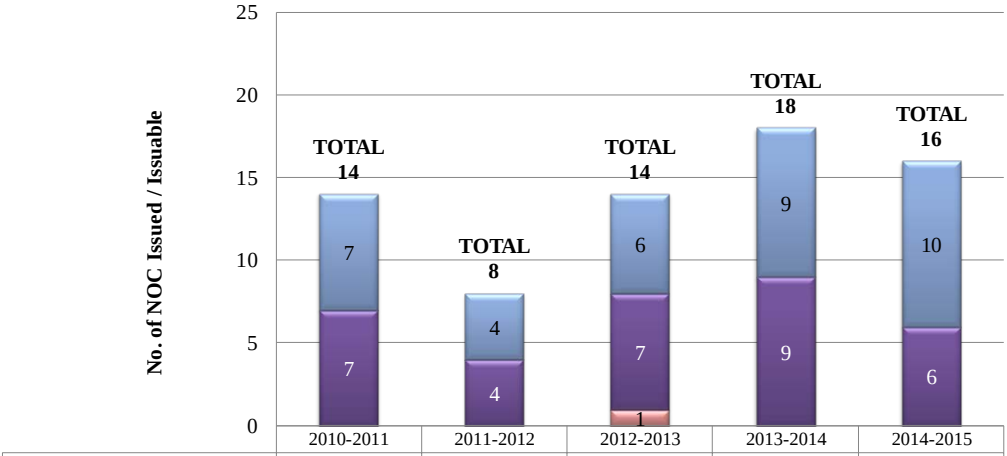
BGTD NDS All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2011-03-31	2012-03-31	2013-03-31	2014-03-31	2015-03-31
Clinical or Non-Clin Only	**0**	**1**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**2**	**9**	**10**	**6**	**8**
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	**4**	**5**	**7**	**10**	**12**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**6**	**15**	**17**	**16**	**20**
Non Backlog	**6**	**15**	**17**	**16**	**20**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**1**	**1**	**3**	**1**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*

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

BGTD 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
Comparative Studies	**2**	**1**	**0**	**0**	**3**
Backlog	0	0	0	0	0
Chemistry & Manufacturing	**17**	**24**	**18**	**15**	**32**
Backlog	0	0	0	0	0
Clinical or Non-Clin Only	**35**	**18**	**38**	**23**	**25**
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	**2**	**3**	**4**	**2**	**5**
Backlog	0	0	0	0	0
Published Data	***0***	***0***	***1***	***0***	**3**
Backlog	0	0	0	0	0
Total	**56**	**46**	**61**	**40**	**68**
Non Backlog	**56**	**46**	**61**	**40**	**68**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**3**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
SNDS-C (Confirmatory)	**1**	**0**	**3**	**0**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*

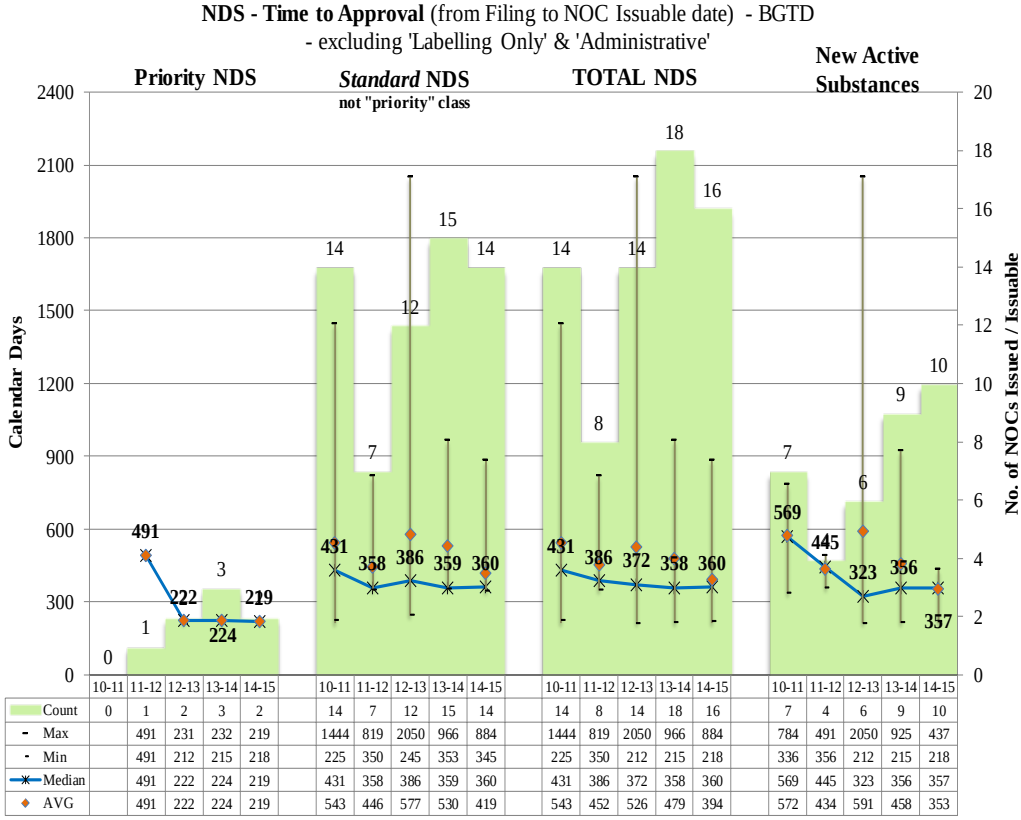
APPROVALS

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



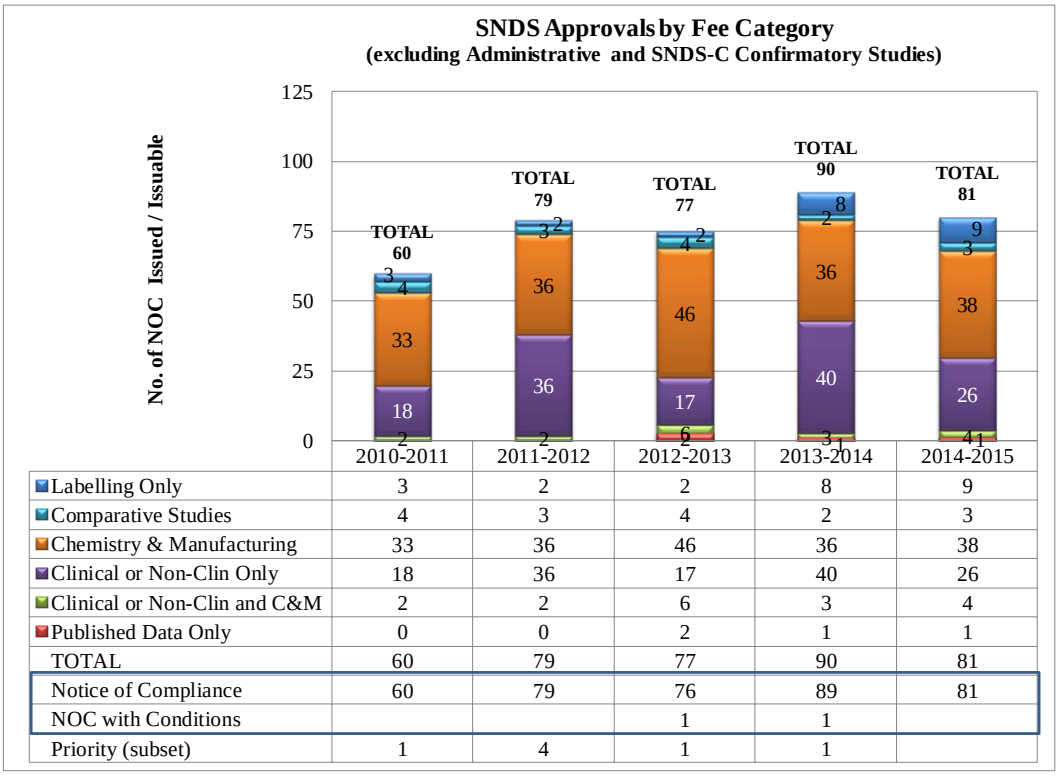
	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
New Active Substance	7	4	6	9	10
Chemistry & Manufacturing					
Clinical or Non-Clin and C&M	7	4	7	9	6
Clinical or Non-Clin Only			1		
TOTAL	14	8	14	18	16
Notice of Compliance	14	7	12	18	16
NOC with Conditions		1	2		
Priority (subset)		1	2	3	2
Subsequent Entry Biologic (SEB)	0	0	0	2	0

NDS Approval Times



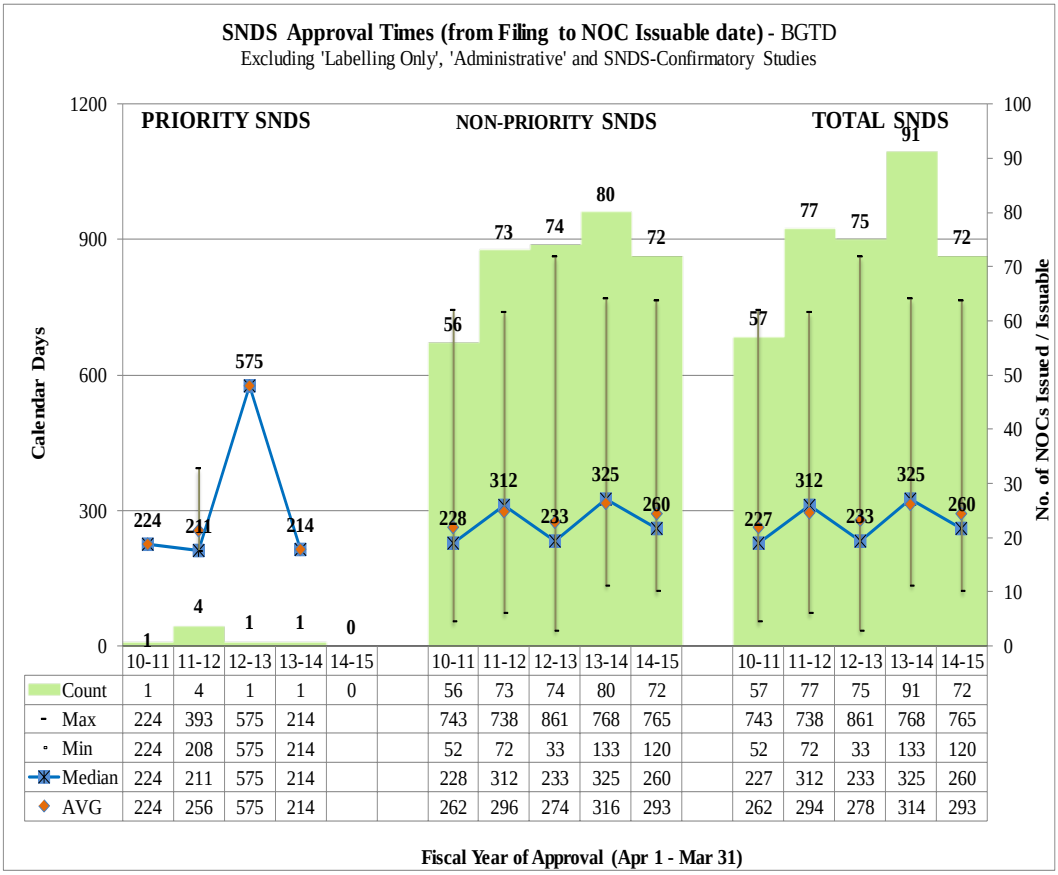
	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15	10-11	11-12	12-13	13-14	14-15
Count	0	1	2	3	2	14	7	12	15	14	14	8	14	18	16	7	4	6	9	10
Max		491	231	232	219	1444	819	2050	966	884	1444	819	2050	966	884	784	491	2050	925	437
Min		491	212	215	218	225	350	245	353	345	225	350	212	215	218	336	356	212	215	218
Median		491	222	224	219	431	358	386	359	360	431	386	372	358	360	569	445	323	356	357
AVG		491	222	224	219	543	446	577	530	419	543	452	526	479	394	572	434	591	458	353

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	3	2	2	8	9
Comparative Studies	4	3	4	2	3
Chemistry & Manufacturing	33	36	46	36	38
Clinical or Non-Clin Only	18	36	17	40	26
Clinical or Non-Clin and C&M	2	2	6	3	4
Published Data Only	0	0	2	1	1
TOTAL	60	79	77	90	81
Notice of Compliance	60	79	76	89	81
NOC with Conditions			1	1	
Priority (subset)	1	4	1	1	

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	1	4	1	1	0		56	73	74	80	72		57	77	75	91	72
Max	224	393	575	214			743	738	861	768	765		743	738	861	768	765
Min	224	208	575	214			52	72	33	133	120		52	72	33	133	120
Median	224	211	575	214			228	312	233	325	260		227	312	233	325	260
AVG	224	256	575	214			262	296	274	316	293		262	294	278	314	293

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New Active Substance Approvals (NAS) – BGTD - Fiscal Year 2014-2015

New Active Substance Approvals (NAS) – BGTD Fiscal Year 2014-2015 (April 1 2014 to March 31 2015)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[5])**	**Approval Date (dd-mon-yy)**
COSENTYX (Secukinumab) - is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.	NAS	Novartis Pharmaceuticals Canada Inc.	17 Dec 13	27 Feb 15
ELELYSO (Taliglucerase Alfa) - is indicated for long-term enzyme replacement therapy (ERT) for adults with a confirmed diagnosis of Type 1 Gaucher disease.	NAS	Pfizer Canada Inc.	18 Jun 13	29 May 14
ELOCTATE (Antihemophilic Factor (Recombinant BDD), FC Fusion Protein) - is indicated in adults and children (≥12 years) with hemophilia A (congenital factor VIII deficiency) for routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes and for control and prevention of bleeding episodes.	NAS	Biogen Idec Canada Inc.	30 Jul 13	22 Aug 14
ENTYVIO (Vedolizumab) - is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, loss of response to, or were intolerant to either conventional therapy or infliximab, a TNFα antagonist.	NAS	Takeda Canada Inc.	21 Nov 13	29 Jan 15
GARDASIL 9 (HUMAN PAPILLOMAVIRUS 9 VALENT VACCINE, RECOMBINANT) (Recombinant Human Papillomavirus Type 6, 11, 16, 18, 31, 33, 45, 52 and 58 L1 Protein) - Girls and Women GARDASIL®9 is a vaccine indicated in girls and women 9 through 45 years of age for the prevention of infection caused by the Human Papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52 and 58 and the following diseases associated with the HPV types included in the vaccine: Cervical, vulvar, and vaginal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58 and Genital warts (condyloma acuminata) caused by HPV types 6 and 11. And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58: Cervical adenocarcinoma in situ (AIS), Cervical intraepithelial neoplasia (CIN) grade 2 and grade 3, Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3, Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3 and Cervical intraepithelial	NAS	Merck Canada Inc.	13 Feb 14	5 Feb 15

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

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

Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date[5])	Approval Date (dd-mon-yy)
neoplasia (CIN) grade 1. GARDASIL®9 is indicated in girls and women 9 through 26 years of age for the prevention of: Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58 and Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3 caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58. **Boys and Men** GARDASIL®9 is indicated in boys and men 9 through 26 years of age for the prevention of infection caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58 and the following diseases associated with the HPV types included in the vaccine: Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58 and Genital warts (condyloma acuminata) caused by HPV types 6 and 11. And anal intraepithelial neoplasia (AIN) grades 1, 2, and 3 caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58.				
GAZYVA (Obinutuzumab) - in combination with chlorambucil is indicated for the treatment of patients with previously untreated chronic lymphocytic leukaemia (CLL).	NAS	Hoffmann_la Roche Limited	2 Oct 13	25 Nov 14
NUWIQ (Simoctocog Alfa) - is indicated for the treatment and prophylaxis of bleeding in patients of all ages suffering with hemophilia A (congenital factor VIII deficiency).	NAS	Octapharma Pharmazeutika Produktionsges M B H	1 Nov 13	23 Oct 14
SYLVANT (Siltuximab) - is indicated for the treatment of patients with multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV)-negative and human herpes virus-8 (HHV-8)-negative.	Priority-NAS	Janssen Inc.	28 Apr 14	3 Dec 14
VIMIZIM (Elosulfase Alfa) - is indicated for long-term enzyme replacement therapy in patients with a confirmed diagnosis of Mucopolysaccharidosis IVA (Morquio A syndrome, or MPS IVA).	Priority-NAS	Biomarin International Limited	26 Nov 13	2 Jul 14
ZONOVATE (Turoctocog Alfa) - is indicated for use in adults and children with hemophilia A (congenital Factor VIII deficiency or classic hemophilia) for treatment and control of bleeding episodes, for perioperative management and for routine prophylaxis to prevent or reduce the frequency of bleeding episodes.	NAS	Novo Nordisk Canada Inc.	16 Dec 13	8 Dec 14

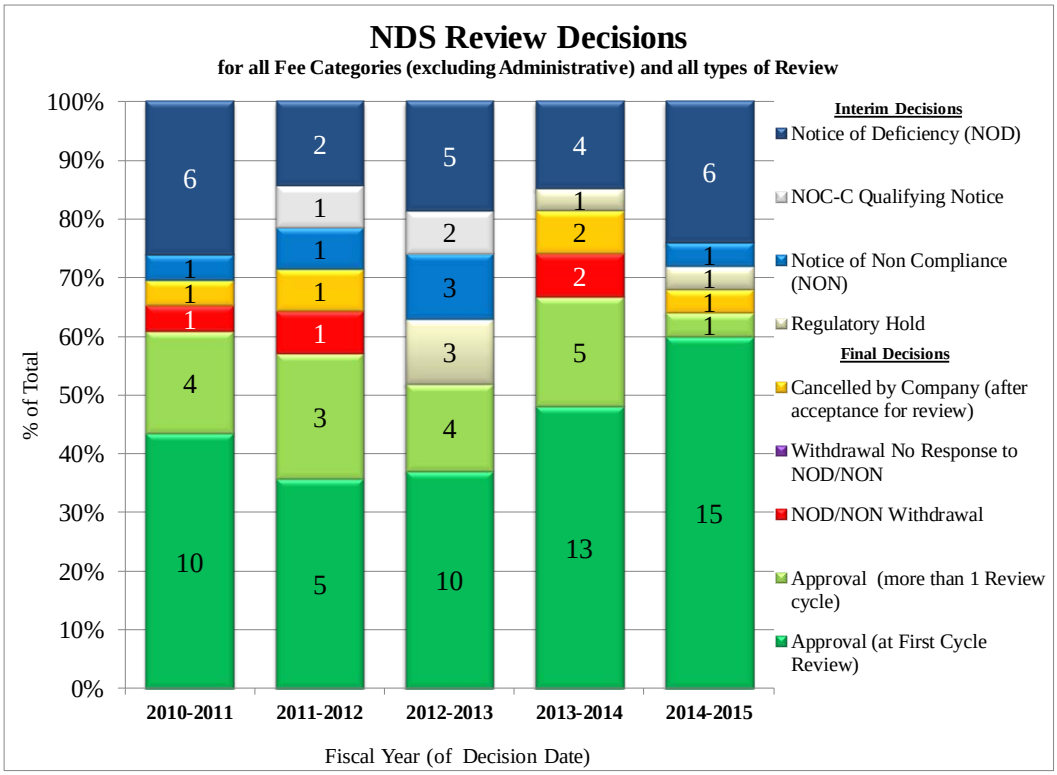
Priority Submission Approvals – BGTD - Fiscal Year 2014-2015

Priority Submission Approvals – BGTD Fiscal Year 2014-2015 (April 1 2014 to March 31 2015)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[6])**	**Approval Date (dd-mon-yy)**
SYLVANT (Siltuximab) - is indicated for the treatment of patients with multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV)-negative and human herpes virus-8 (HHV-8)-negative.	PRIORITY-NAS	Janssen Inc.	28 Apr 14	3 Dec 14
VIMIZIM (Elosulfase Alfa) - is indicated for long-term enzyme replacement therapy in patients with a confirmed diagnosis of Mucopolysaccharidosis IVA (Morquio A syndrome, or MPS IVA).	PRIORITY-NAS	Biomarin International Limited	26 Nov 13	2 Jul 14

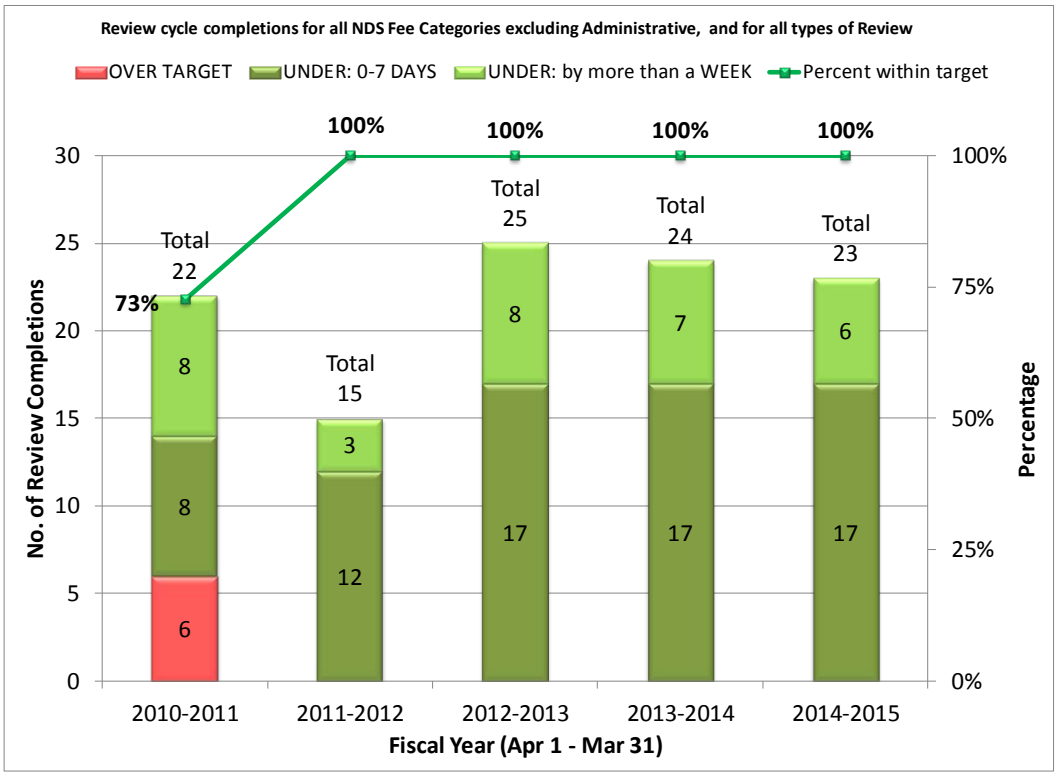
[6] The CR Date is the date the submission is received and considered administratively complete by Health Canada

REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

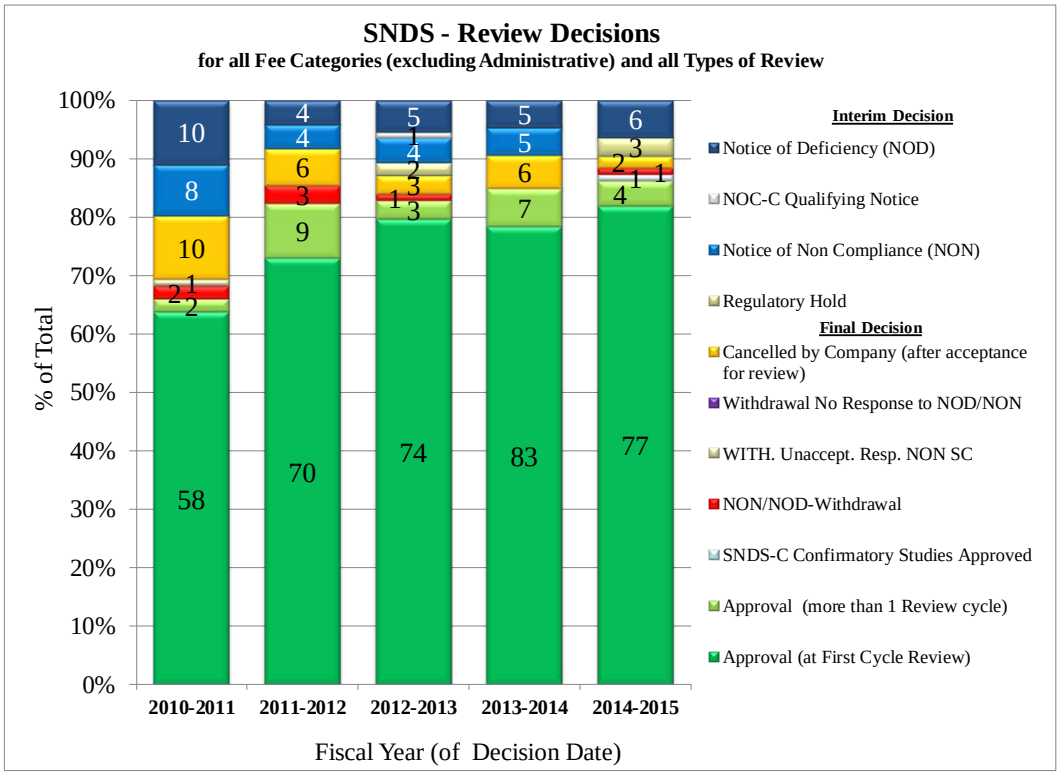


NDS - Review Cycle Completions Showing Percentage Within Target

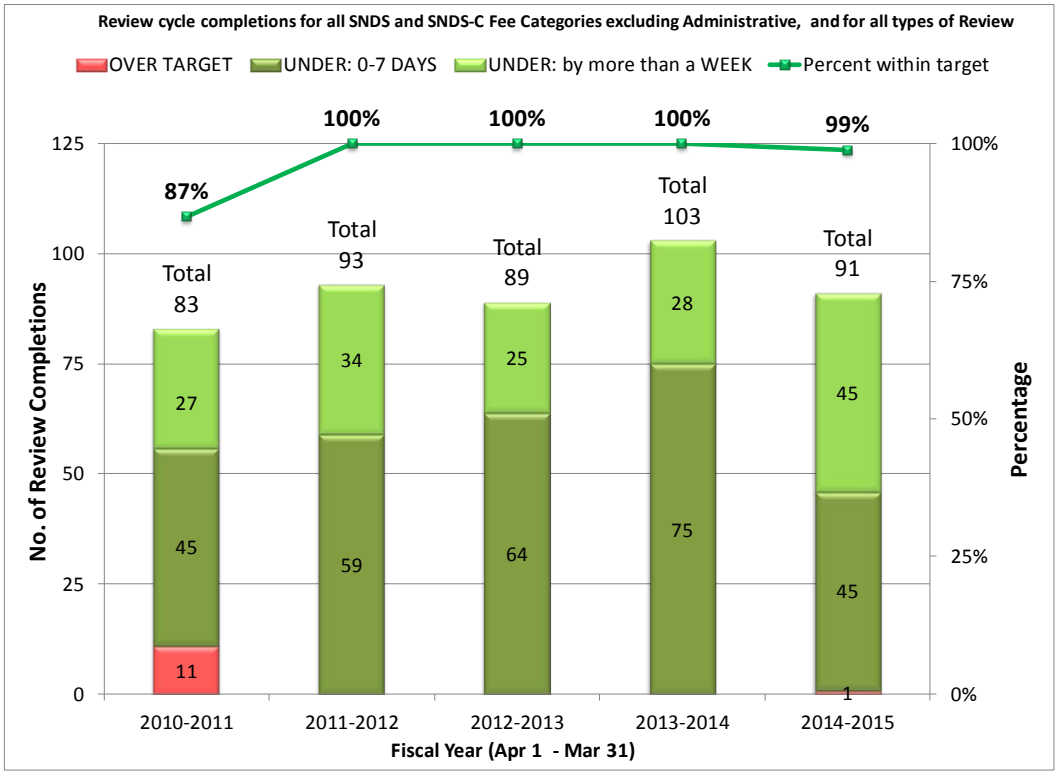


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

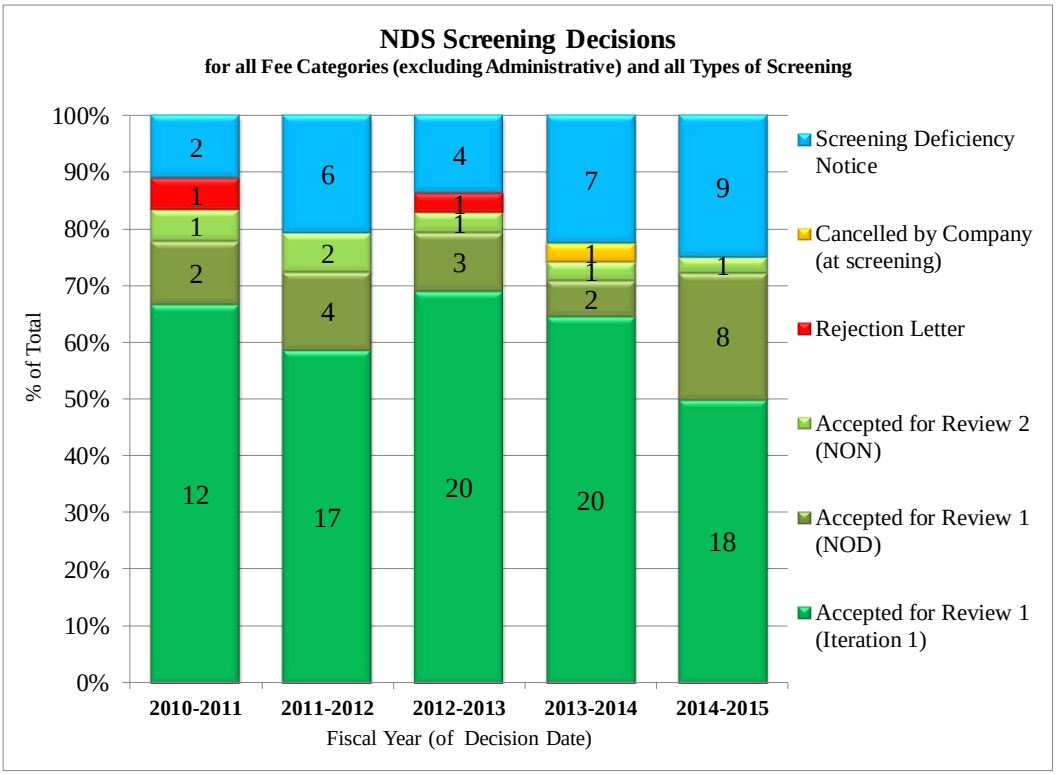


SNDS - Review Cycle Completions Showing Percentage Within Target

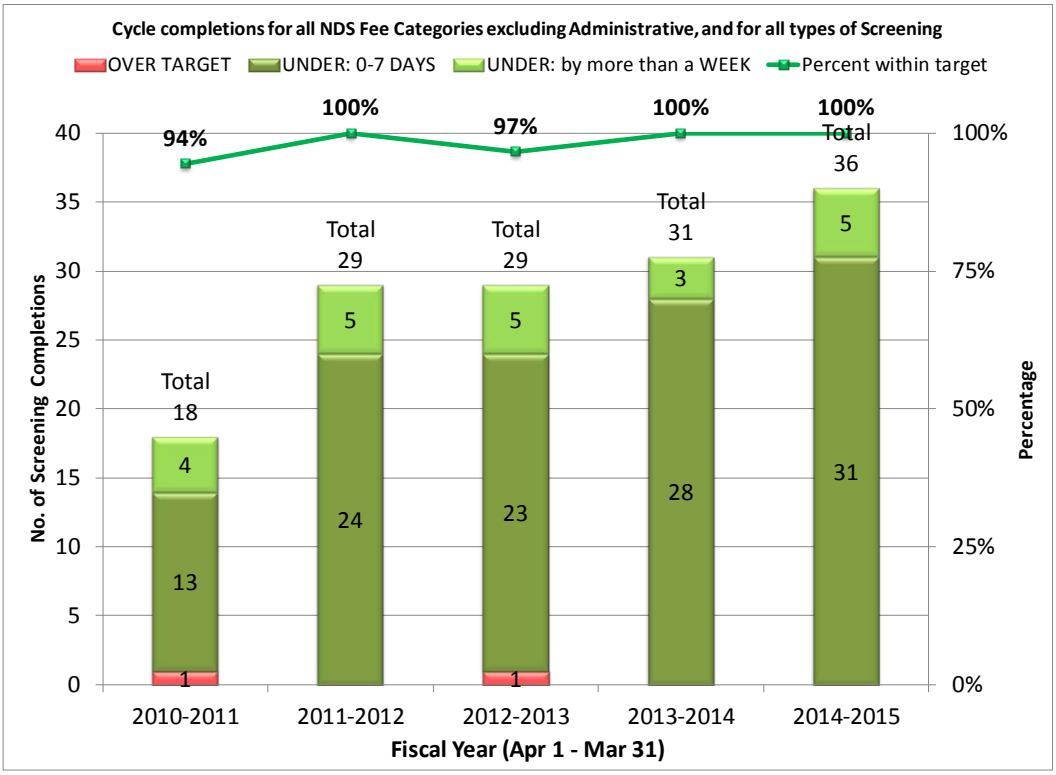


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

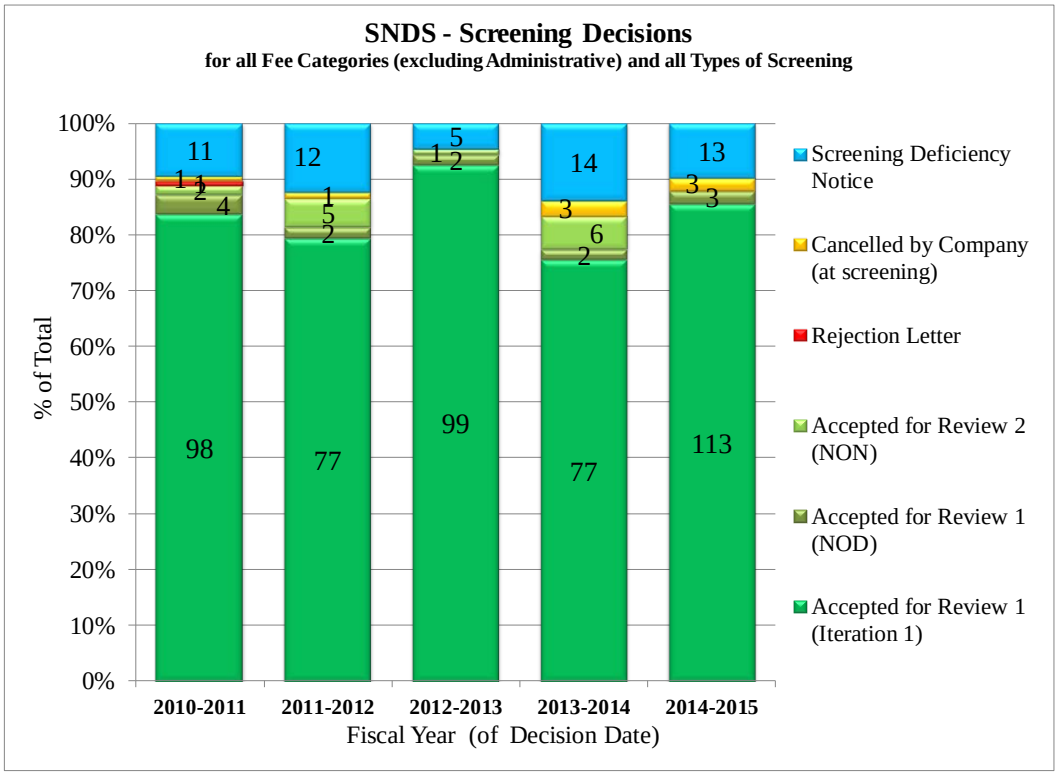


NDS - Screening Cycle Completions Showing Percentage Within Target

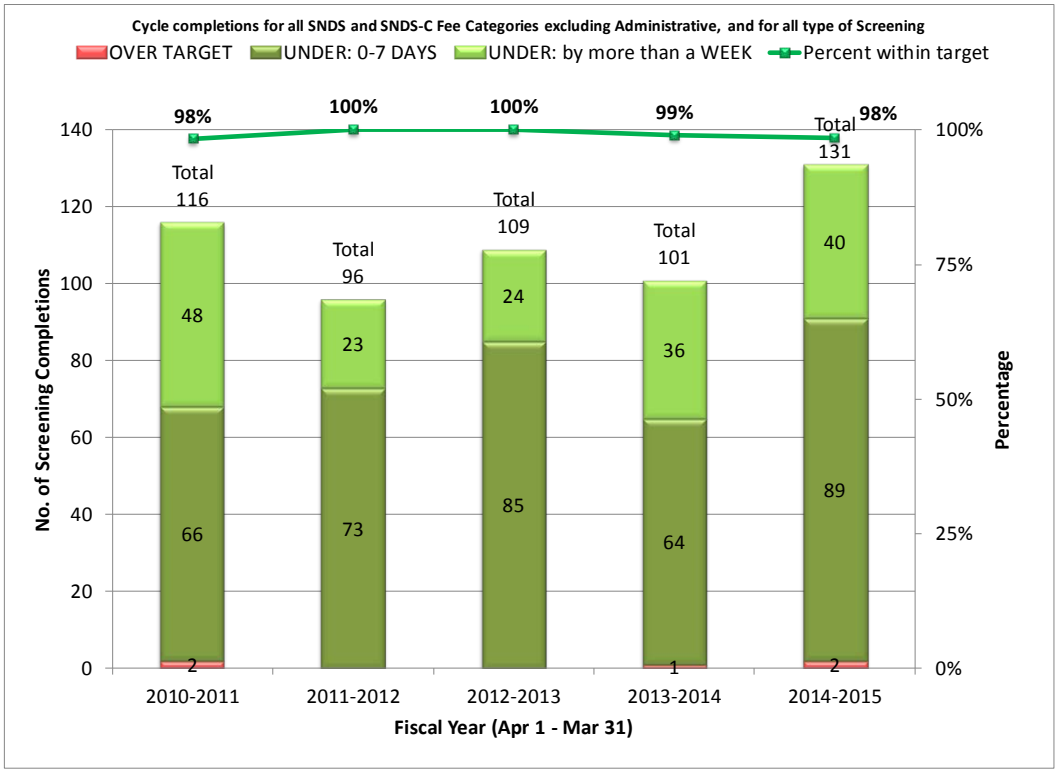


SCREENING CYCLE DECISIONS

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 & Supplemental New Drug Submissions (NDS, SNDS & ANDS)

NDS & SNDS					
	Year of Reconsideration Request				
	10-11	11-12	12-13	13-14	14-15
NDS Total	0	0	0	0	0
SNDS Total	0	0	1	1	0

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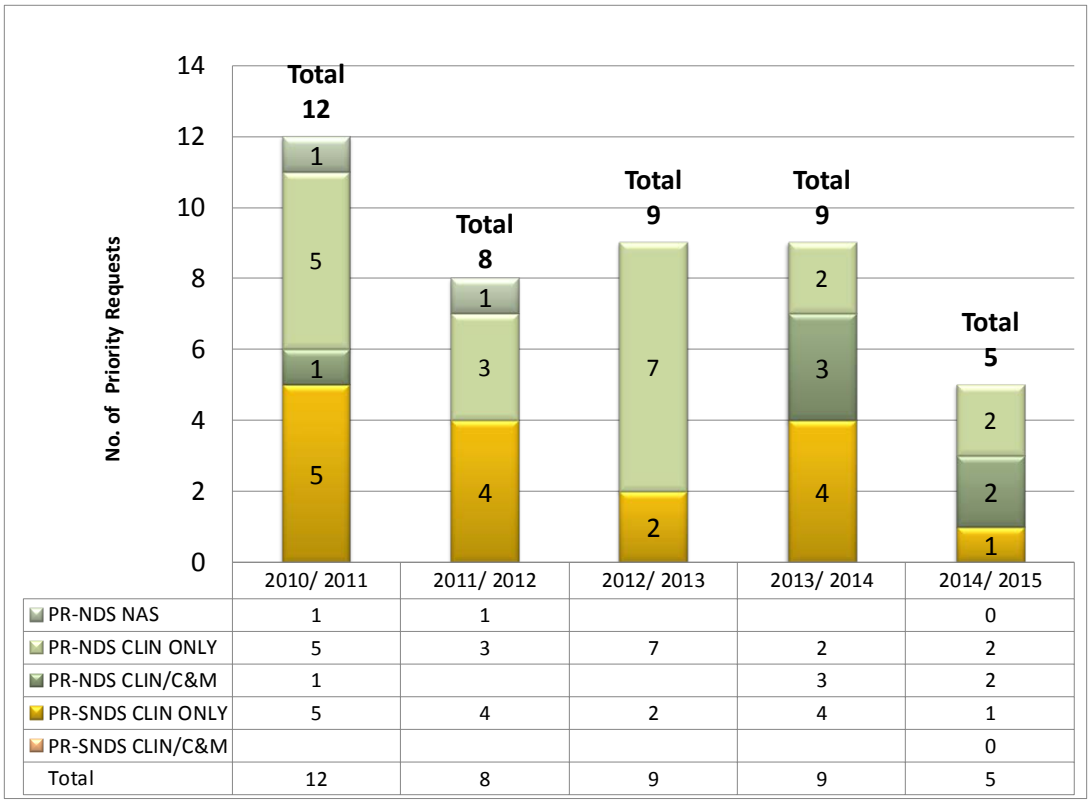
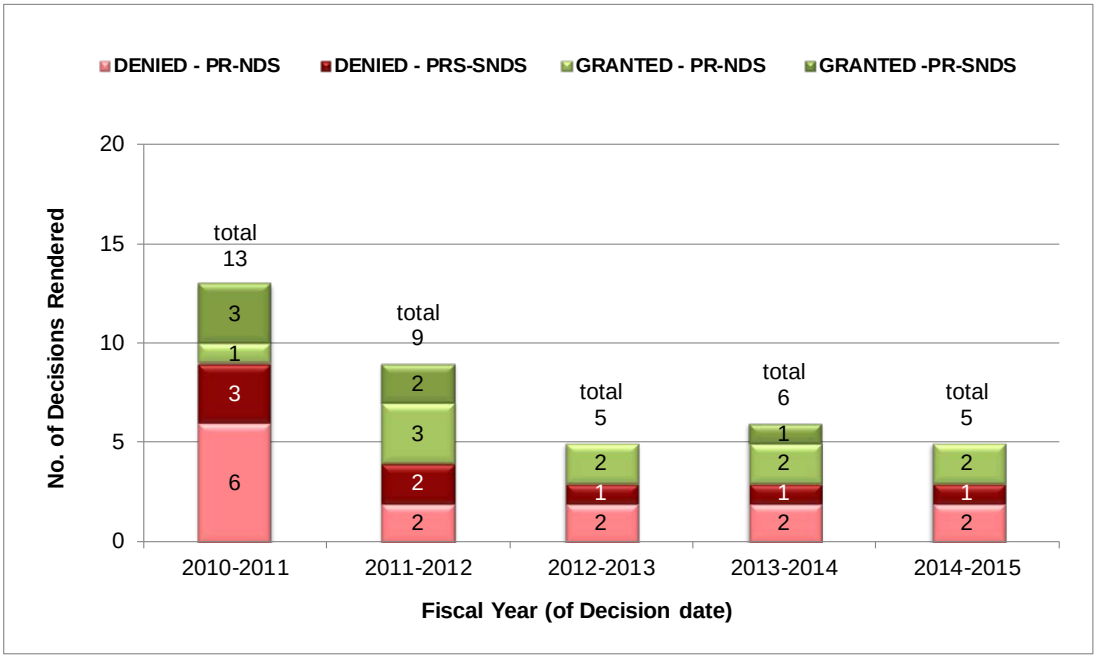
PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests Received



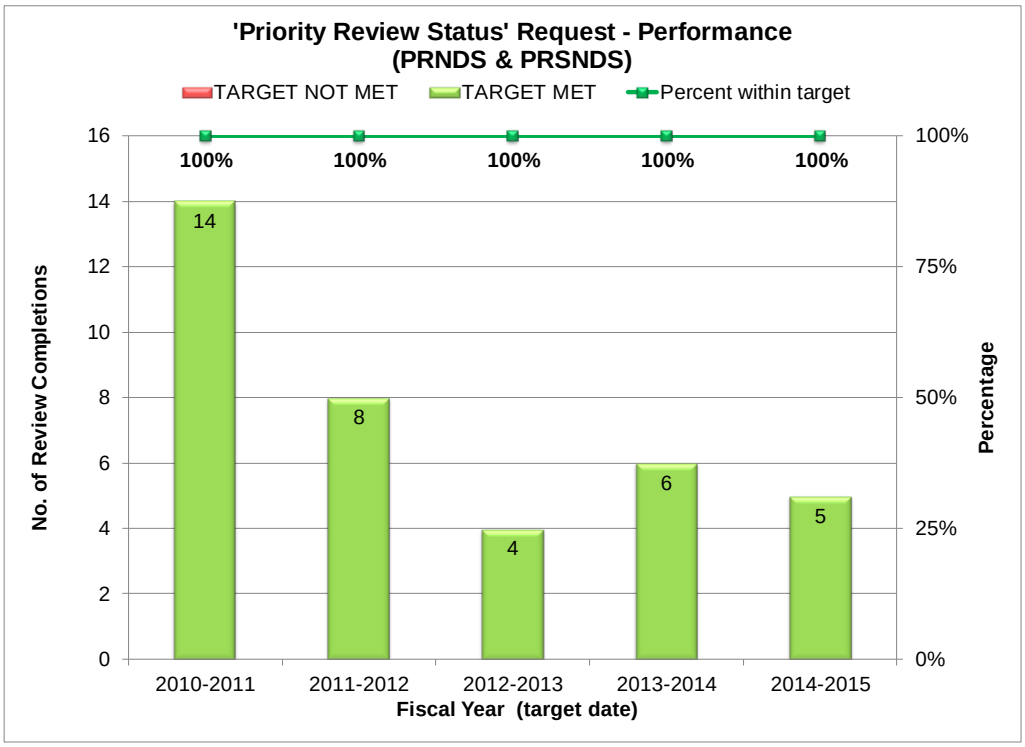
	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
PR-NDS NAS	1	1			0
PR-NDS CLIN ONLY	5	3	7	2	2
PR-NDS CLIN/C&M	1			3	2
PR-SNDS CLIN ONLY	5	4	2	4	1
PR-SNDS CLIN/C&M					0
Total	12	8	9	9	5

Priority Review Status Requests: Decisions Rendered



PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests: Performance



REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

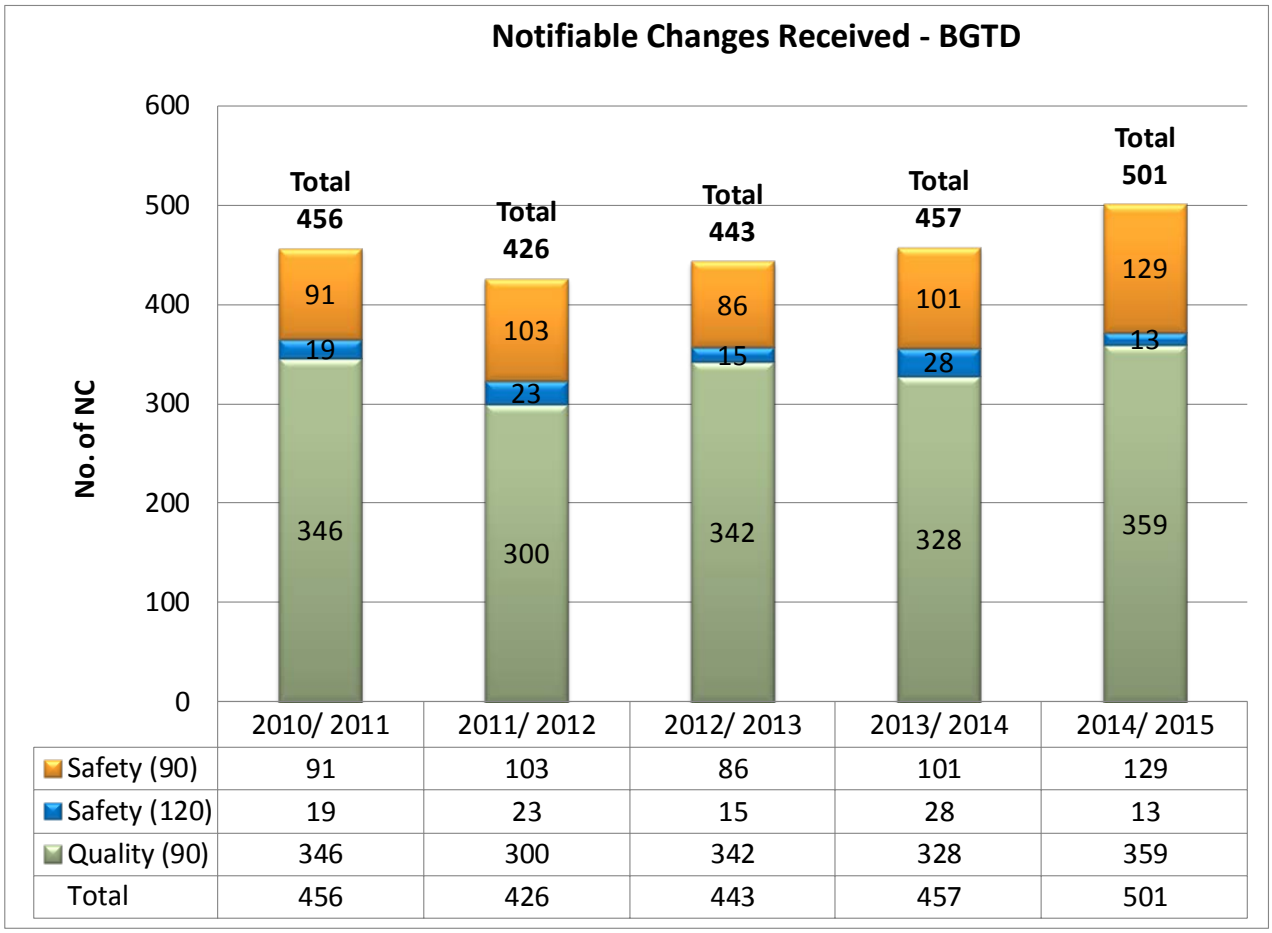
Requests for Reconsideration of Final Decisions – Priority Review Requests (for NDS and SNDS)

"Priority Review Request" - Requests for Reconsideration of Final Decisions Fiscal Year of Request (Arp - Mar)							
Breakdown by Reconsideration Decision	**10-11**	**11-12**	**12-13**	**13-14**	**14-15**	**Final Decision in Dispute**	**Submission Status as May 25 2015**
Total Received	**0**	**0**	**1**	**0**	**0**		
Total Granted	***0***	***0***	***1***	***0***	***0***	Priority review request Denied	CLEARED

NOTIFIABLE CHANGES (NC)

NOTIFIABLE CHANGES[7,8]

Number Received - Notifiable Changes (NC)



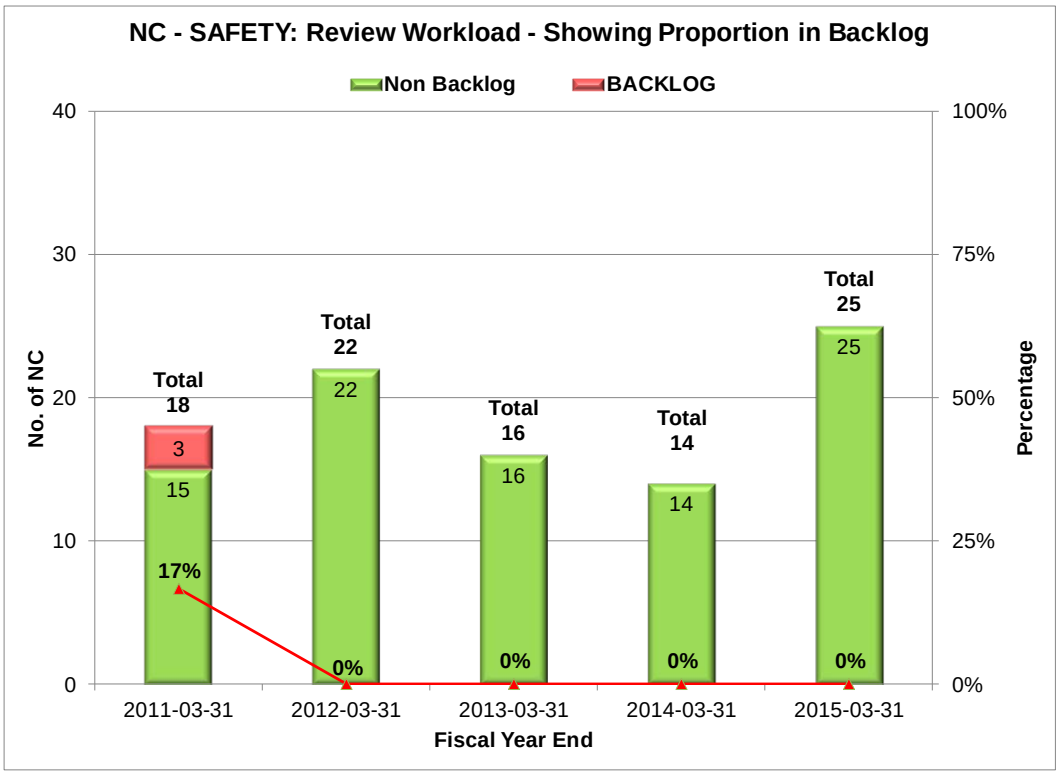
	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
Safety (90)	91	103	86	101	129
Safety (120)	19	23	15	28	13
Quality (90)	346	300	342	328	359
Total	456	426	443	457	501

[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

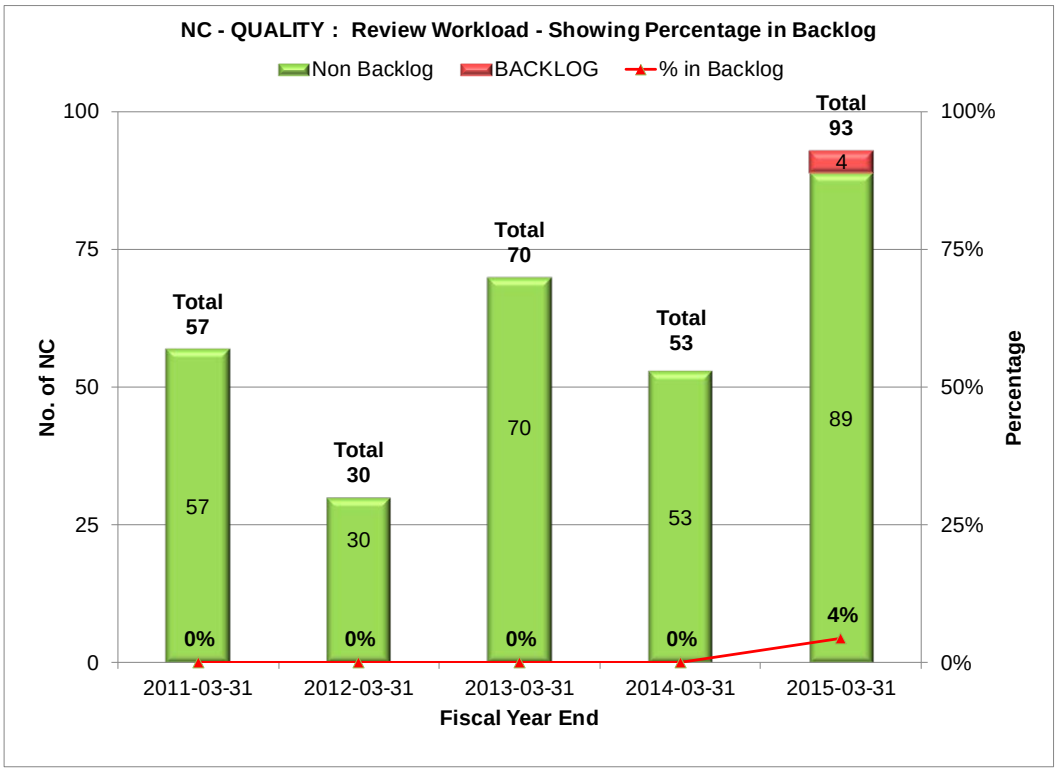
[8] Post-Notice of Compliance (NOC) Changes - Quality Guidance Appendix 1 for Human Pharmaceuticals became effective October 17, 2011.

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.

WORKLOAD

Notifiable Change (NC) SAFETY: Review Workload by Class

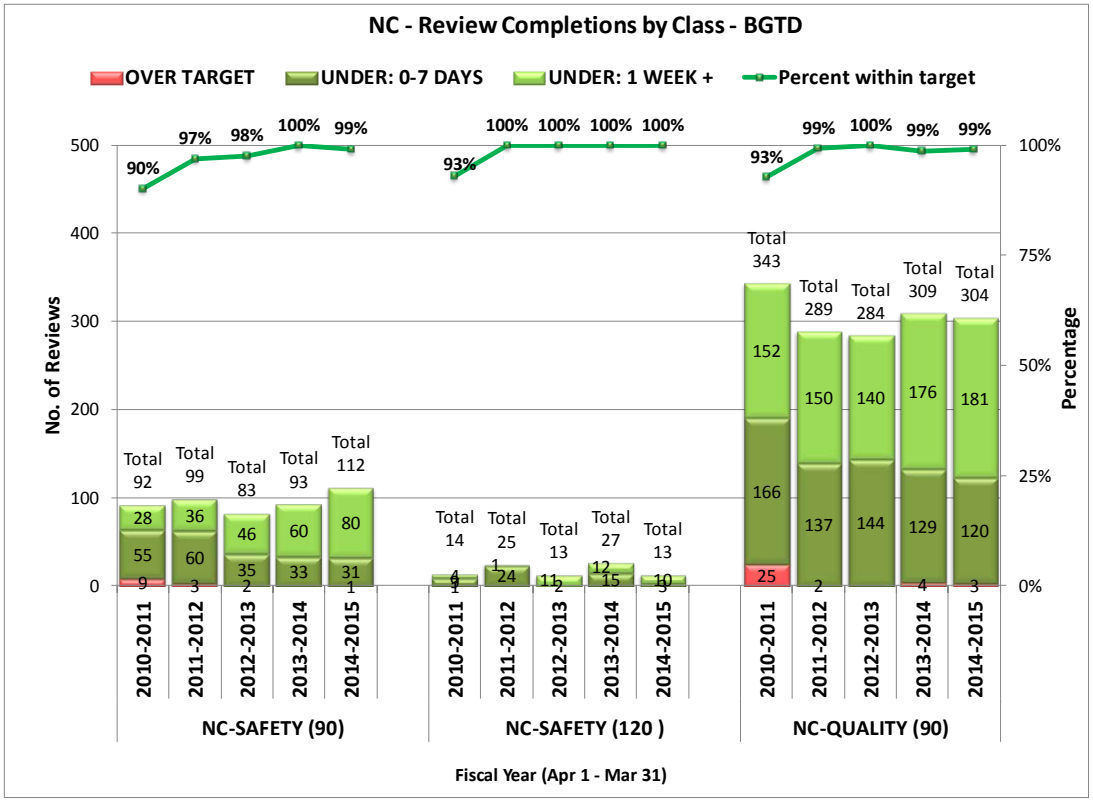
BGTD NC- SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2011-03-31	2012-03-31	2013-03-31	2014-03-31	2015-03-31
SAFETY - 90 day	15	20	13	11	22
Backlog	*3*	*0*	*0*	*0*	*0*
SAFETY - 120 day	3	2	3	3	3
	0	*0*	*0*	*0*	*0*
Total	18	22	16	14	25
Non Backlog	15	22	16	14	25
BACKLOG	3	0	0	0	0
% in Backlog	17%	0%	0%	0%	0%

Notifiable Change (NC) QUALITY: Review Workload by Class

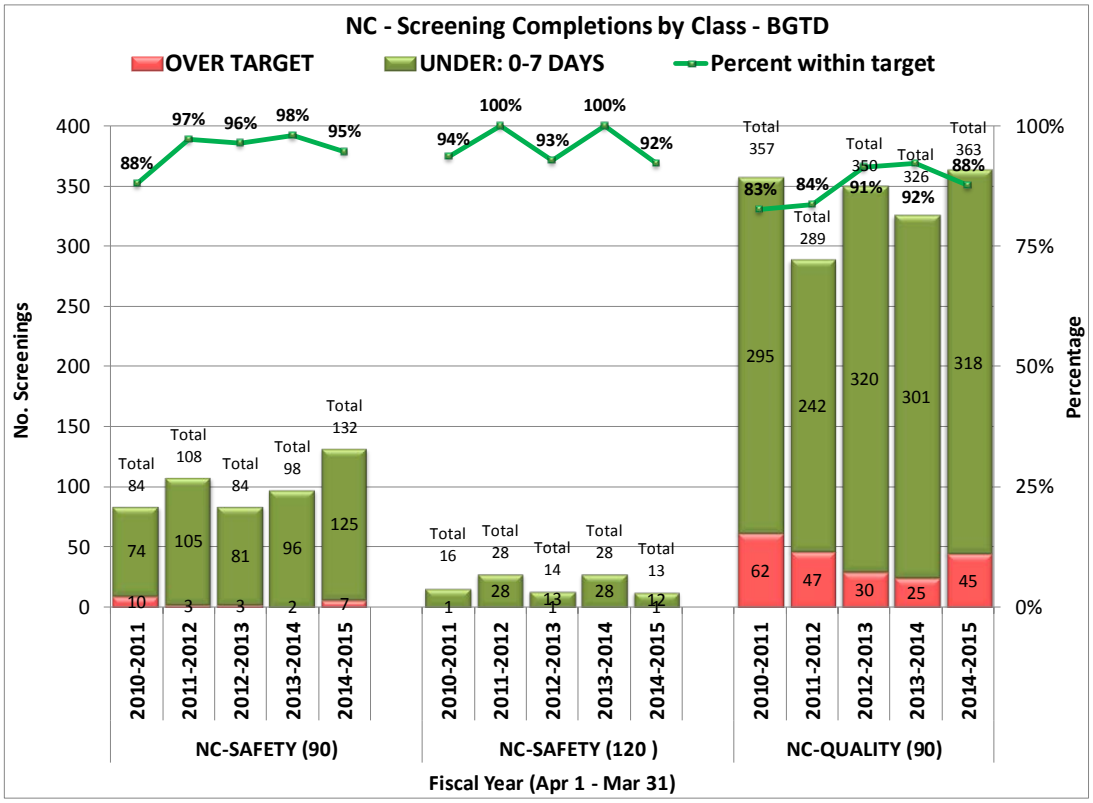
BGTD NC- QUALITY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2011-03-31	2012-03-31	2013-03-31	2014-03-31	2015-03-31
QUALITY - 90 day	57	30	70	53	93
Backlog	*0*	*0*	*0*	*0*	*4*
Total	57	30	70	53	93
Non Backlog	57	30	70	53	89
BACKLOG	0	0	0	0	4
% in Backlog	0%	0%	0%	0%	4%

PERFORMANCE

REVIEW Completions by Class - Notifiable Changes (NC)



SCREENING Completions by Class - Notifiable Changes (NC)



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	330	315	278	301	302
NOT SATISFACTORY NOTICE	26	27	4	4	
REJECTION LETTER (SCR)	3	5	19	22	8
CANCELLED BY COMPANY	9	7	8	13	3
SCREENING DEFICIENCY NOTICE	15	7	3	6	12

NC - SAFETY (90)					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER	89	98	81	92	112
NOT SATISFACTORY NOTICE			2		
REJECTION LETTER (SCR)	3	5	6	1	5
CANCELLED BY COMPANY	7	4	2	7	4
SCREENING DEFICIENCY NOTICE		2		1	1

NC - SAFETY (120)					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER	13	25	13	27	12
NOT SATISFACTORY NOTICE	1				
REJECTION LETTER (SCR)		3			
SCREENING DEFICIENCY NOTICE		1			
CANCELLED BY COMPANY				1	1

REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

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

NC					
	Year of Reconsideration Request				
	10-11	**11-12**	**12-13**	**13-14**	**14-15**
Total	**0**	**0**	**0**	**0**	**0**

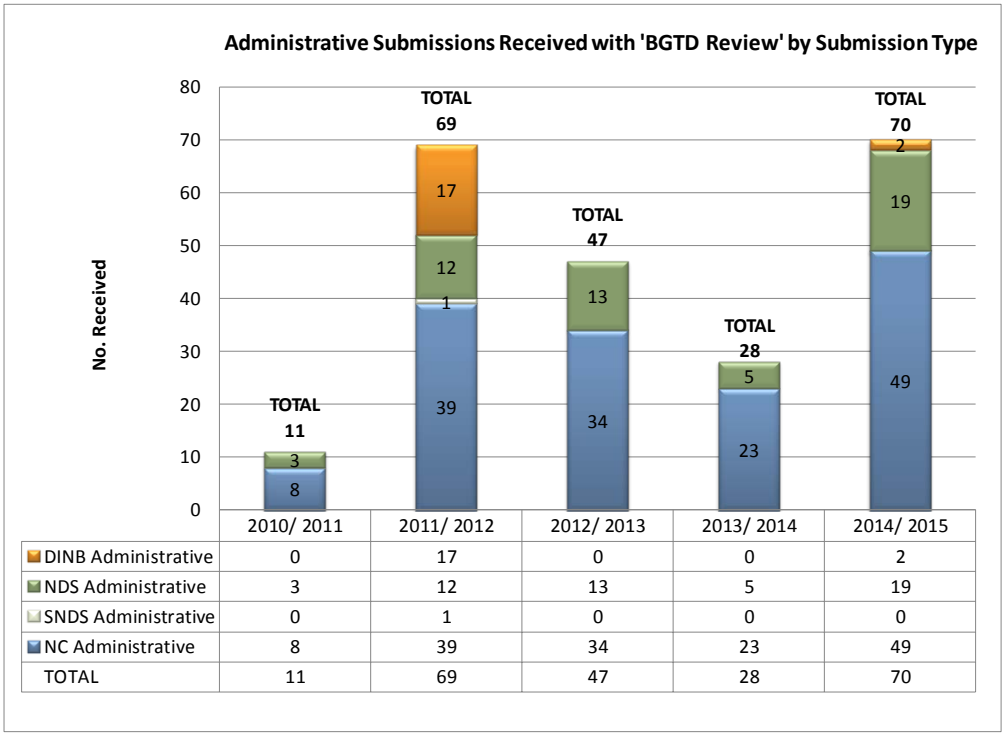
Administrative Submissions

Submissions in support of a manufacturer or product name change.

ADMINISTRATIVE SUBMISSIONS with BGTD review

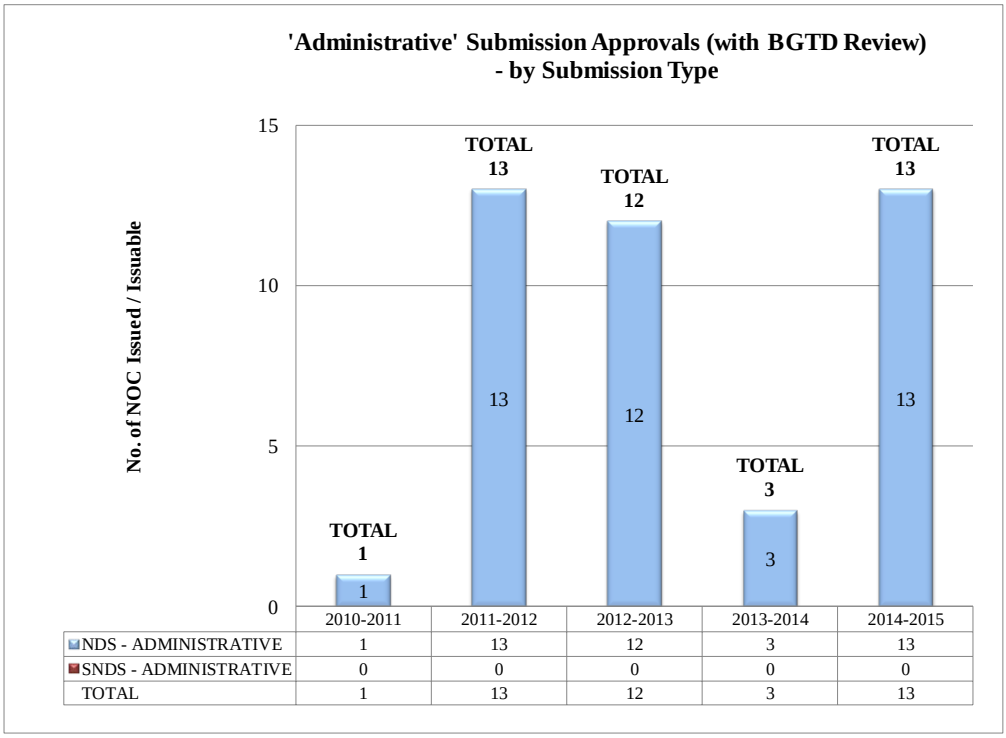
(such as product name change that requires a drug name review)

Administrative Submissions Received (with BGTD review)



	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
DINB Administrative	0	17	0	0	2
NDS Administrative	3	12	13	5	19
SNDS Administrative	0	1	0	0	0
NC Administrative	8	39	34	23	49
TOTAL	11	69	47	28	70

Administrative Submission Approvals (with BGTD Review)

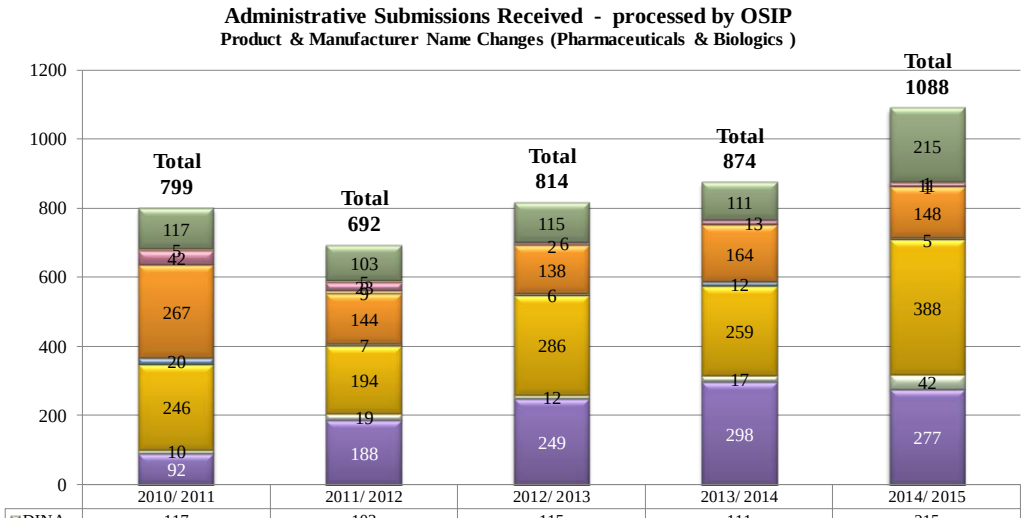


	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
NDS - ADMINISTRATIVE	1	13	12	3	13
SNDS - ADMINISTRATIVE	0	0	0	0	0
TOTAL	1	13	12	3	13

ADMINISTRATIVE SUBMISSIONS (Processed by OSIP)

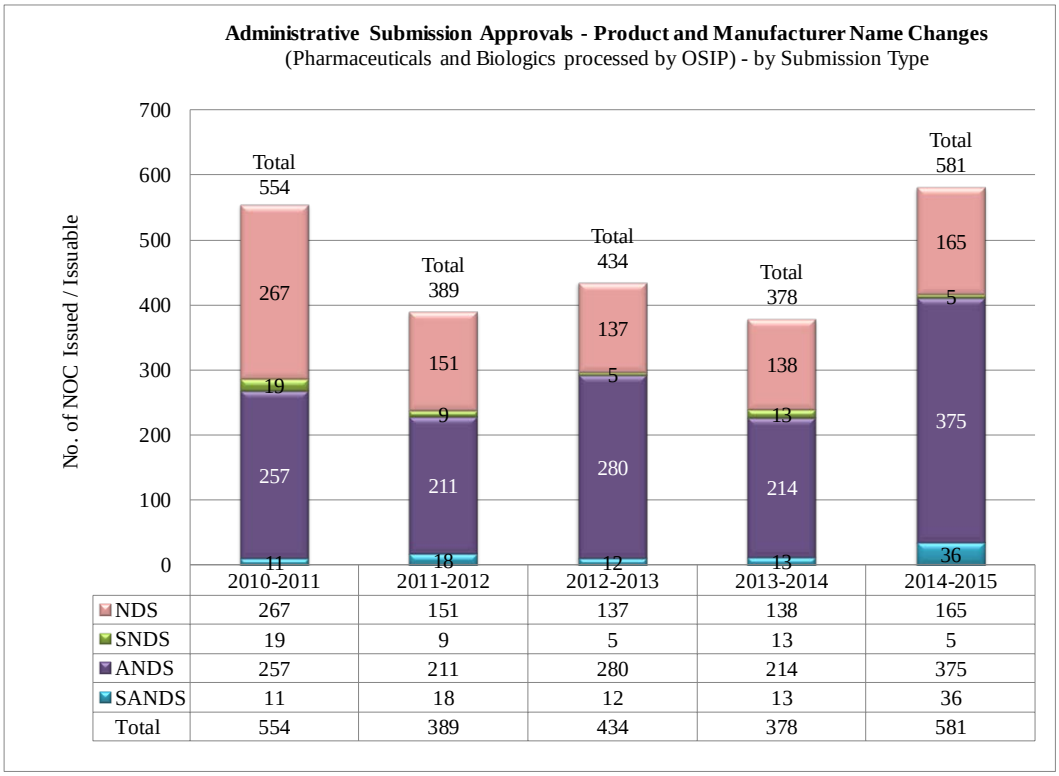
(Product & Manufacturer Name Changes)
(Admin Ncs are for cross-referenced changes)

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



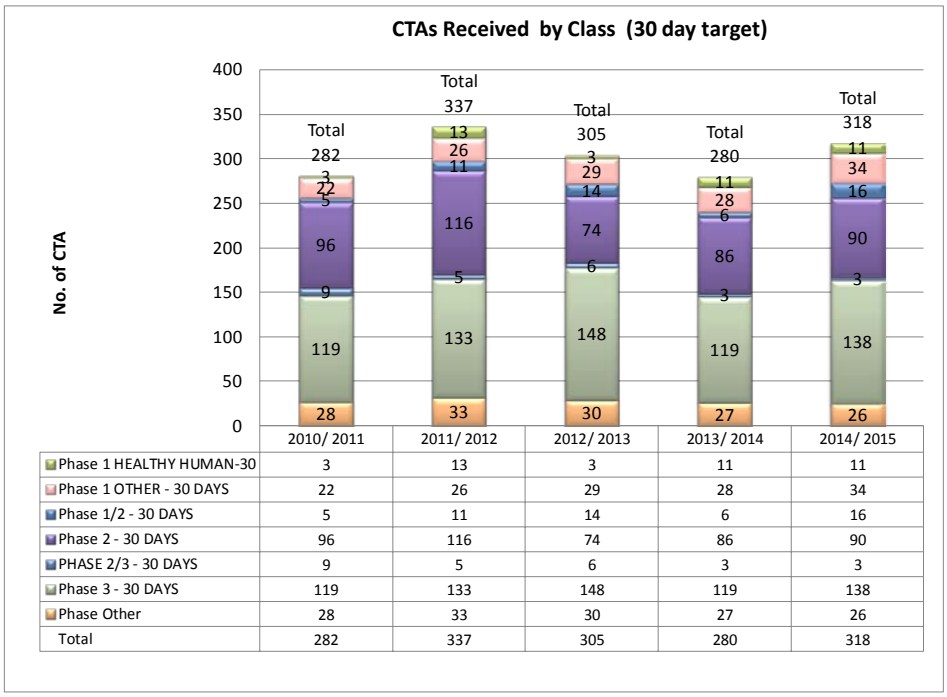
	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
NDS	267	151	137	138	165
SNDS	19	9	5	13	5
ANDS	257	211	280	214	375
SANDS	11	18	12	13	36
Total	554	389	434	378	581

Clinical Trial Applications and Amendments

(CTA & CTA-A)

CLINICAL TRIAL APPLICATIONS

Number Received - Clinical Trial Application (CTA)

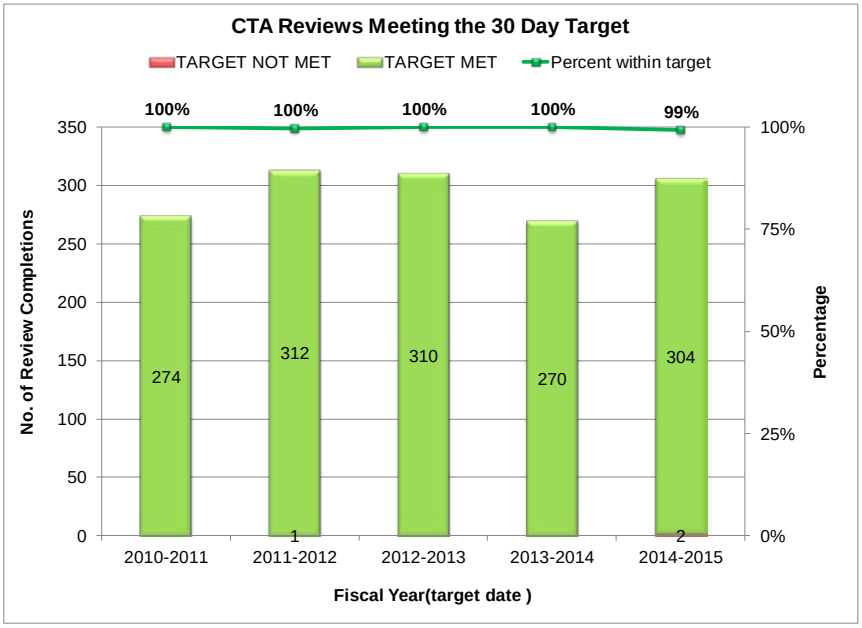


	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
Phase 1 HEALTHY HUMAN-30	3	13	3	11	11
Phase 1 OTHER - 30 DAYS	22	26	29	28	34
Phase 1/2 - 30 DAYS	5	11	14	6	16
Phase 2 - 30 DAYS	96	116	74	86	90
PHASE 2/3 - 30 DAYS	9	5	6	3	3
Phase 3 - 30 DAYS	119	133	148	119	138
Phase Other	28	33	30	27	26
Total	282	337	305	280	318

Decision Documents - Clinical Trial Application (CTA)

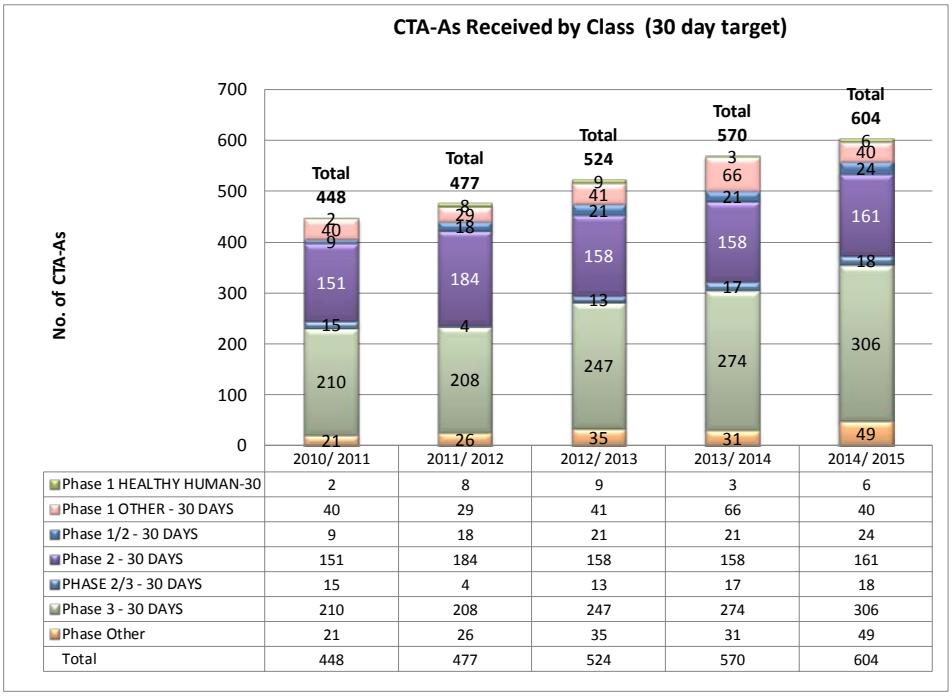
CTA (30 day target)					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER	272	299	302	255	283
CANCELLED BY COMPANY DURING REVIEW	5	17	7	7	18
CANCELLED BY COMPANY AT PROCESSING	3	5	4	0	5
NOT SATISFACTORY NOTICE	3	2	1	6	4
REFUSAL LETTER	0	0	0	0	0
REJECTION LETTER (SCR)	1	1	1	0	1

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



CLINICAL TRIAL APPLICATION-AMENDMENTS

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

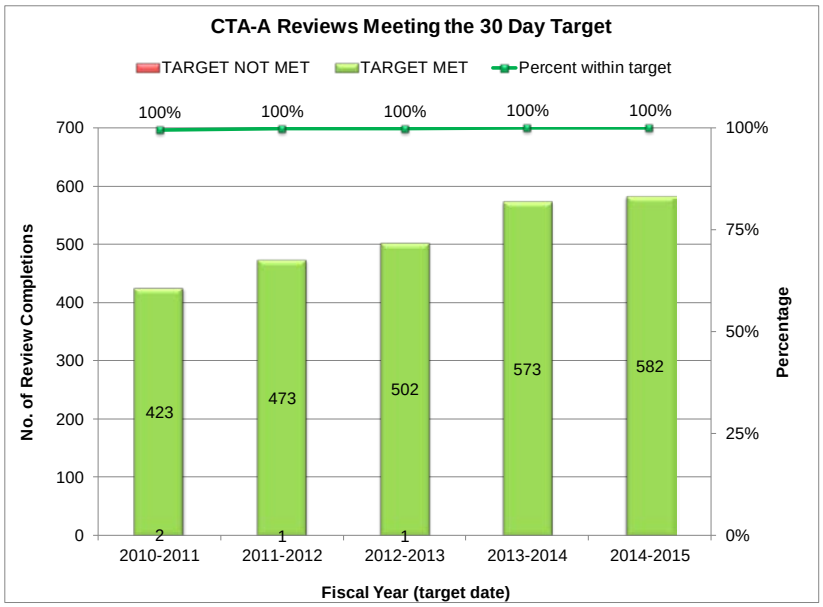


	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
Phase 1 HEALTHY HUMAN-30	2	8	9	3	6
Phase 1 OTHER - 30 DAYS	40	29	41	66	40
Phase 1/2 - 30 DAYS	9	18	21	21	24
Phase 2 - 30 DAYS	151	184	158	158	161
PHASE 2/3 - 30 DAYS	15	4	13	17	18
Phase 3 - 30 DAYS	210	208	247	274	306
Phase Other	21	26	35	31	49
Total	448	477	524	570	604

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

CTA-A (30 day target)					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER	433	475	491	572	574
CANCELLED BY COMPANY DURING REVIEW	5	2	9	3	8
CANCELLED BY COMPANY AT PROCESSING	1	3	3	0	6
NOT SATISFACTORY NOTICE	2	3	3	0	0
REJECTION LETTER (SCR)	6	0	8	3	5

Performance - Clinical Trial Application Amendments (CTA-A) Reviews



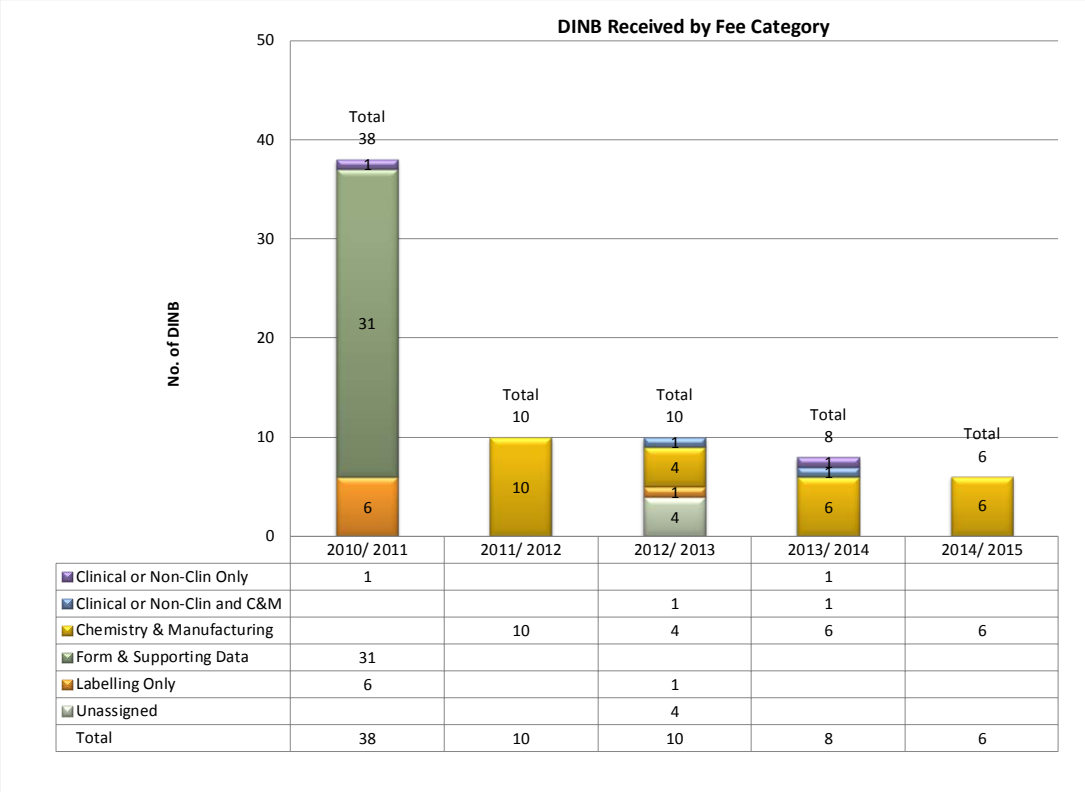
Application for a Drug Identification Number

DINB

Biological Products

DINB: Application for a Drug Identification Number – BIOLOGICAL Products

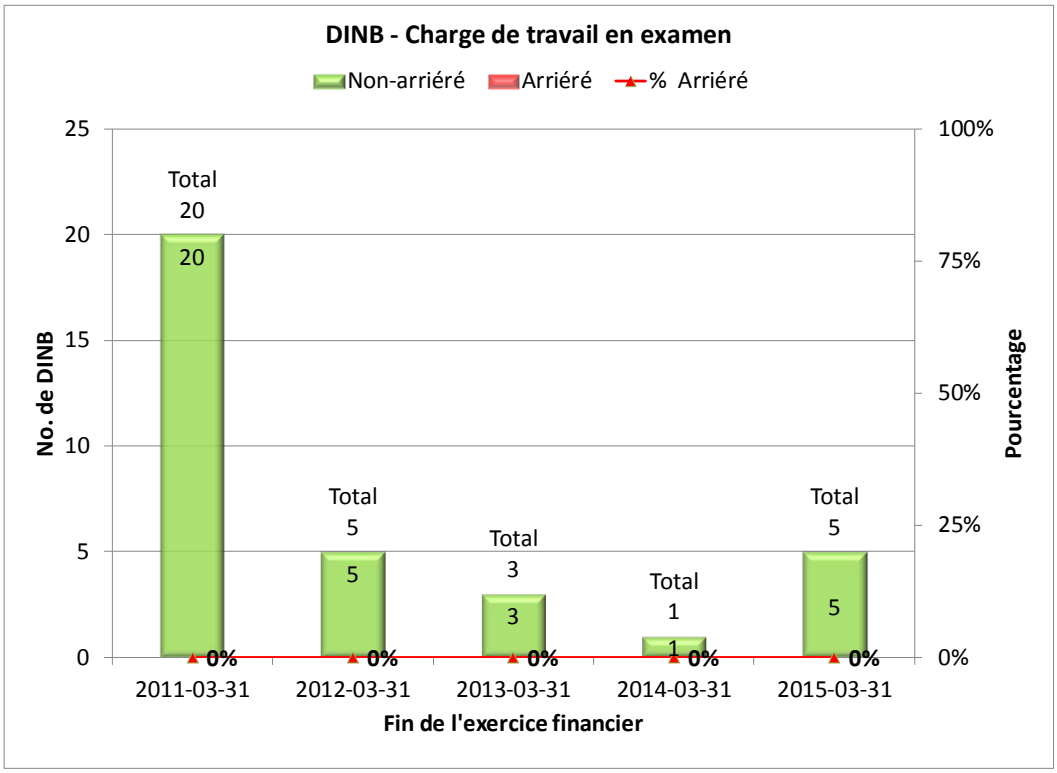
Number Received - DINB



	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
Clinical or Non-Clin Only	1			1	
Clinical or Non-Clin and C&M			1	1	
Chemistry & Manufacturing		10	4	6	6
Form & Supporting Data	31				
Labelling Only	6		1		
Unassigned			4		
Total	38	10	10	8	6

REVIEW WORKLOAD

Review Workload / Backlog – Showing Percentage in Backlog - DINB

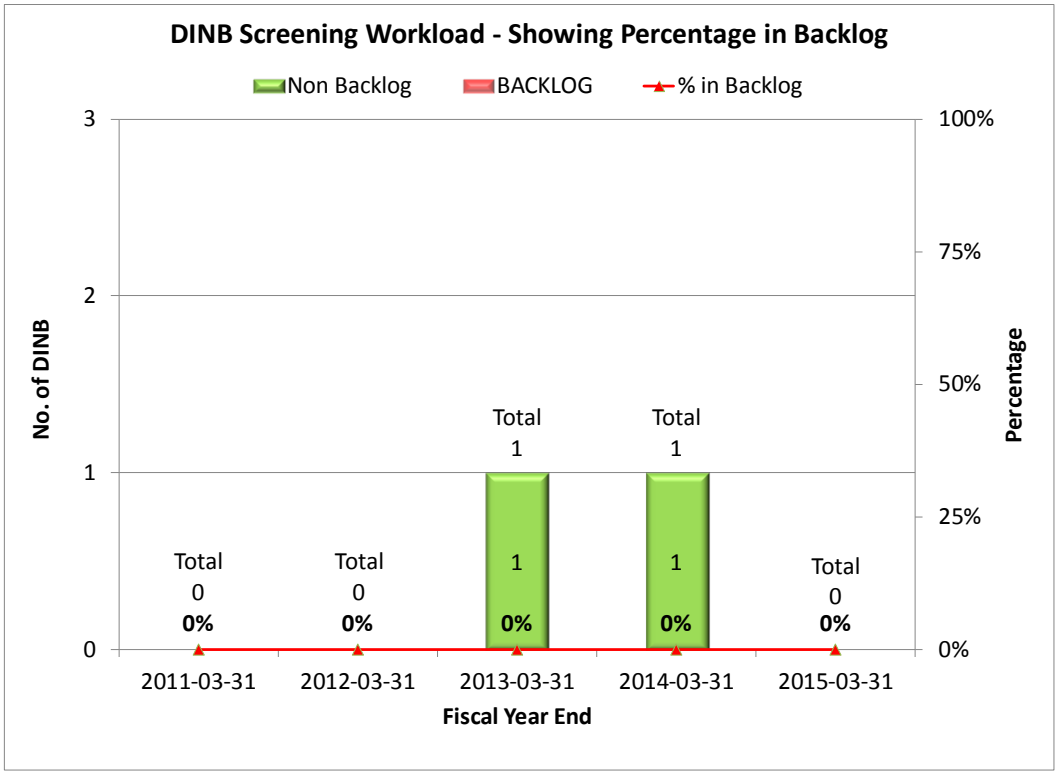


Review Workload by Class - DINB

BGTD DINB 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
Form	**5**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Form and Supporting Data	**15**	**1**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**0**	**4**	**3**	**1**	**5**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**20**	**5**	**3**	**1**	**5**
Non Backlog	**20**	**5**	**3**	**1**	**5**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

SCREENING WORKLOAD

Screening Workload / Backlog – Showing Percentage in Backlog - DINB



Screening Workload by Class - DINB

BGTD DINB All SCREENING WORKLOAD BY FEE CATEGORY (excluding dministrative) and Fiscal Year End					
	2011-03-31	2012-03-31	2013-03-31	2014-03-31	2015-03-31
Labelling Only	**0**	**0**	**0**	**0**	**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**	**0**	**0**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**0**	**0**	**1**	**1**	**0**
Non Backlog	**0**	**0**	**1**	**1**	**0**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

DECISION DOCUMENTS

Decision Documents – DINB by class

DINB - LABELLING ONLY (FORM)					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER	1	5			
SCREENING DEFICIENCY NOTICE	4				
NOTICE OF DEFICIENCY					
CANCELLED BY COMPANY			1		

DINB - FORM AND SUPPORTING DATA					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER	33	9			
NOTIFICATION FORM DIN SUB		3			
NOT SATISFACTORY NOTICE					
NOTICE OF DEFICIENCY	1	1			
NOD WITHDRAWAL LETTER		1			
REJECTION LETTER (SCR)					
REFUSAL LETTER					
SCREENING DEFICIENCY NOTICE	5				

DINB - CLIN ONLY					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER		1			

DINB - CHEMISTRY & MANUFACTURING					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER		2	1	4	
NOTICE OF DEFICIENCY		1			
NOTIFICATION FORM DIN SUB					1
SCREENING DEFICIENCY NOTICE		6		1	6
CANCELLED BY COMPANY		2			

DINB - CLIN/C&M					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NO OBJECTION LETTER				1	
SCREENING DEFICIENCY NOTICE					2

DINB - ADMINISTRATIVE					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
NOTIFICATION FORM/DIN ISSUED		6	11		2

DINB - UNASSIGNED					
DOCUMENT TYPE	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
CANCELLED BY COMPANY			4		

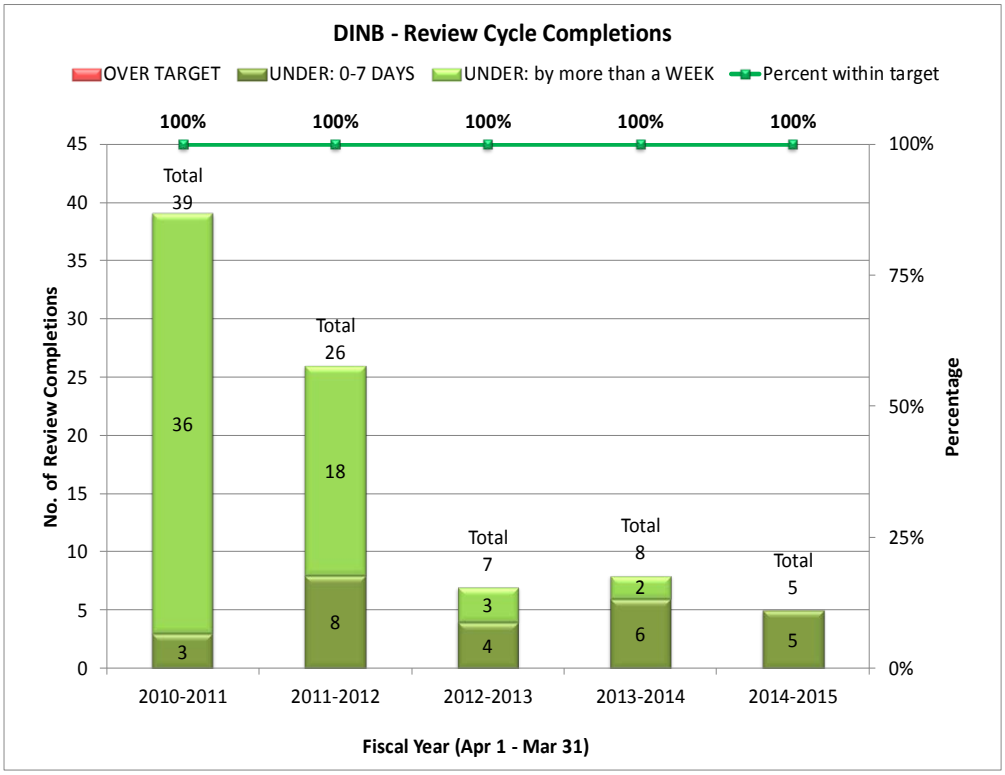
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – DINB

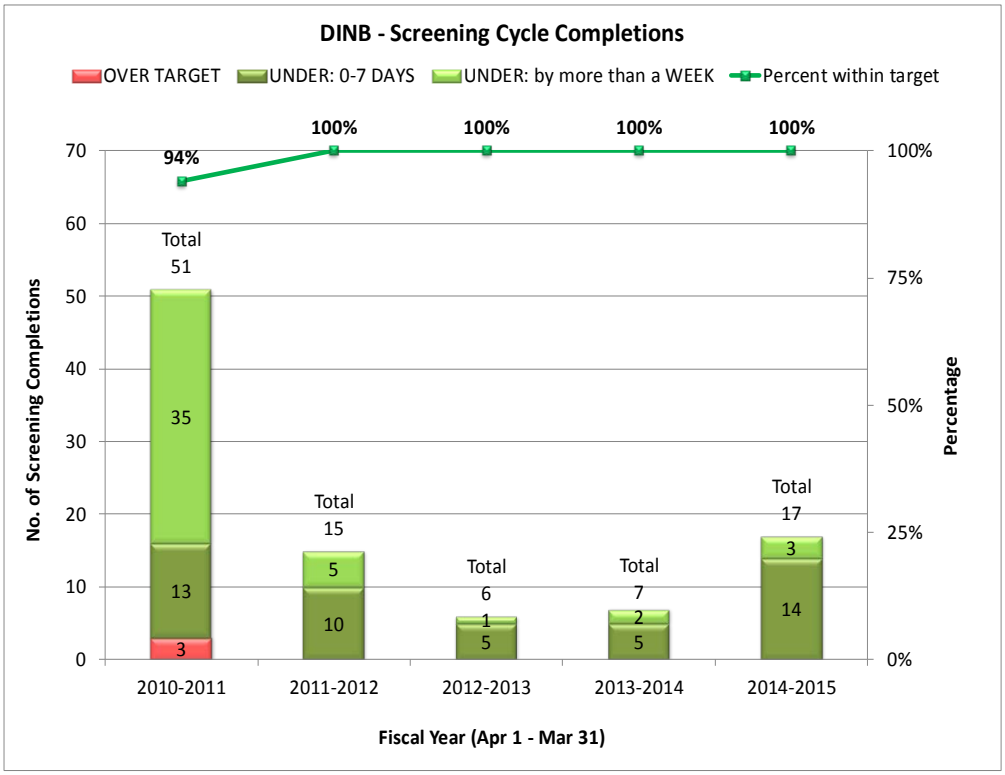
DINB					
	Year of Reconsideration Request				
	10-11	**11-12**	**12-13**	**13-14**	**14-15**
Total	**0**	**0**	**0**	**0**	**0**

PERFORMANCE

Review Cycle Completions - DINB

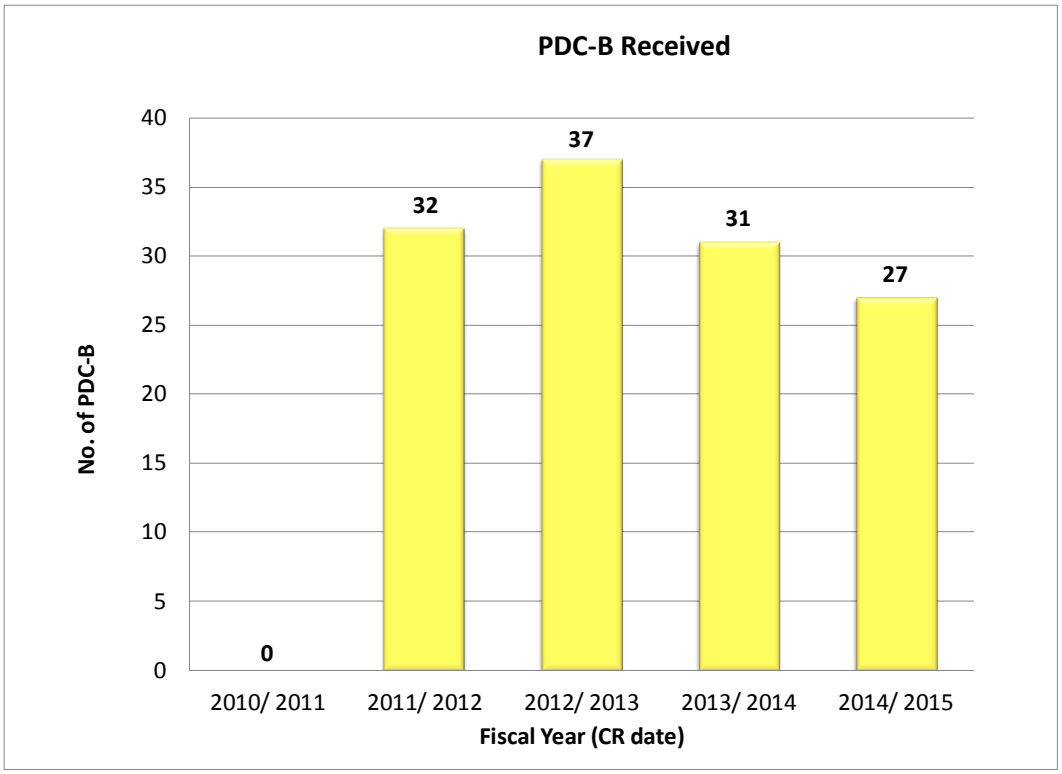


Screening Cycle Completions - DINB



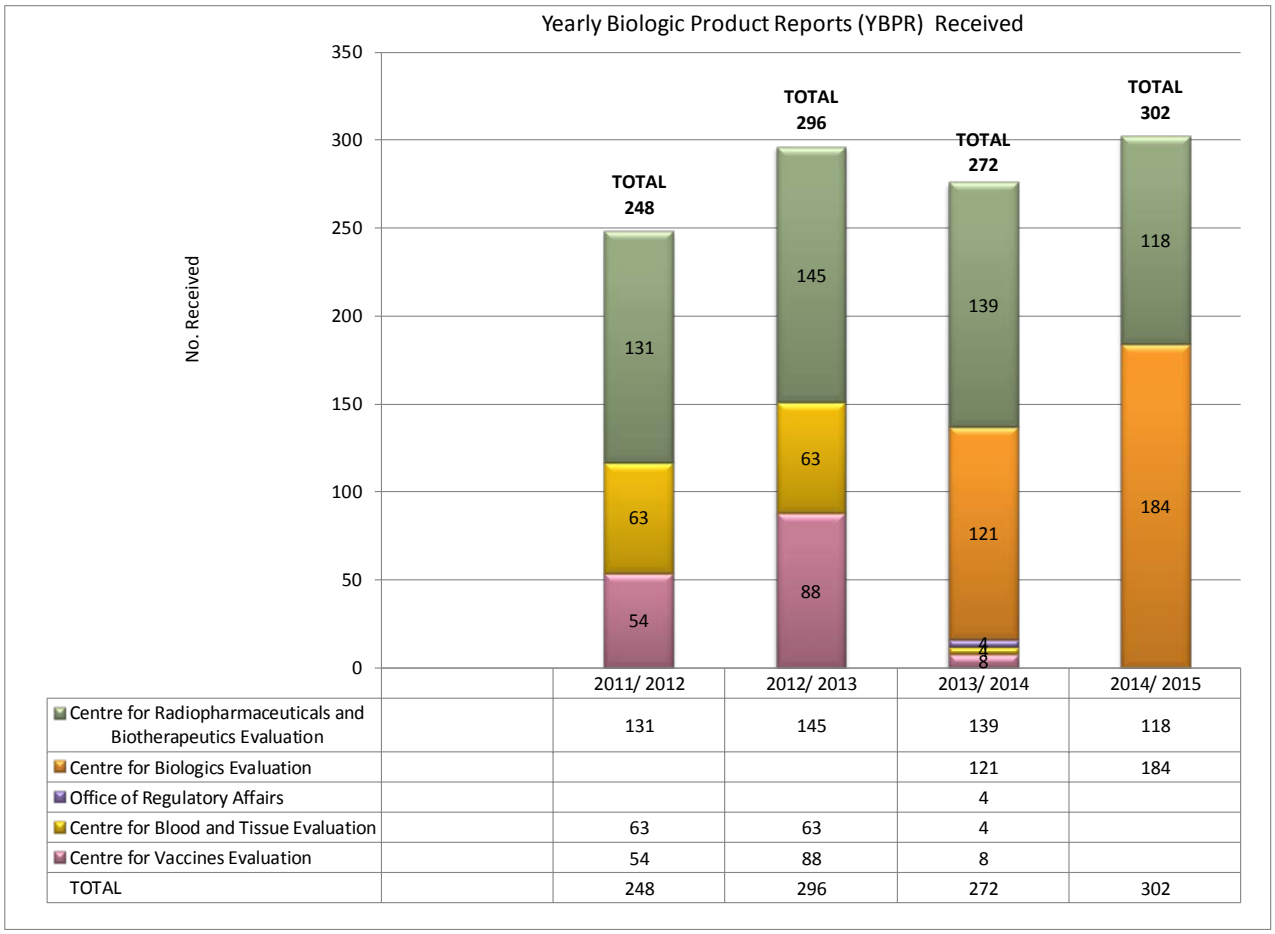
PDC-B: Post Authorization Division 1 Changes - Biologics

PDC-B: Post Authorization Division 1 Changes- Biologics Received



Yearly Biologic Product Reports[9] (YBPR)

Yearly Biologic Product Reports (YBPR) Received



	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015
Centre for Radiopharmaceuticals and Biotherapeutics Evaluation	131	145	139	118
Centre for Biologics Evaluation			121	184
Office of Regulatory Affairs			4	
Centre for Blood and Tissue Evaluation	63	63	4	
Centre for Vaccines Evaluation	54	88	8	
TOTAL	248	296	272	302

[9] Yearly Biologic Product Report (YBPR), is a report that must be submitted annually by manufacturers of all Schedule D (Biologic) drugs. The report contains production information on both drug substance and drug product lots, including test methods and results, reasons for any recalls and corrective action taken, as well as other pertinent post-market information.

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