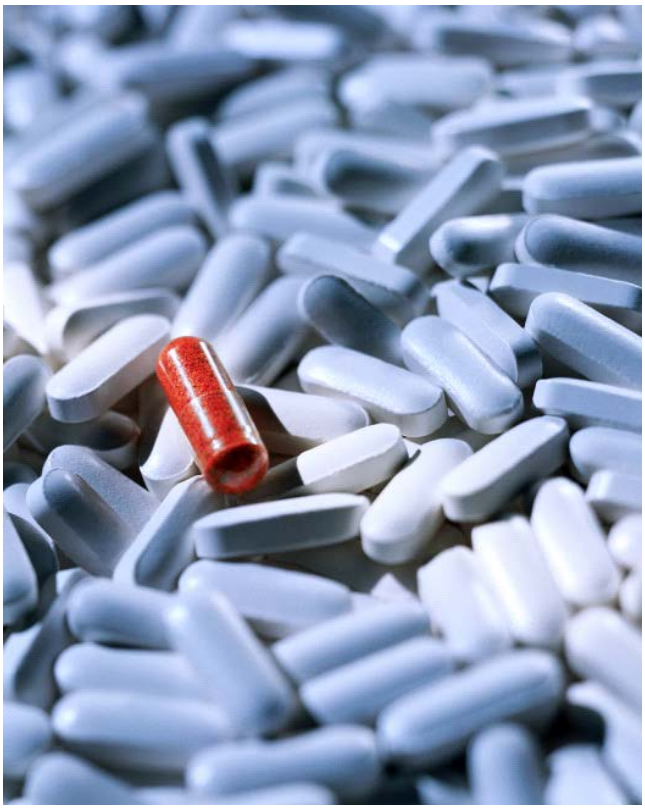
Biologics and Genetic Therapies Directorate
Drug Submission Performance Annual Report

Fiscal Year
2015 – 2016

Apr 1 2015 – Mar 31 2016



Canada

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Table of Contents

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 2011-12 to 2015-16.

Statistics are provided by submission type and show the number received, the number in workload, the number of decisions, the number of approvals and approval times. The report lists details of Priority Submissions and New Active Substances approved during the fiscal year Apr 1 2015 to March 31 2016.

What's New

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

General Information

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

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

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

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

Workload is the number of submissions "under active review" on a given day.
"Backlog" is the proportion of the workload that is over target. Often the term workload is used to mean the amount of work received over a period of time and is a common source of confusion.

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

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.

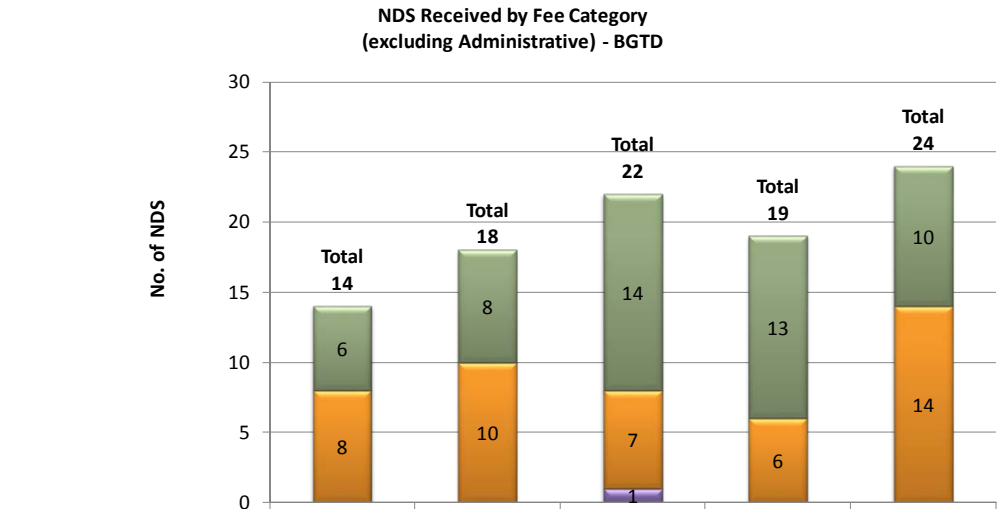
New Drug Submission (NDS)

&

Supplemental New Drug Submission (SNDS)

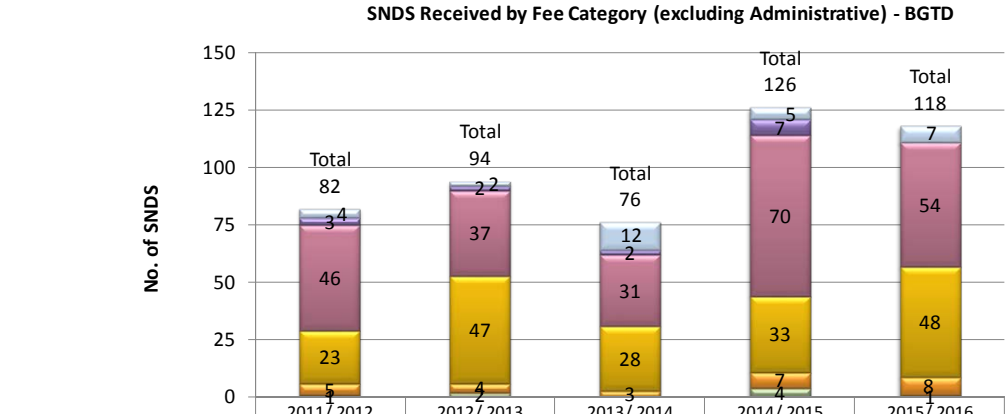
SUBMISSIONS RECEIVED

New Drug Submissions (NDS) Received by Fee Category



	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
New Active Substance	6	8	14	13	10
Clinical or Non-Clin and C&M	8	10	7	6	14
Comparative Studies	0	0	1	0	0
Total	14	18	22	19	24
Priority (subset)	3	3	1	3	2
Emergency Use NDS	0	0	0	0	1
Subsequent Entry Biologic (SEB)	0	4	1	2	4

Supplemental New Drug Submissions (SNDS) Received by Fee Category

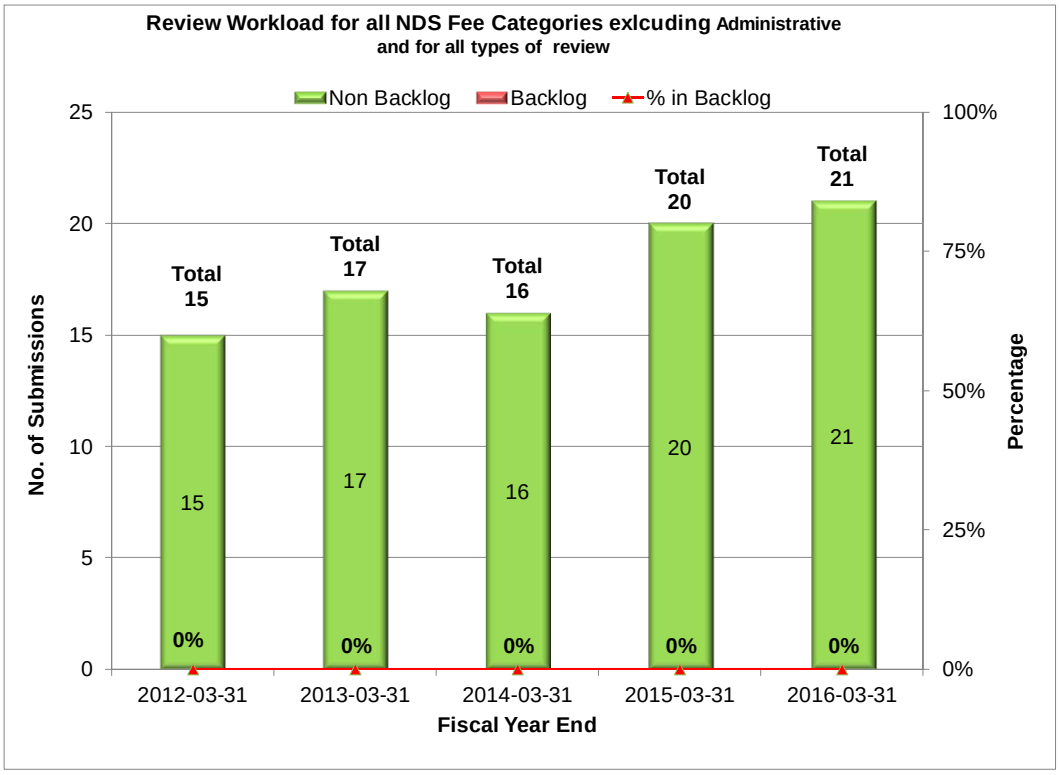


	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
Labelling Only	4	2	12	5	7
Comparative Studies	3	2	2	7	0
Chemistry & Manufacturing	46	37	31	70	54
Clinical or Non-Clin Only	23	47	28	33	48
Clinical or Non-Clin and C&M	5	4	3	7	8
Published Data Only	1	2	0	4	1
Total	82	94	76	126	118
Priority (subset)	1	0	1	0	2
SNDS Confirmatory	0	4	1	2	4
Subsequent Entry Biologic (SEB)				1*	3

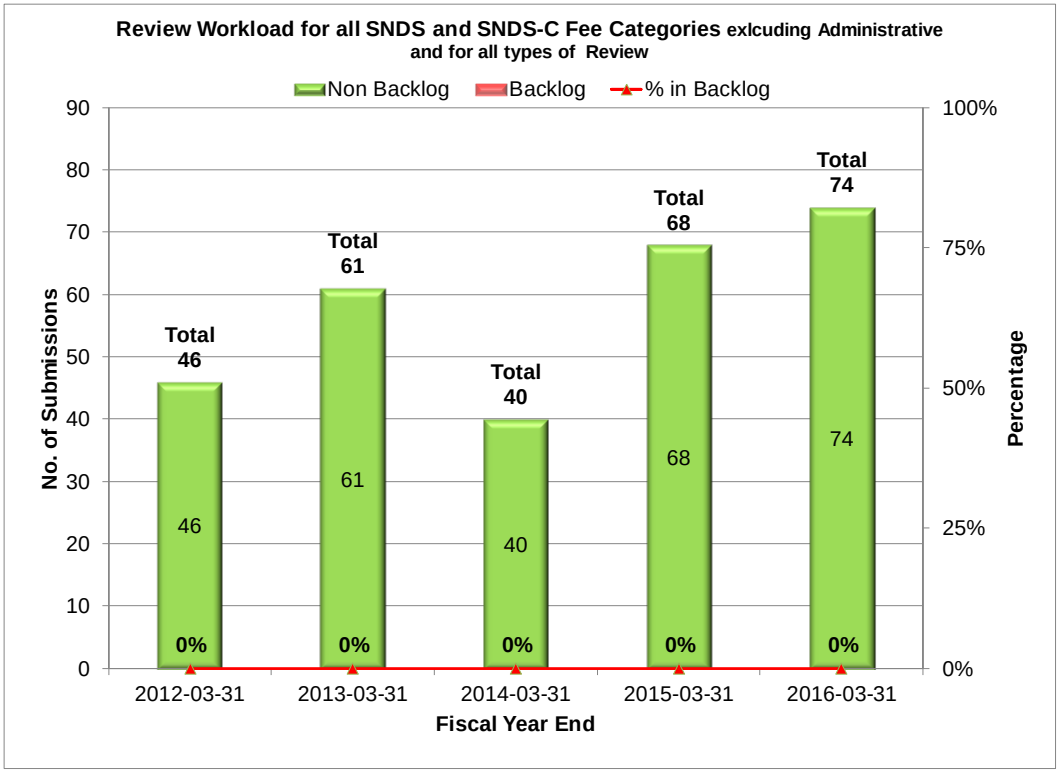
* Revised 17 June 2016

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

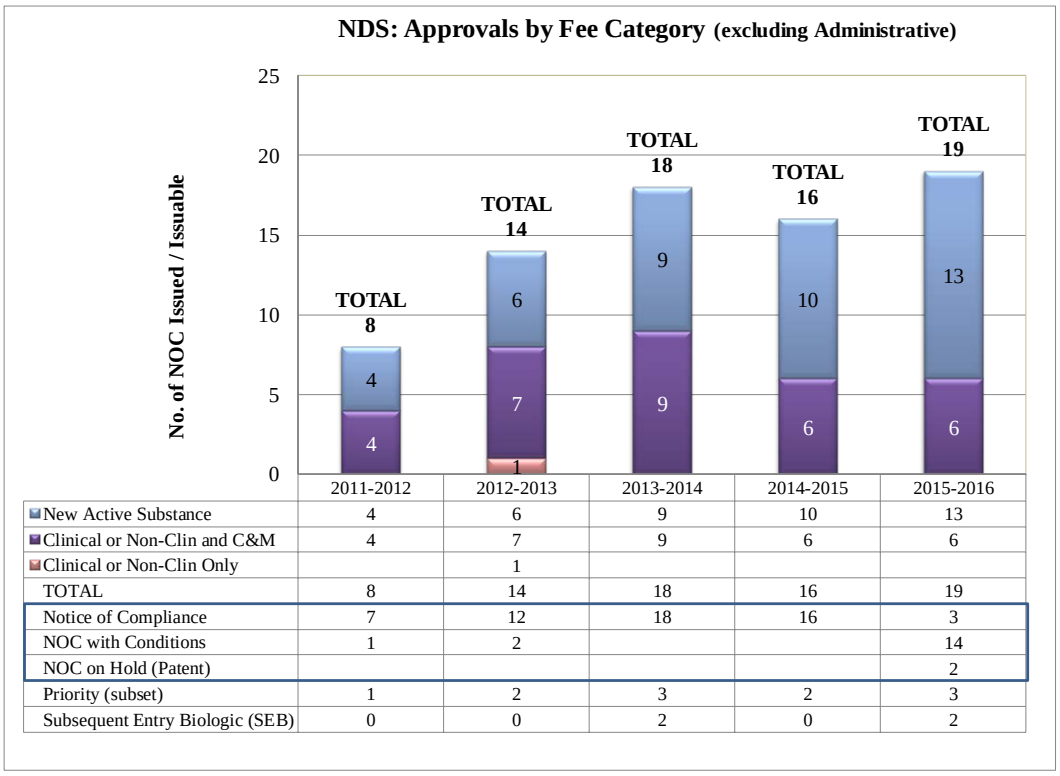
NDS All REVIEW WORKLOAD BY FEE CATEGORY - BGTD (excluding administrative) and Fiscal Year End					
	2012-03-31	2013-03-31	2014-03-31	2015-03-31	2016-03-31
Clinical or Non-Clin Only	**1**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**9**	**10**	**6**	**8**	**11**
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	**5**	**7**	**10**	**12**	**10**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**15**	**17**	**16**	**20**	**21**
Non Backlog	**15**	**17**	**16**	**20**	**21**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**1**	**3**	**1**	**2**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*

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

SNDS and SNDS-C All REVIEW WORKLOAD BY FEE CATEGORY - BGTD (excluding administrative) and Fiscal Year End					
	2012-03-31	2013-03-31	2014-03-31	2015-03-31	2016-03-31
Comparative Studies	**1**	**0**	**0**	**3**	**0**
Backlog	0	0	0	0	0
Chemistry & Manufacturing	**24**	**18**	**15**	**32**	**25**
Backlog	0	0	0	0	0
Clinical or Non-Clin Only	**18**	**38**	**23**	**25**	**37**
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	**3**	**4**	**2**	**5**	**10**
Backlog	0	0	0	0	0
Published Data	***0***	***1***	***0***	***3***	**1**
Backlog	0	0	0	0	0
Total	**46**	**61**	**40**	**68**	**74**
Non Backlog	**46**	**61**	**40**	**68**	**74**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**0**	**0**	**0**	**0**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*
SNDS-C (Confirmatory)	**0**	**3**	**0**	**2**	**3**
Backlog	*0*	*0*	*0*	*0*	*0*

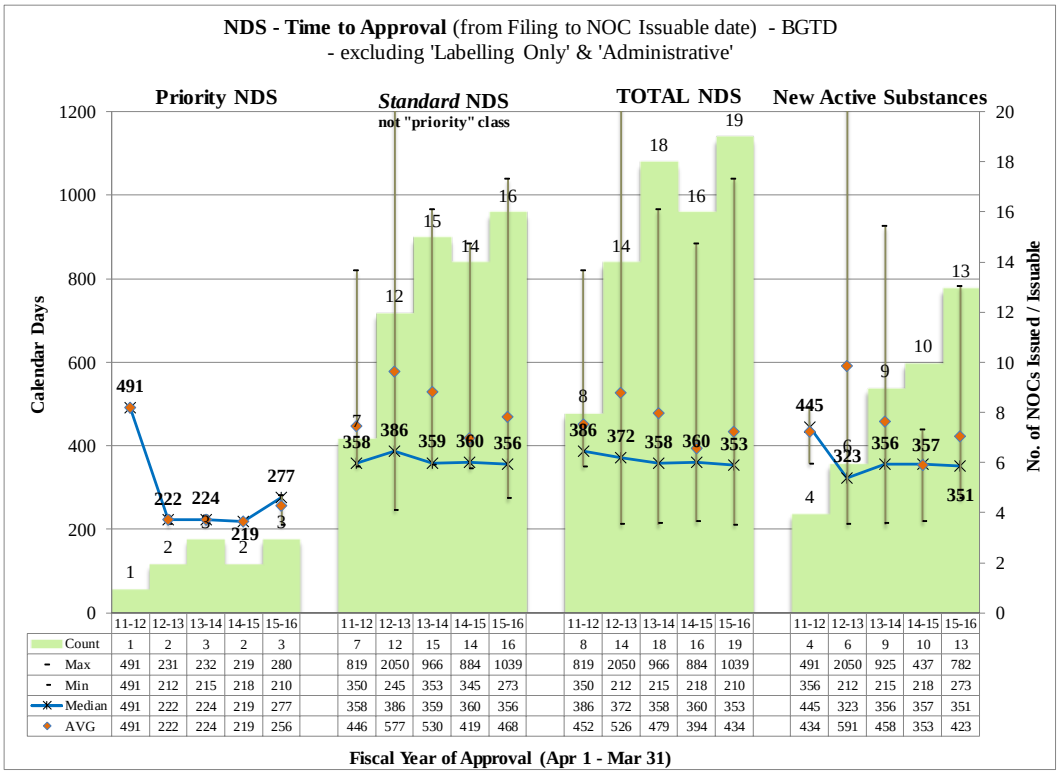
APPROVALS

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



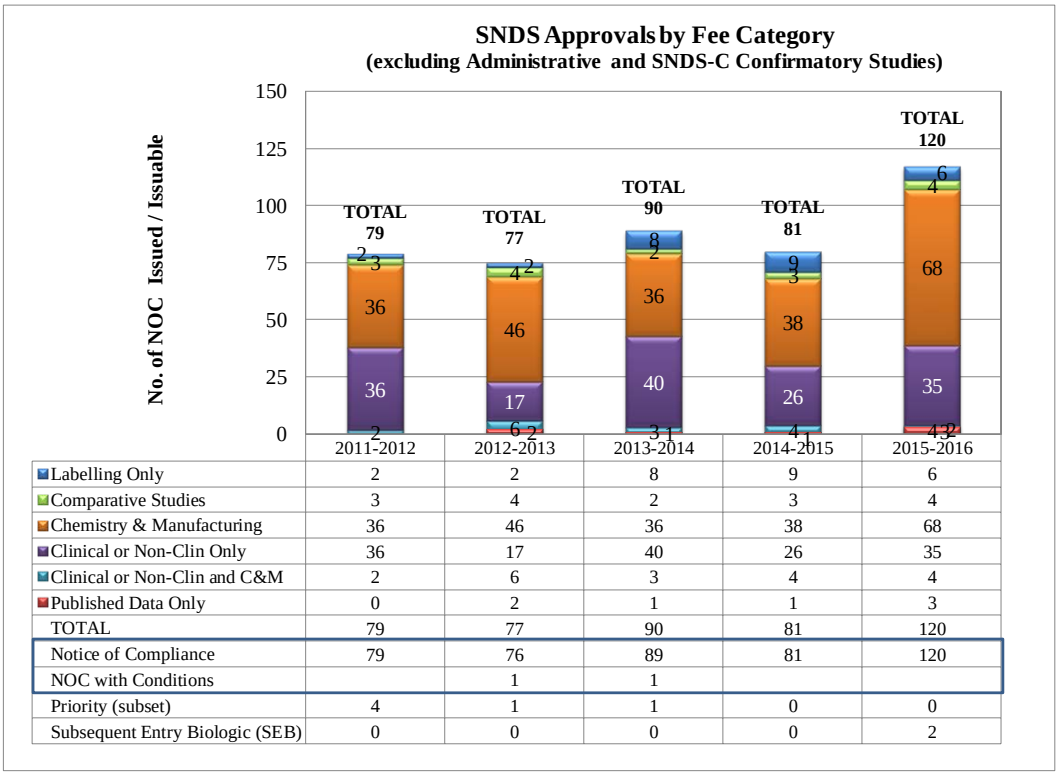
	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
New Active Substance	4	6	9	10	13
Clinical or Non-Clin and C&M	4	7	9	6	6
Clinical or Non-Clin Only		1			
TOTAL	8	14	18	16	19
Notice of Compliance	7	12	18	16	3
NOC with Conditions	1	2			14
NOC on Hold (Patent)					2
Priority (subset)	1	2	3	2	3
Subsequent Entry Biologic (SEB)	0	0	2	0	2

NDS Approval Times



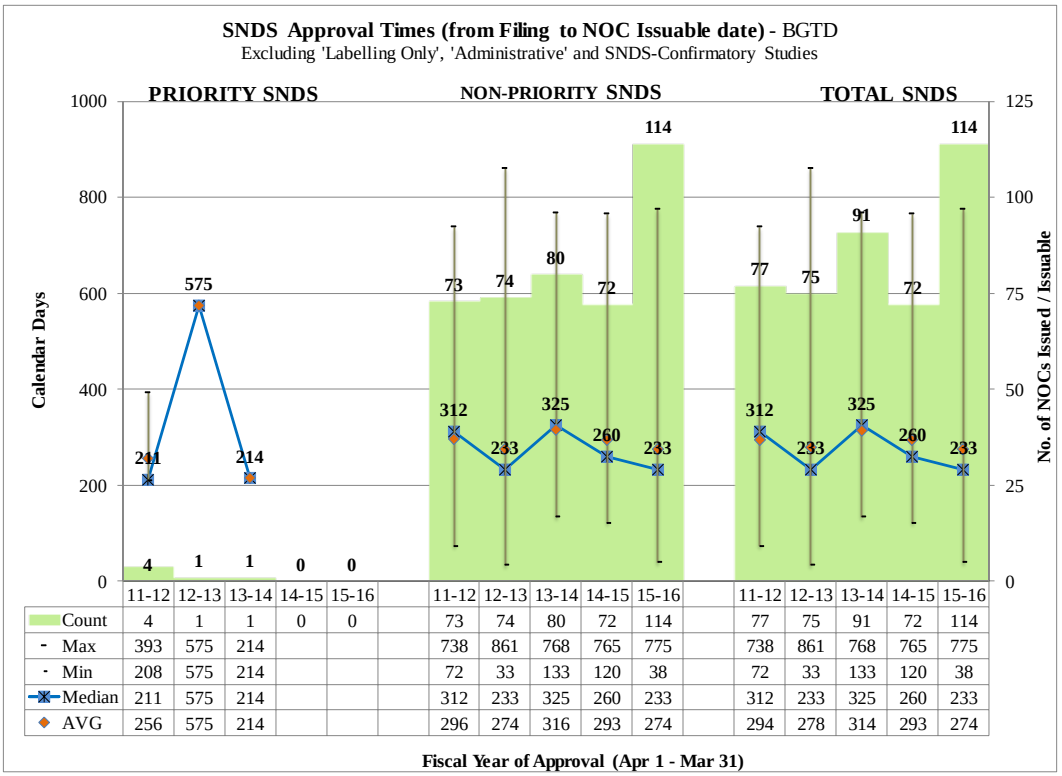
	Priority NDS					Standard NDS					TOTAL NDS					New Active Substances				
	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16
Count	1	2	3	2	3	7	12	15	14	16	8	14	18	16	19	4	6	9	10	13
Max	491	231	232	219	280	819	2050	966	884	1039	819	2050	966	884	1039	491	2050	925	437	782
Min	491	212	215	218	210	350	245	353	345	273	350	212	215	218	210	356	212	215	218	273
Median	491	222	224	219	277	358	386	359	360	356	386	372	358	360	353	445	323	356	357	351
AVG	491	222	224	219	256	446	577	530	419	468	452	526	479	394	434	434	591	458	353	423

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



	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
Labelling Only	2	2	8	9	6
Comparative Studies	3	4	2	3	4
Chemistry & Manufacturing	36	46	36	38	68
Clinical or Non-Clin Only	36	17	40	26	35
Clinical or Non-Clin and C&M	2	6	3	4	4
Published Data Only	0	2	1	1	3
TOTAL	79	77	90	81	120
Notice of Compliance	79	76	89	81	120
NOC with Conditions		1	1		
Priority (subset)	4	1	1	0	0
Subsequent Entry Biologic (SEB)	0	0	0	0	2

SNDS Approval Times



	PRIORITY SNDS					NON-PRIORITY SNDS					TOTAL SNDS				
	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16	11-12	12-13	13-14	14-15	15-16
Count	4	1	1	0	0	73	74	80	72	114	77	75	91	72	114
Max	393	575	214			738	861	768	765	775	738	861	768	765	775
Min	208	575	214			72	33	133	120	38	72	33	133	120	38
Median	211	575	214			312	233	325	260	233	312	233	325	260	233
AVG	256	575	214			296	274	316	293	274	294	278	314	293	274

New Active Substance Approvals (NAS) – BGTD - Fiscal Year 2015-2016

New Active Substance Approvals (NAS) – BGTD Fiscal Year 2015-2016 (April 1 2015 to March 31 2016)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[5])**	**Approval Date (dd-mon-yy)**
BLINCYTO (Blinatumomab) - is indicated for: the treatment of adults with Philadelphia chromosome-negative relapsed or refractory B precursor acute lymphoblastic leukemia (ALL).	NOC-C NAS	Amgen Canada Inc.	30-Jan-15	22-Dec-15 NOC-C
CYRAMZA (Ramucirumab) - as a single agent or in combination with paclitaxel is indicated for the treatment of patients with advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma, with disease progression on or after prior platinum and fluoropyrimidine chemotherapy.	NAS	Eli Lilly Canada Inc.	28-Jul-14	16-Jul-15
EPERZAN (Albiglutide) - is indicated for once-weekly administration for the treatment of adults with type 2 diabetes mellitus, as an adjunct to diet and exercise to improve glycemic control as monotherapy in patients inadequately controlled by diet, exercise and when metformin is inappropriate due to contraindication or intolerance and in combination with one of the following therapeutic options in patients who have not achieved adequate glycemic control: - metformin, when diet and exercise plus maximal tolerated dose of metformin do not achieve adequate glycemic control - metformin and sulfonylurea, when diet and exercise plus dual therapy with metformin and sulfonylurea do not achieve adequate glycemic control - basal insulin with oral antidiabetic therapies, when diet and exercise plus basal insulin with oral antidiabetic therapies do not achieve adequate glycemic control (See CLINICAL TRIALS). The combination of EPERZAN™ with prandial insulin (short acting) has not been studied. EPERZAN™ should not be used in Type 1 diabetes (formerly known as insulin-dependent diabetes mellitus or IDDM) or for the treatment of patients with diabetic ketoacidosis.	NAS	GlaxoSmithKline Inc.	24-May-13	15-Jul-15
IDELVION (Albutrepenonacog Alfa) - is an antihemophilic factor indicated in patients with hemophilia B (congenital FIX deficiency) or Christmas disease for: routine prophylaxis to prevent or reduce the frequency of bleeding episodes; control and prevention of bleeding episodes; and control and prevention of bleeding in the perioperative setting.	NAS	CSL Behring Canada Inc.	9-Feb-15	26-Jan-16

[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 2015-2016
(April 1 2015 to March 31 2016)

Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date[5])	Approval Date (dd-mon-yy)
KEYTRUDA (Pembrolizumab) - is indicated for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab therapy and, if BRAF V600 mutation positive, following a BRAF or MEK inhibitor. An improvement in survival or disease-related symptoms has not yet been established.	NOC-C NAS	Merck Canada Inc.	23-Jun-14	19-May-15 NOC-C
NUCALA (Mepolizumab) - is indicated as add-on maintenance treatment of adult patients with severe eosinophilic asthma who: are inadequately controlled with high-dose inhaled corticosteroids and an additional asthma controller(s) (e.g LABA), and have a blood eosinophil count of ≥ 150 cells/µL (0.15 GI/L) at initiation of treatment with NUCALA™ OR ≥ 300 cells/µL (0.3 GI/L) in the past 12 months.	NAS	GlaxoSmithKline Inc.	19-Nov-14	3-Dec-15
OBIZUR (Antihemophilic Factor (Recombinant) Porcine Sequence) - is indicated for: Treatment of bleeding episodes in patients with Acquired Hemophilia A (AHA).	NAS	Baxalta Canada Corporation	15-Aug-14	14-Oct15
OPDIVO (Nivolumab) - is indicated for the treatment of unresectable or metastatic BRAF V600 wild-type melanoma in previously untreated adults.	PRIORITY-NAS	Bristol-Myers Squibb Canada	19-Dec-14	25-Sep-15
PLEGRIDY (Peginterferon Beta-1A) - is indicated for treatment of relapsing remitting multiple sclerosis (RRMS) for adult patients to reduce the frequency of clinical exacerbations and to slow the progression of disability.	NAS	Biogen Idec Canada Inc.	31-Jul-13	10-Aug-15
REPATHA (Evolocumab) - is indicated as an adjunct to diet and maximally tolerated statin therapy in adult patients with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C). is indicated as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in adult patients and adolescent patients aged 12 years and over with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.	NAS	Amgen Canada Inc.	25-Sep-14	10-Sep-15

New Active Substance Approvals (NAS) – BGTD Fiscal Year 2015-2016 (April 1 2015 to March 31 2016)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[5])**	**Approval Date (dd-mon-yy)**
REVESTIVE (Teduglutide) - is indicated for treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support.	PRIORITY-NAS	NPS Pharma Holdings Limited	1-Dec-14	4-Sep-15
STRENSIQ (Asfotase Alfa) - is indicated as enzyme replacement therapy for patients with confirmed diagnosis of paediatric-onset hypophosphatasia.	NOC-C NAS	Alexion Pharma International Sarl	14-Nov-14	14-Aug-15 NOC-C
TRULICITY (Dulaglutide) - is indicated for the once-weekly treatment of adult patients with type 2 diabetes mellitus to improve glycemic control, in combination with: diet and exercise in patients for whom metformin is inappropriate due to contraindication or intolerance; metformin, when diet and exercise plus maximal tolerated dose of metformin do not achieve adequate glycemic control; metformin and a sulfonylurea, when diet and exercise plus dual therapy with metformin and a sulfonylurea do not achieve adequate glycemic control and prandial insulin with metformin, when diet and exercise plus basal or basal-bolus insulin therapy (up to two injections of basal or basal plus prandial insulin per day) with or without oral antihyperglycemic medications, do not achieve adequate glycemic control (see CLINICAL TRIALS). TRULICITY has not been studied in combination with basal insulin (long acting). TRULICITY is not a substitute for insulin. TRULICITY should not be used in patients with Type 1 diabetes mellitus (formerly known as insulin-dependent diabetes mellitus or IDDM) or for the treatment of diabetic ketoacidosis.	NAS	Eli Lilly Canada Inc.	10-Feb-14	10-Nov-15

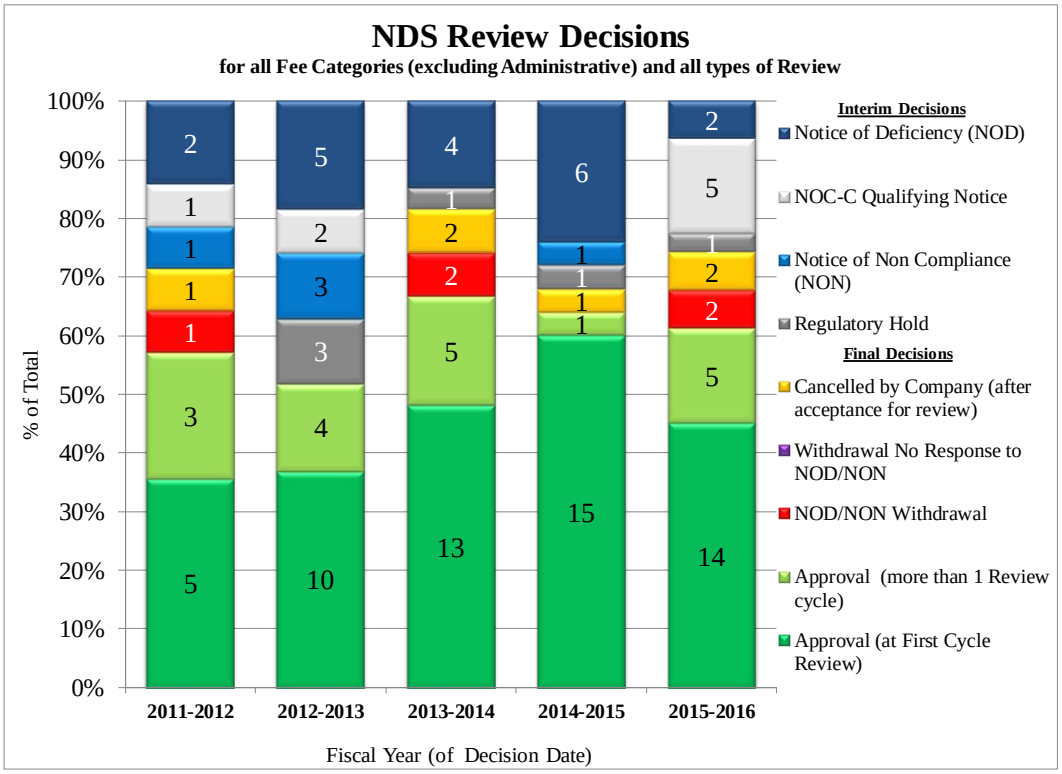
Priority Submission Approvals – BGTD - Fiscal Year 2015-2016

Priority Submission Approvals – BGTD Fiscal Year 2015-2016 (April 1 2015 to March 31 2016)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[6])**	**Approval Date (dd-mon-yy)**
OPDIVO (Nivolumab) - is indicated for the treatment of unresectable or metastatic BRAF V600 wild-type melanoma in previously untreated adults.	PRIORITY-NAS	Bristol-Myers Squibb Canada	19-Dec-14	25-Sep-15
OPDIVO (Nivolumab) - is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumour aberrations should have disease progression on a therapy for these aberrations prior to receiving OPDIVO.	PRIORITY-CLIN/C&M	Bristol-Myers Squibb Canada	31-Jul-15	26-Feb-16
REVESTIVE (Teduglutide) - is indicated for treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support.	PRIORITY-NAS	NPS Pharma Holdings Limited	1-Dec-14	4-Sep-15

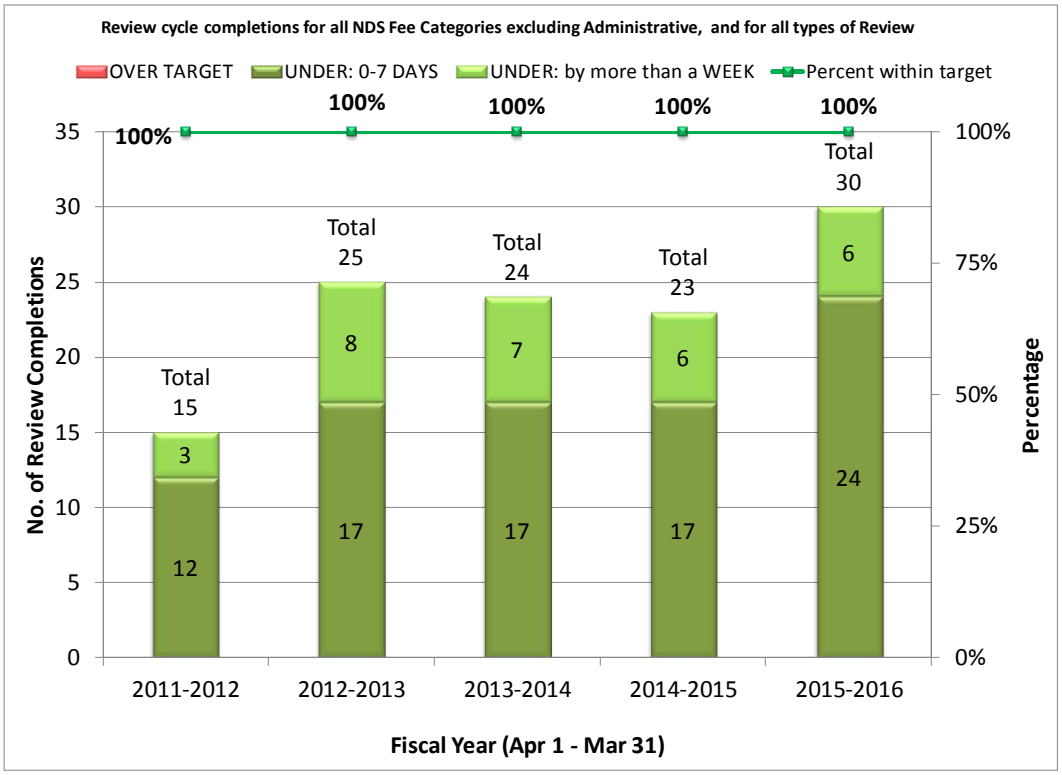
[6] The CR Date is the date the submission is received and considered administratively complete by Health Canada

REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

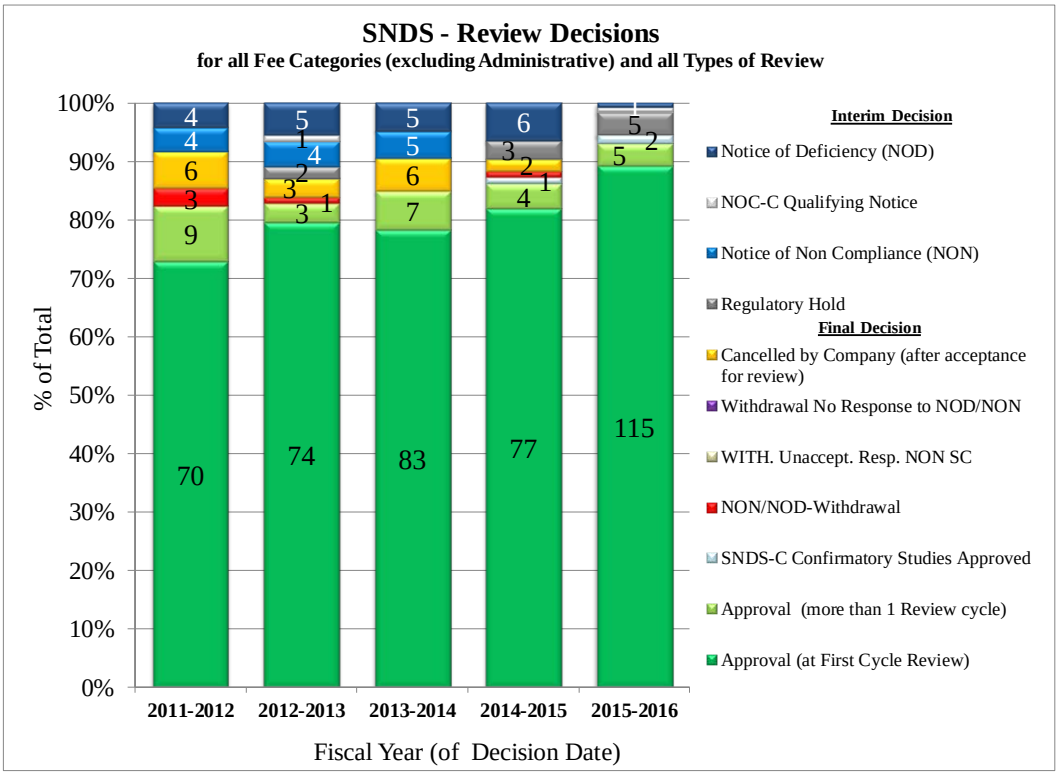


NDS - Review Cycle Completions Showing Percentage Within Target

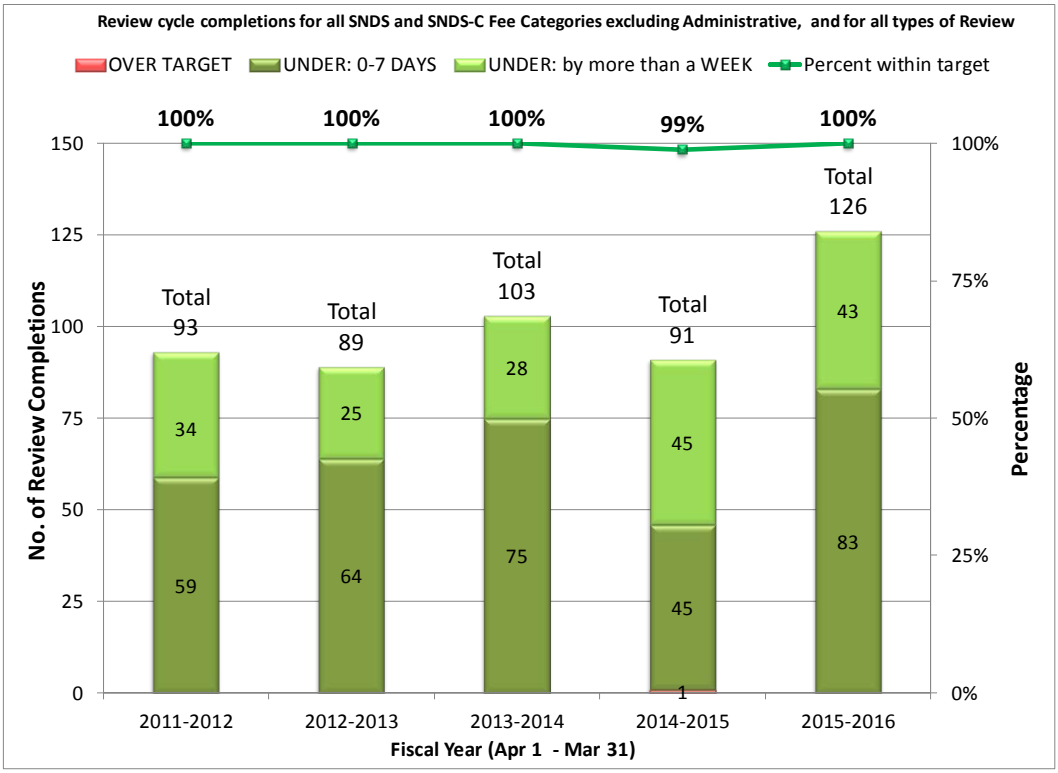


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

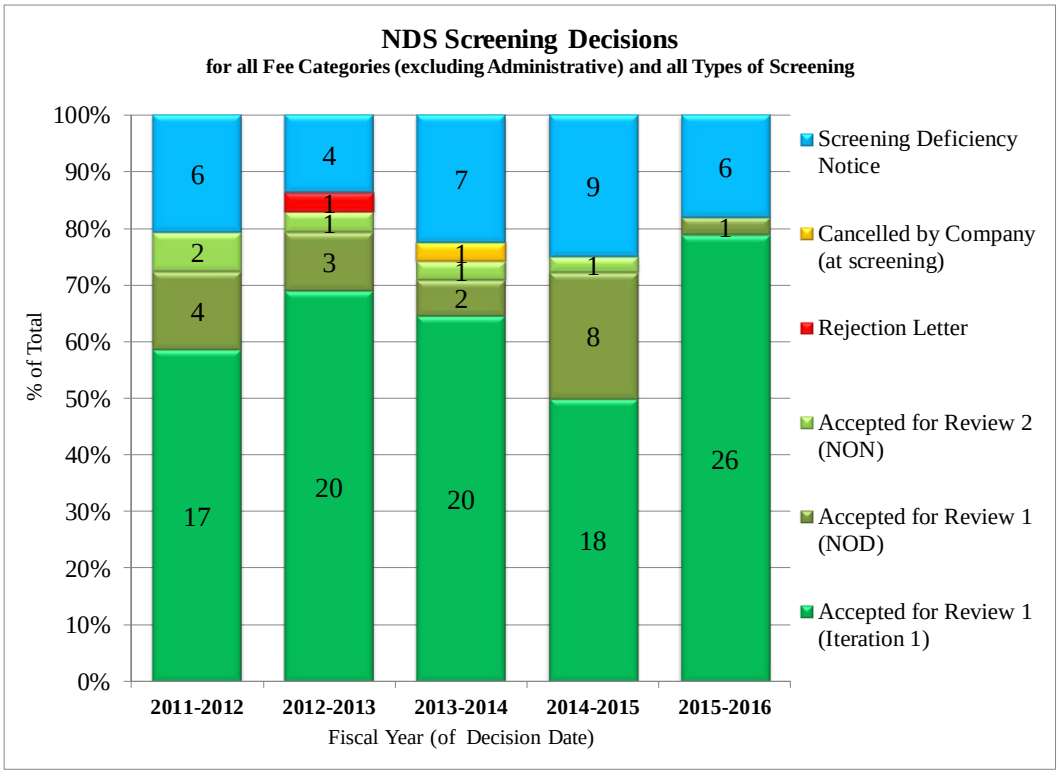


SNDS - Review Cycle Completions Showing Percentage Within Target

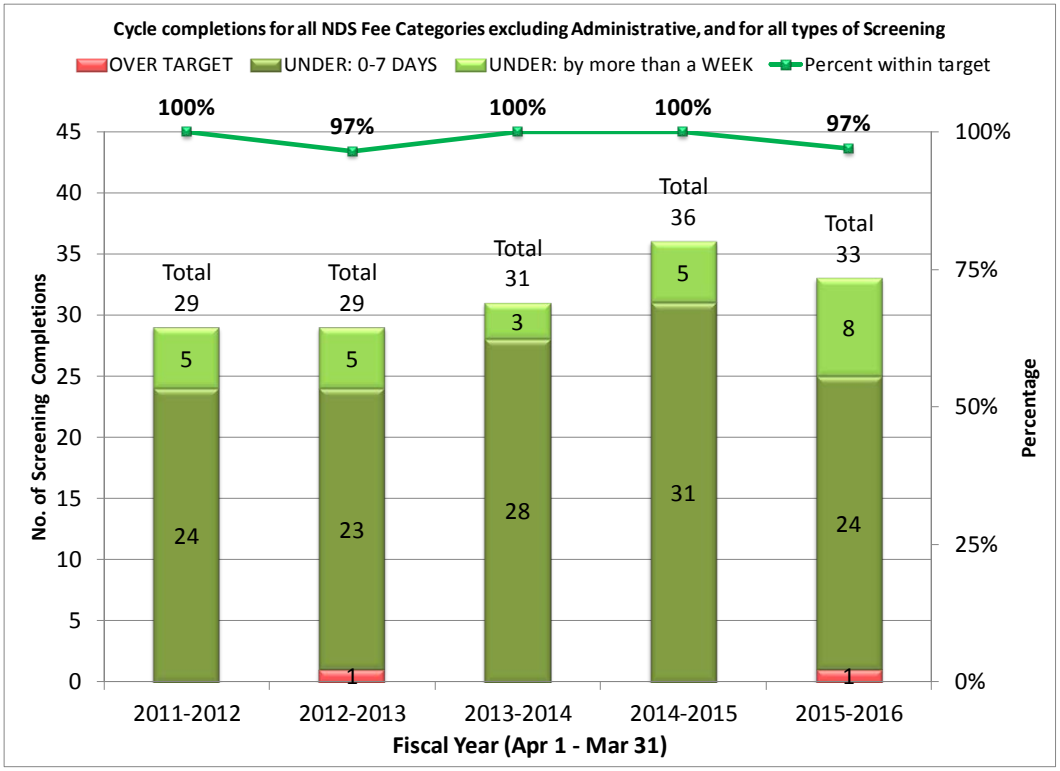


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

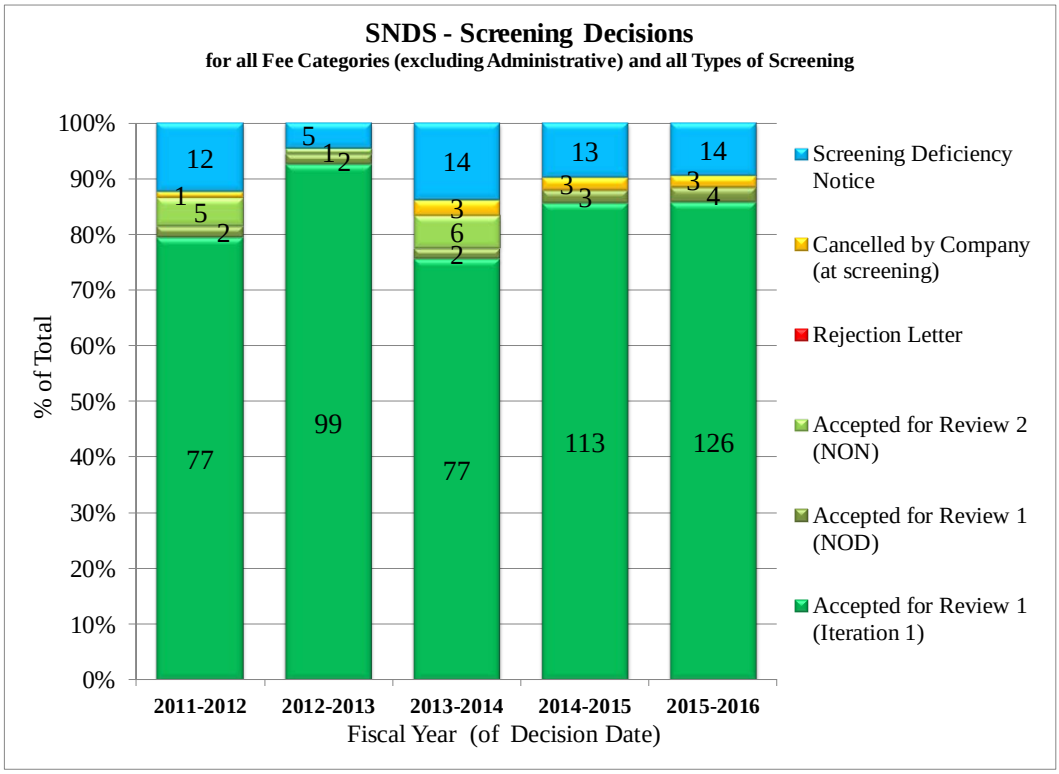


NDS - Screening Cycle Completions Showing Percentage Within Target

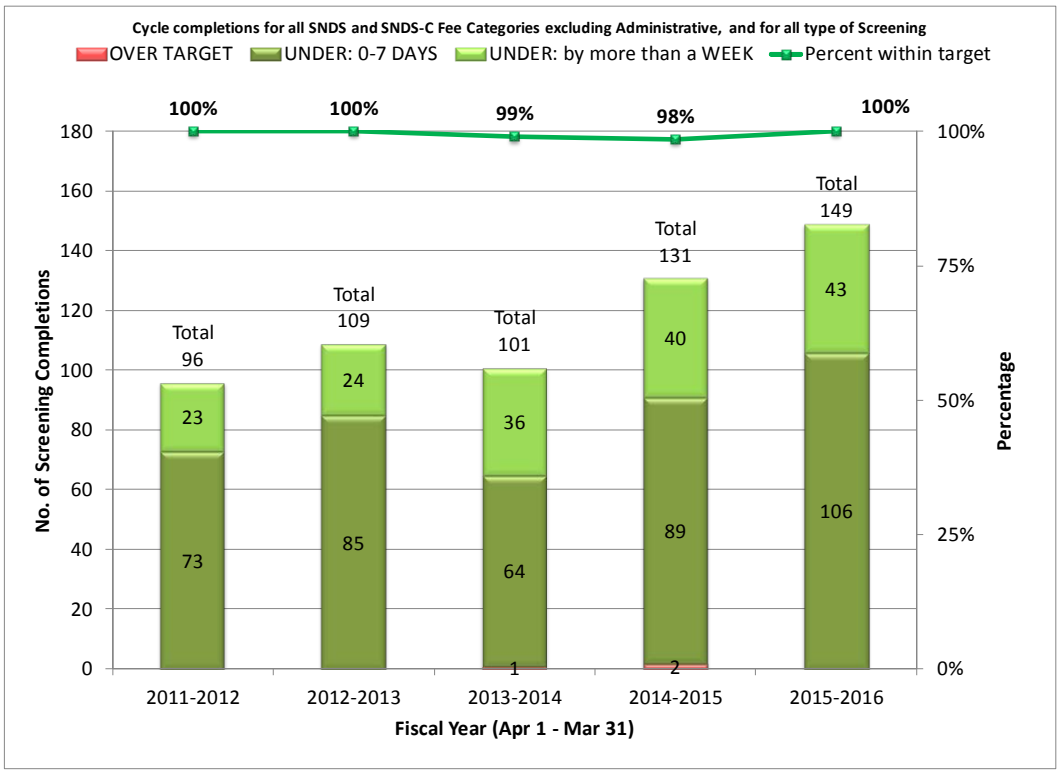


SCREENING CYCLE DECISIONS

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 –NDS, SNDS & ANDS

Reconsideration of Final Decisions Requests Received - NDS, SNDS & ANDS Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	**11-12**	**12-13**	**13-14* revised**	**14-15**	**15-16**	**Final Decision in Dispute**	**NDS Status (as of Apr 18 2016)**
Total Received	**0**	**1**	**1**	**0**	**0**		
NDS	**0**	**0**	**0**	**0**	**0**		
Total Granted	**0**	**1**	**1**	**0**	**0**		
SNDS	0	1	0	0	0	NON Withdrawal	Withdrawn
ANDS	0	0	1	0	0	NOD Withdrawal	Withdrawn
Total Denied	0	0	0	0	0		

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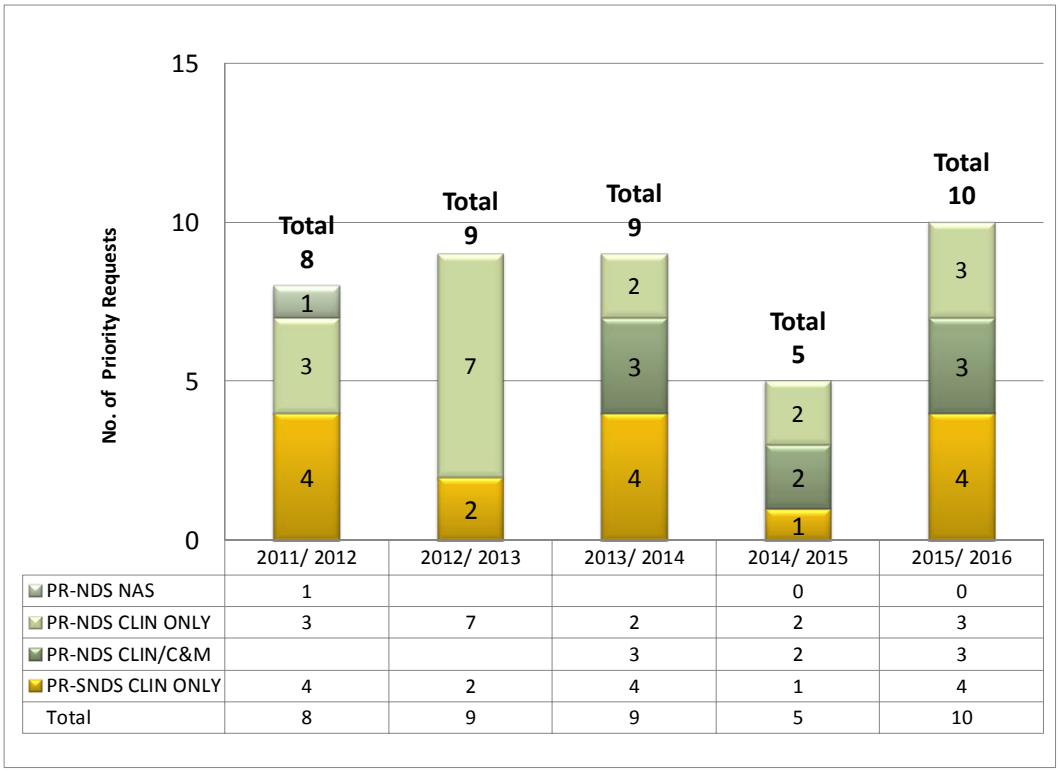
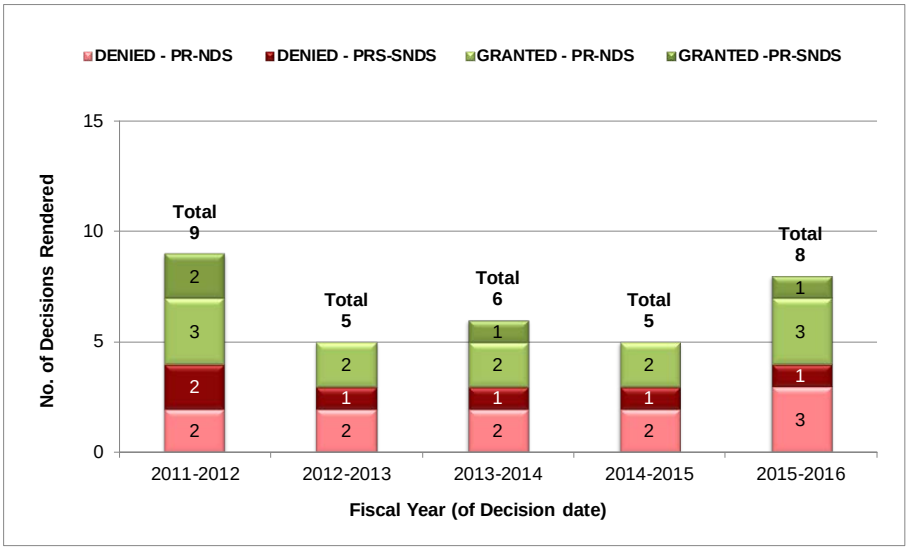
PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests Received



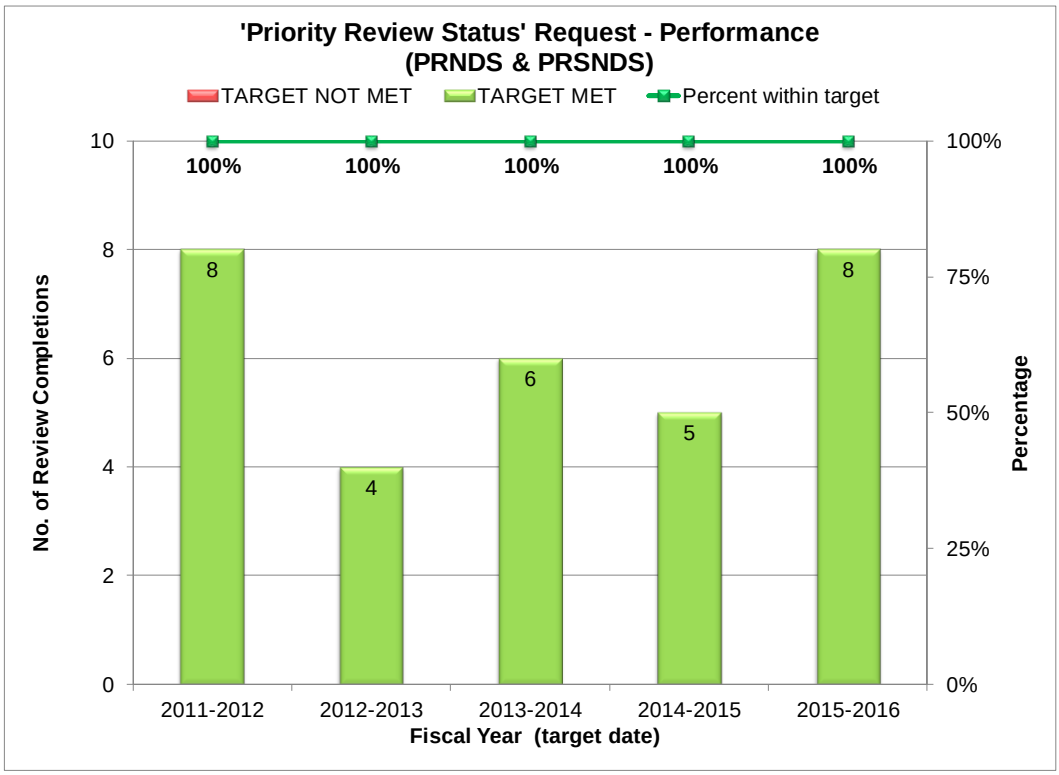
	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
PR-NDS NAS	1			0	0
PR-NDS CLIN ONLY	3	7	2	2	3
PR-NDS CLIN/C&M			3	2	3
PR-SNDS CLIN ONLY	4	2	4	1	4
Total	8	9	9	5	10

Priority Review Status Requests: Decisions Rendered



PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests: Performance



REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

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

"Priority Review Request" - Requests for Reconsideration of Final Decisions

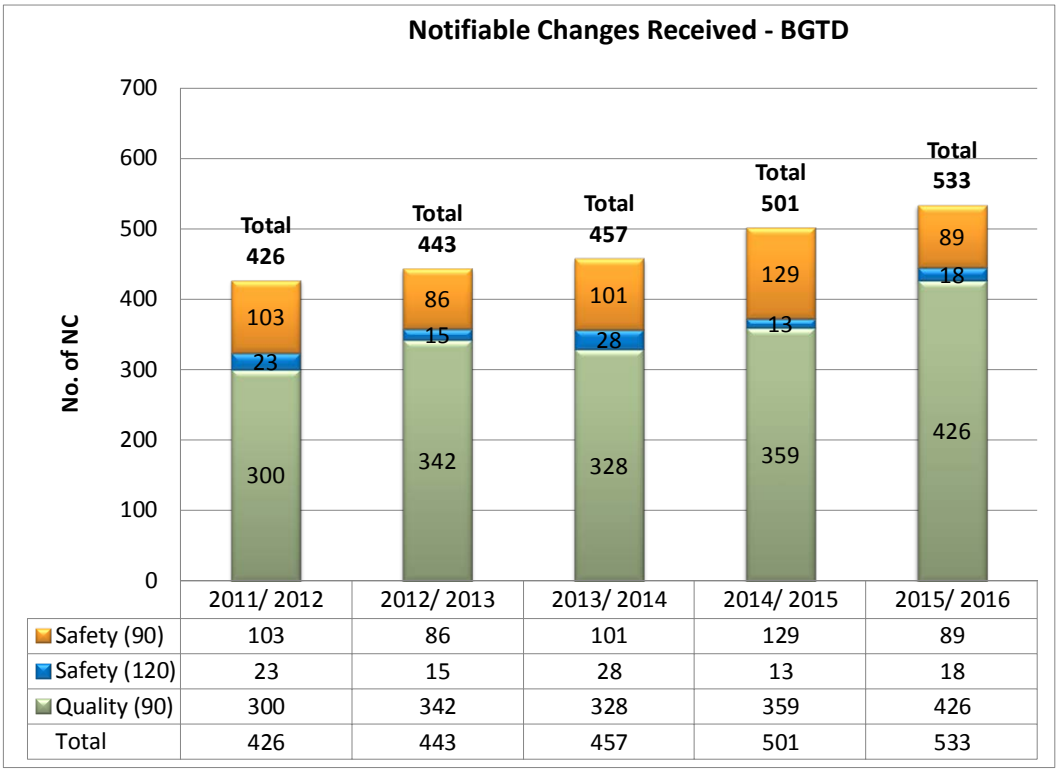
Fiscal Year of Request (Apr - Mar)

Breakdown by Reconsideration Decision	11-12	12-13	13-14	14-15	15-16	Final Decision in Dispute	Submission Status as of Apr 18 2016
Total Received	**0**	**1**	**0**	**0**	**0**		
Total Granted	***0***	***1***	***0***	***0***	***0***	Priority review request Denied	CLEARED

NOTIFIABLE CHANGES (NC)

NOTIFIABLE CHANGES[7,8]

Number Received - Notifiable Changes (NC)



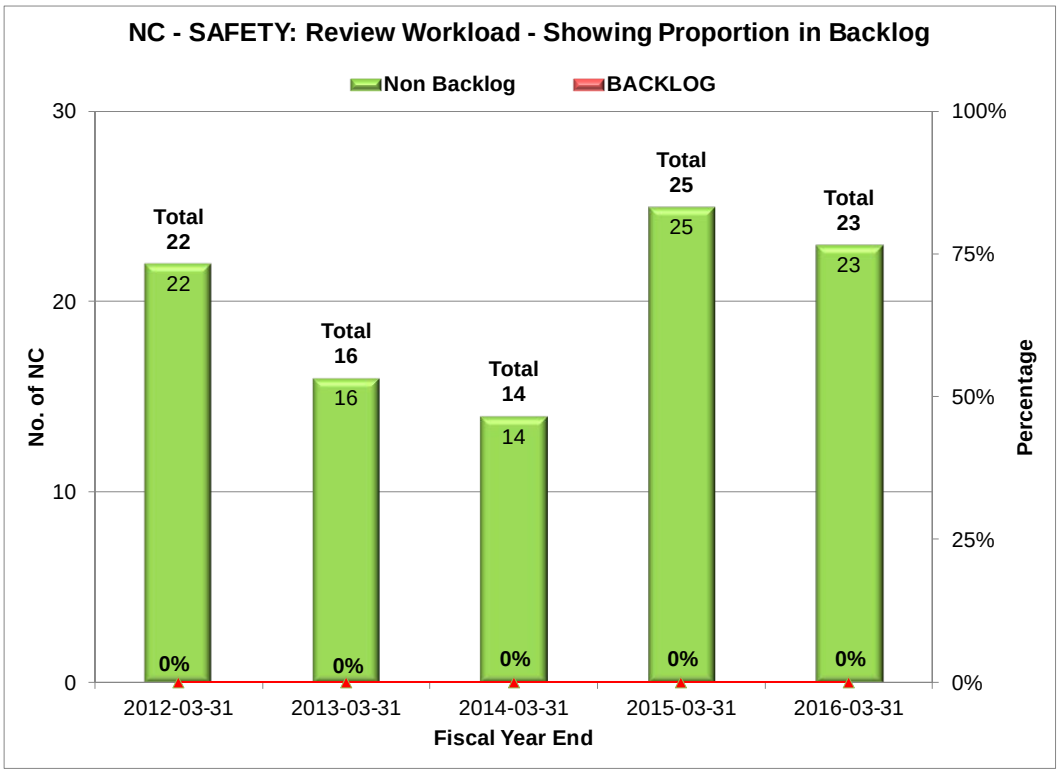
	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
Safety (90)	103	86	101	129	89
Safety (120)	23	15	28	13	18
Quality (90)	300	342	328	359	426
Total	426	443	457	501	533

[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

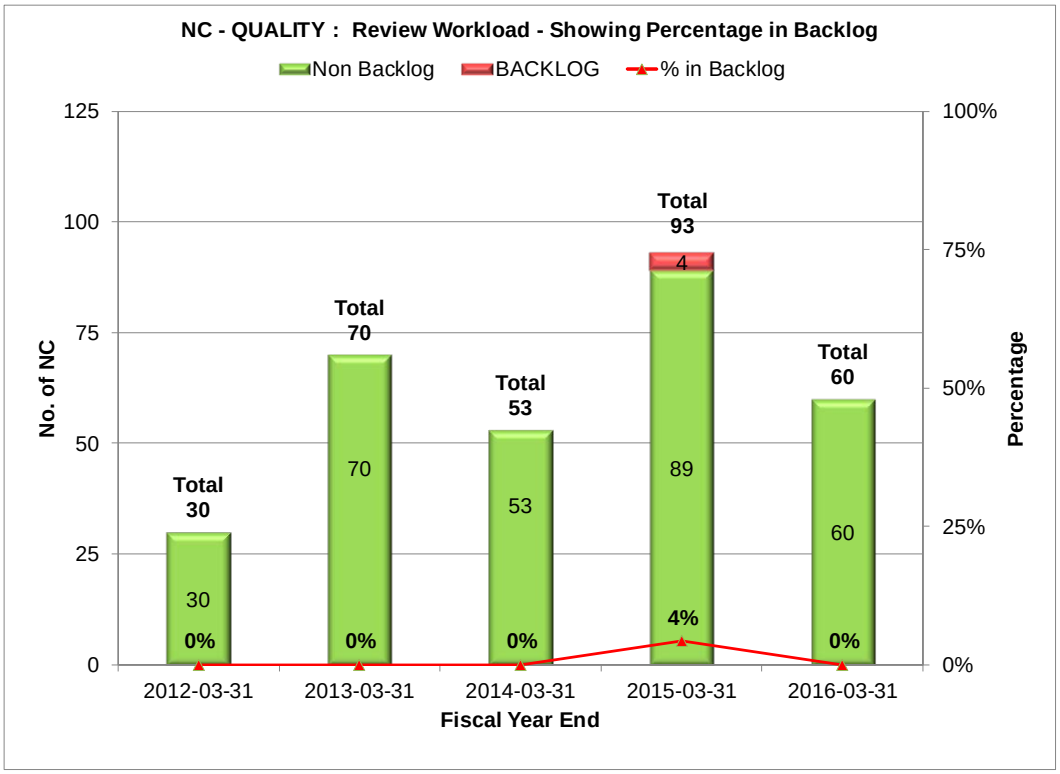
[8] Post-Notice of Compliance (NOC) Changes - Quality Guidance Appendix 1 for Human Pharmaceuticals became effective October 17, 2011.

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

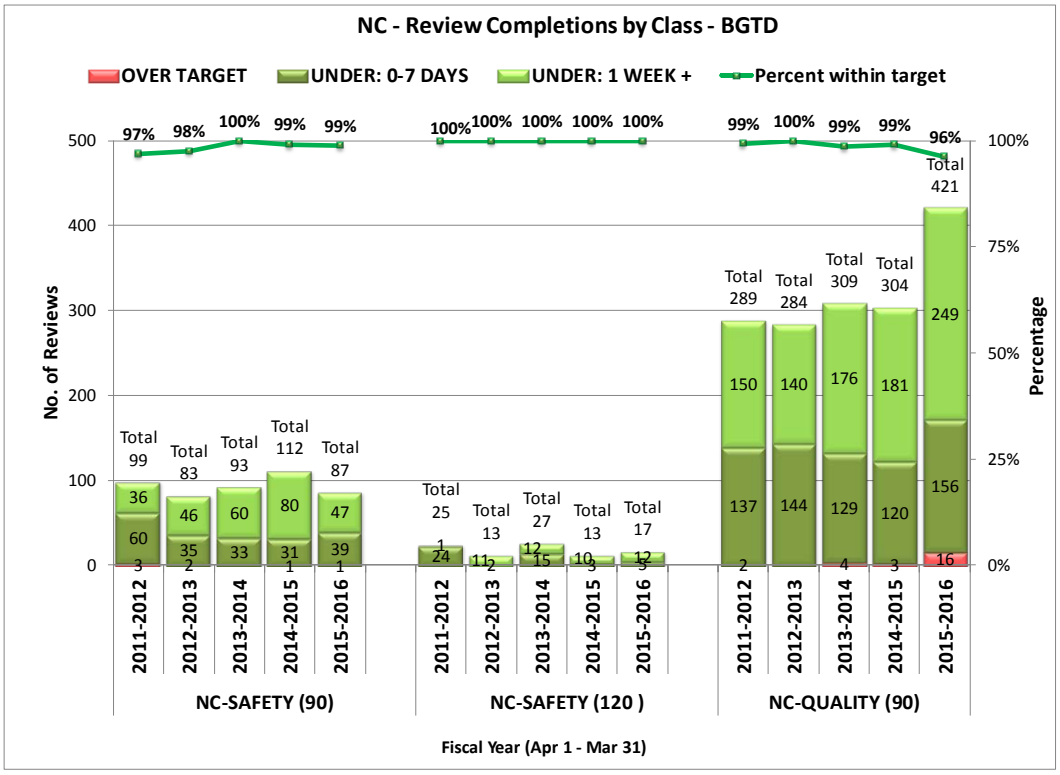
BGTD NC- SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2012-03-31	2013-03-31	2014-03-31	2015-03-31	2016-03-31
SAFETY - 90 day	20	13	11	22	20
Backlog	*0*	*0*	*0*	*0*	*0*
SAFETY - 120 day	2	3	3	3	3
	0	*0*	*0*	*0*	*0*
Total	22	16	14	25	23
Non Backlog	22	16	14	25	23
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

Notifiable Change (NC) QUALITY: Review Workload by Class

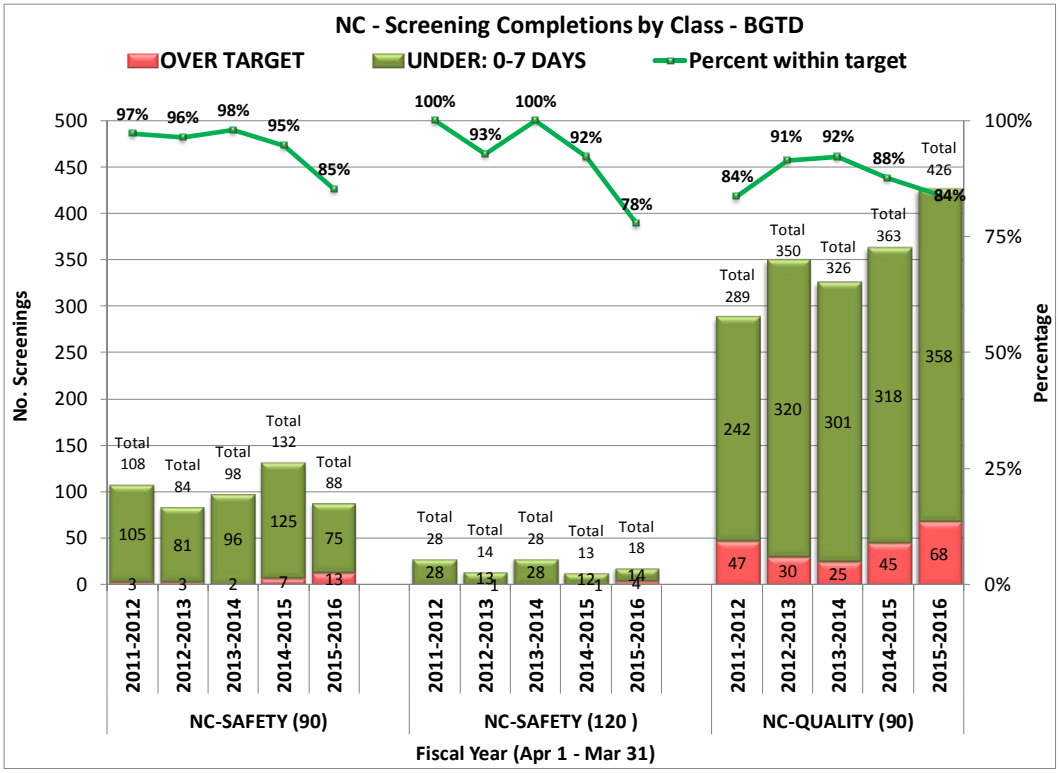
BGTD NC- QUALITY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2012-03-31	2013-03-31	2014-03-31	2015-03-31	2016-03-31
QUALITY - 90 day	30	70	53	93	60
Backlog	*0*	*0*	*0*	*4*	*0*
Total	30	70	53	93	60
Non Backlog	30	70	53	89	60
BACKLOG	0	0	0	4	0
% in Backlog	0%	0%	0%	4%	0%

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	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER	315	278	301	302	410
NOT SATISFACTORY NOTICE	27	4	4		3
REJECTION LETTER (SCR)	5	19	22	8	33
CANCELLED BY COMPANY	7	8	13	3	6
SCREENING DEFICIENCY NOTICE	7	3	6	12	7

NC - SAFETY (90)					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER	98	81	92	112	81
NOT SATISFACTORY NOTICE		2			2
REJECTION LETTER (SCR)	5	6	1	5	1
CANCELLED BY COMPANY	4	2	7	4	4
SCREENING DEFICIENCY NOTICE	2		1	1	1
NC - HOLD (PATENT)					1

NC - SAFETY (120)					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER	25	13	27	12	15
NOT SATISFACTORY NOTICE					2
REJECTION LETTER (SCR)	3				
SCREENING DEFICIENCY NOTICE	1				
CANCELLED BY COMPANY			1	1	1

REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

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

NC					
Year of Reconsideration Request					
	11-12	**12-13**	**13-14**	**14-15**	**15-16**
Total	**0**	**0**	**0**	**0**	**0**

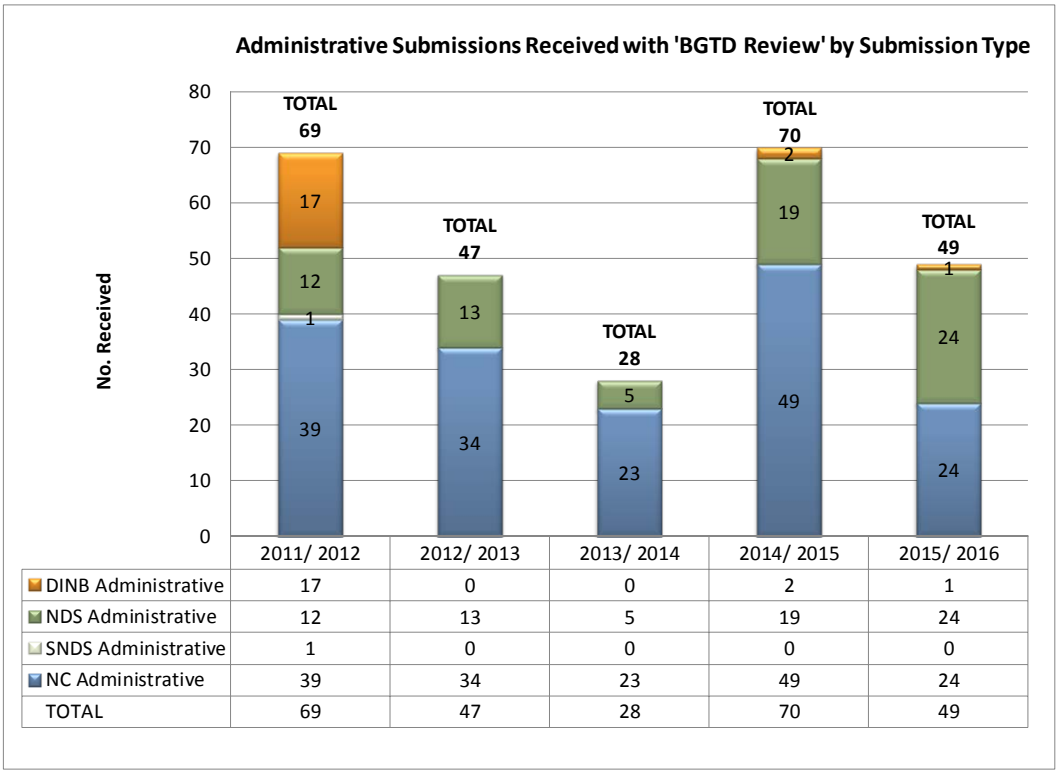
Administrative Submissions

Submissions in support of a manufacturer or product name change.

ADMINISTRATIVE SUBMISSIONS with BGTD review

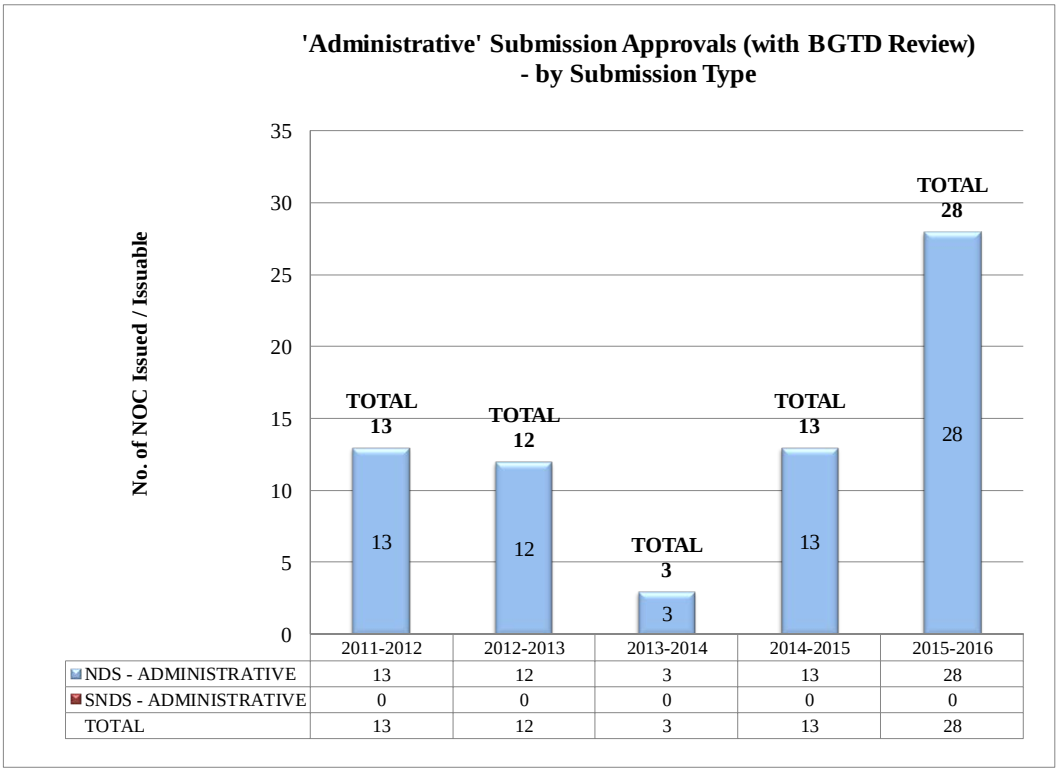
(such as product name change that requires a drug name review)

Administrative Submissions Received (with BGTD review)



	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
DINB Administrative	17	0	0	2	1
NDS Administrative	12	13	5	19	24
SNDS Administrative	1	0	0	0	0
NC Administrative	39	34	23	49	24
TOTAL	69	47	28	70	49

Administrative Submission Approvals (with BGTD Review)

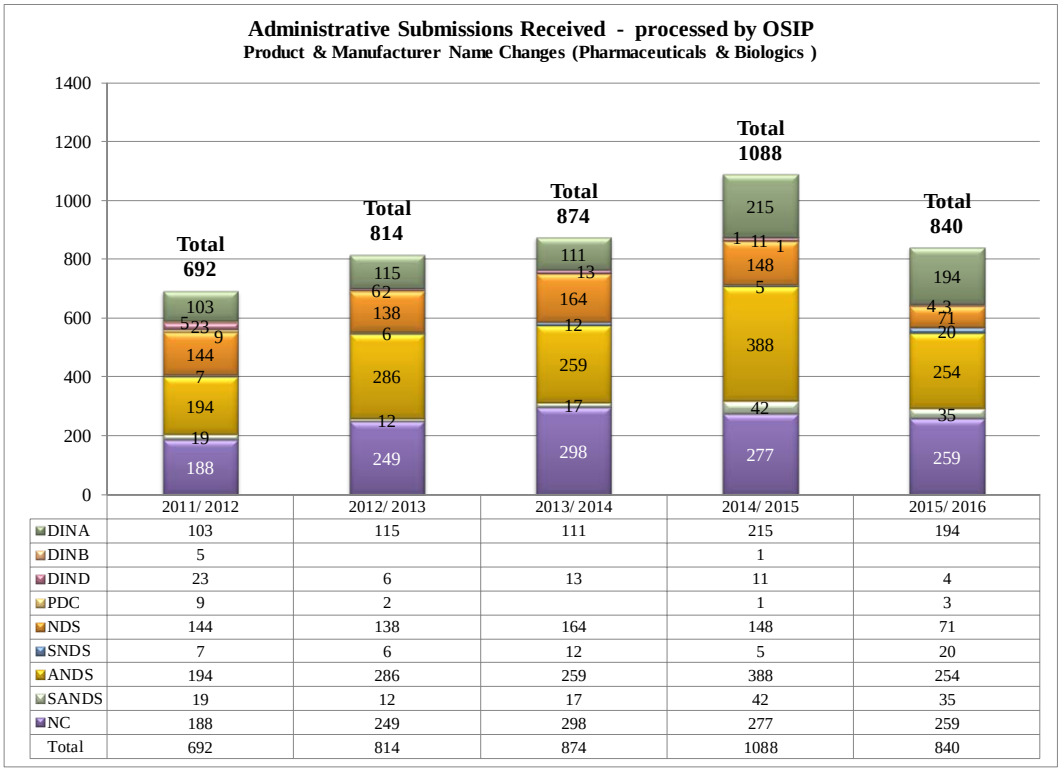


	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
NDS - ADMINISTRATIVE	13	12	3	13	28
SNDS - ADMINISTRATIVE	0	0	0	0	0
TOTAL	13	12	3	13	28

ADMINISTRATIVE SUBMISSIONS (Processed by OSIP)

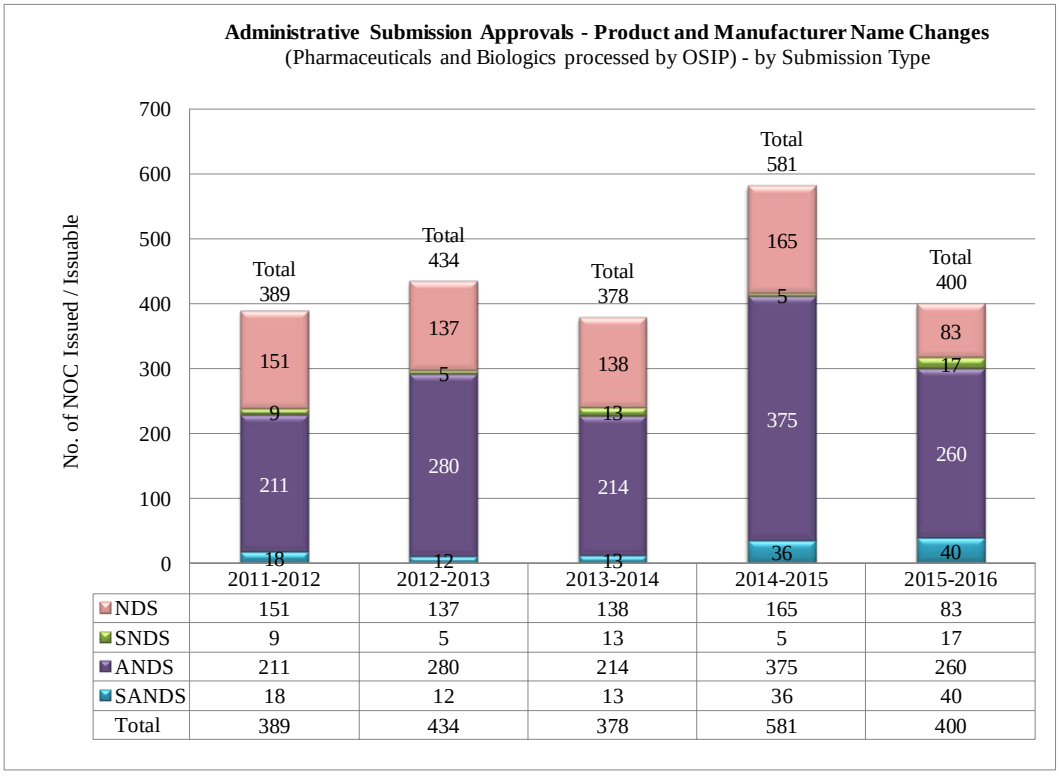
(Product & Manufacturer Name Changes)
(Admin Ncs are for cross-referenced changes)

Administrative Submissions Received by Submission Type (OSIP)



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

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



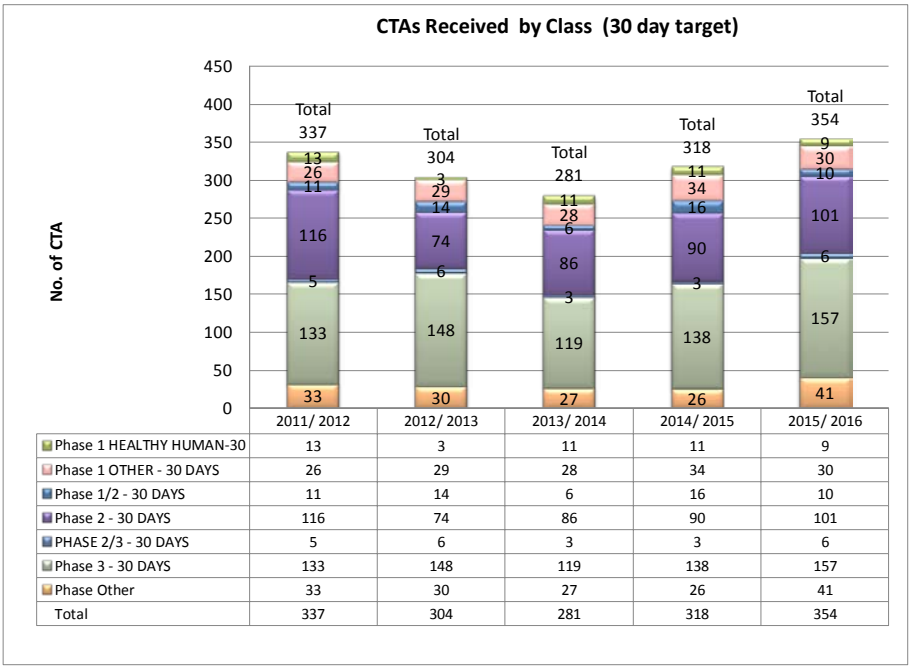
	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
NDS	151	137	138	165	83
SNDS	9	5	13	5	17
ANDS	211	280	214	375	260
SANDS	18	12	13	36	40
Total	389	434	378	581	400

Clinical Trial Applications and Amendments

(CTA & CTA-A)

CLINICAL TRIAL APPLICATIONS

Number Received - Clinical Trial Application (CTA)

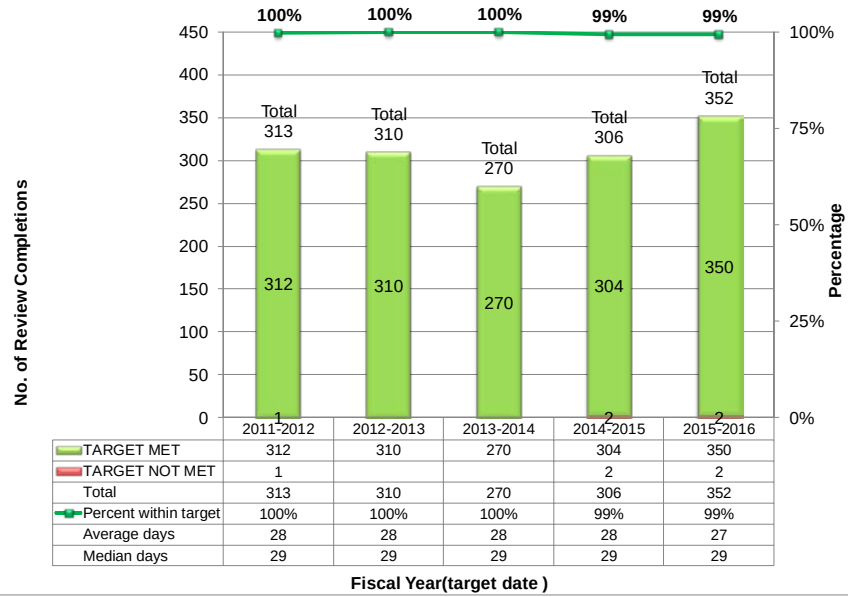


	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
Phase 1 HEALTHY HUMAN-30	13	3	11	11	9
Phase 1 OTHER - 30 DAYS	26	29	28	34	30
Phase 1/2 - 30 DAYS	11	14	6	16	10
Phase 2 - 30 DAYS	116	74	86	90	101
PHASE 2/3 - 30 DAYS	5	6	3	3	6
Phase 3 - 30 DAYS	133	148	119	138	157
Phase Other	33	30	27	26	41
Total	337	304	281	318	354

Decision Documents - Clinical Trial Application (CTA)

CTA (30 day target)					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER	299	302	255	283	336
CANCELLED BY COMPANY DURING REVIEW	17	7	7	18	10
CANCELLED BY COMPANY AT PROCESSING	5	4	0	5	2
NOT SATISFACTORY NOTICE	2	1	6	4	3
REFUSAL LETTER	0	0	0	0	0
REJECTION LETTER (SCR)	1	1	0	1	1
SCREENING DEFICIENCY NOTICE	0	0	0	0	3

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

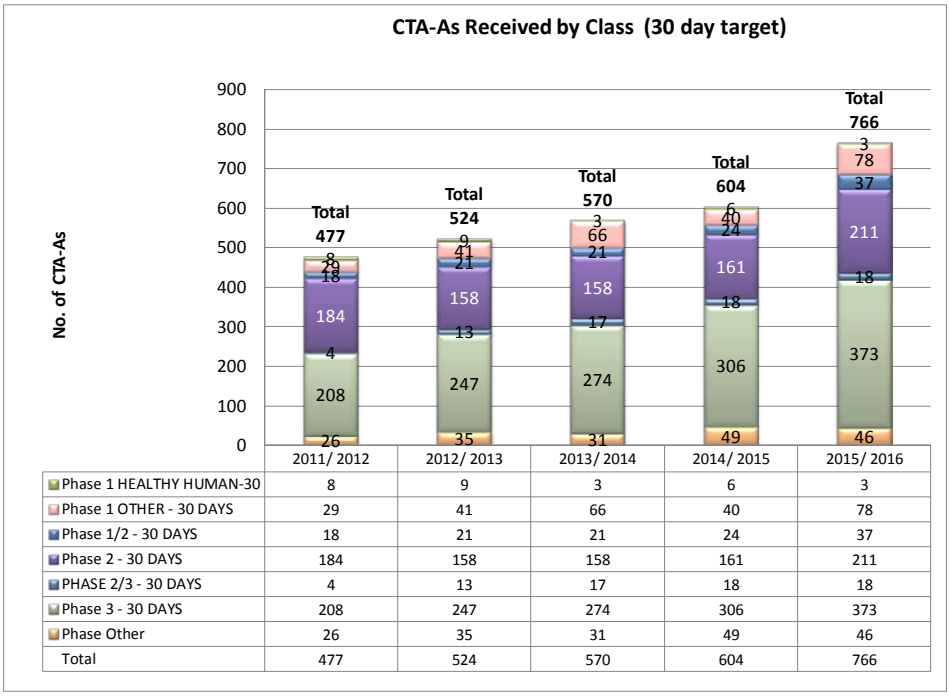


	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
TARGET MET	312	310	270	304	350
TARGET NOT MET	1			2	2
Total	313	310	270	306	352
Percent within target	100%	100%	100%	99%	99%
Average days	28	28	28	28	27
Median days	29	29	29	29	29

Fiscal Year(target date)

CLINICAL TRIAL APPLICATION-AMENDMENTS

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

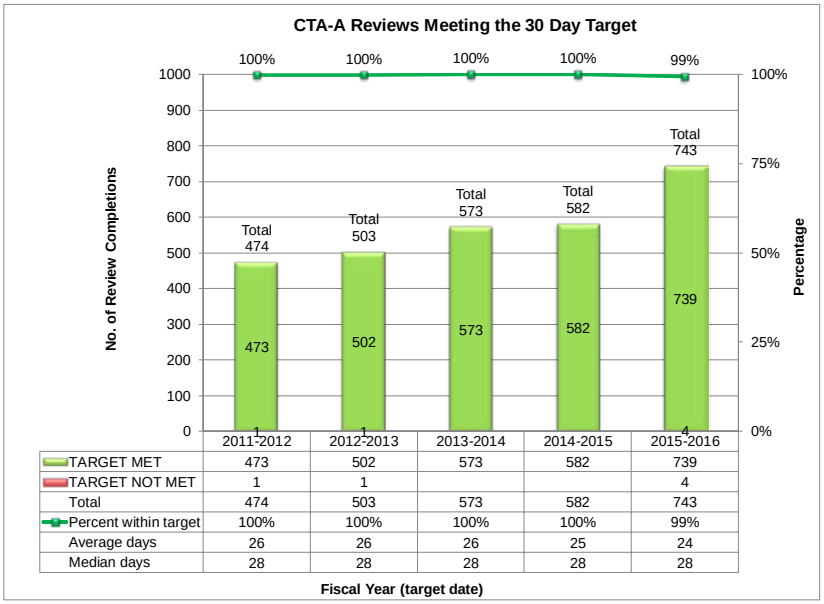


	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
Phase 1 HEALTHY HUMAN-30	8	9	3	6	3
Phase 1 OTHER - 30 DAYS	29	41	66	40	78
Phase 1/2 - 30 DAYS	18	21	21	24	37
Phase 2 - 30 DAYS	184	158	158	161	211
PHASE 2/3 - 30 DAYS	4	13	17	18	18
Phase 3 - 30 DAYS	208	247	274	306	373
Phase Other	26	35	31	49	46
Total	477	524	570	604	766

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

CTA-A (30 day target)					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER	475	491	572	574	747
CANCELLED BY COMPANY DURING REVIEW	2	9	3	8	5
CANCELLED BY COMPANY AT PROCESSING	3	3	0	6	2
NOT SATISFACTORY NOTICE	3	3	0	0	2
REJECTION LETTER (SCR)	0	8	3	5	10

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



	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
TARGET MET	473	502	573	582	739
TARGET NOT MET	1	1			4
Total	474	503	573	582	743
Percent within target	100%	100%	100%	100%	99%
Average days	26	26	26	25	24
Median days	28	28	28	28	28

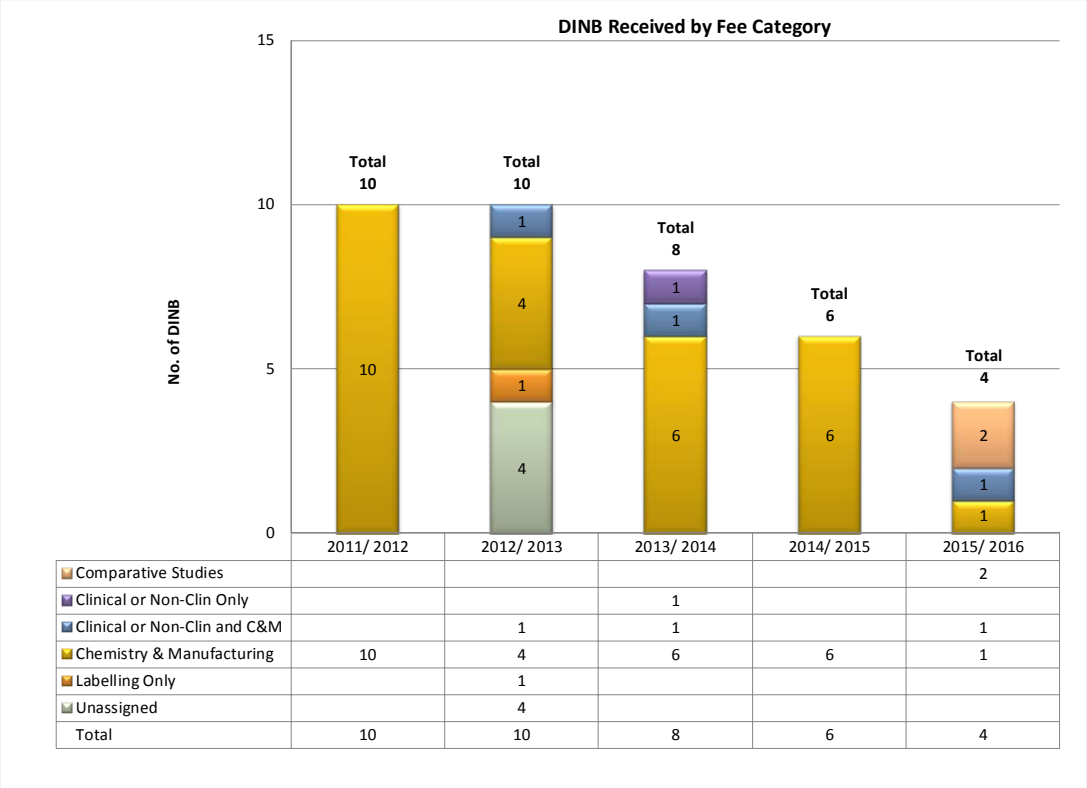
Application for a Drug Identification Number

DINB

Biological Products

DINB: Application for a Drug Identification Number – BIOLOGICAL Products

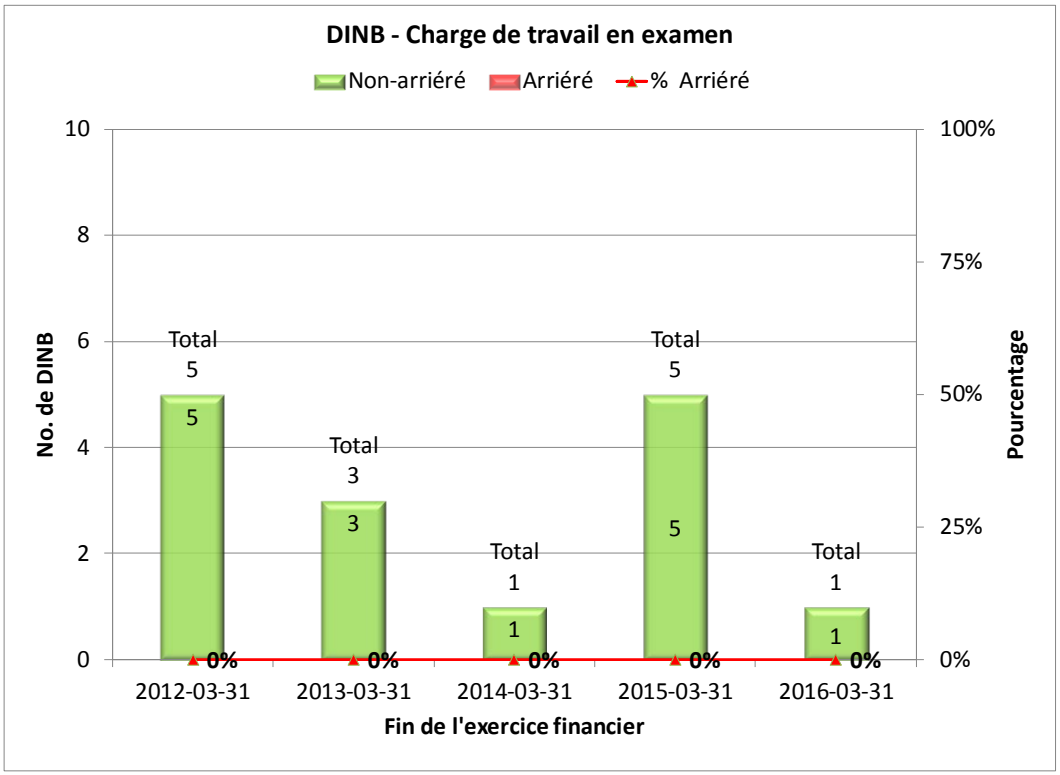
Number Received - DINB



	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
Comparative Studies					2
Clinical or Non-Clin Only			1		
Clinical or Non-Clin and C&M		1	1		1
Chemistry & Manufacturing	10	4	6	6	1
Labelling Only		1			
Unassigned		4			
Total	10	10	8	6	4

REVIEW WORKLOAD

Review Workload / Backlog – Showing Percentage in Backlog - DINB

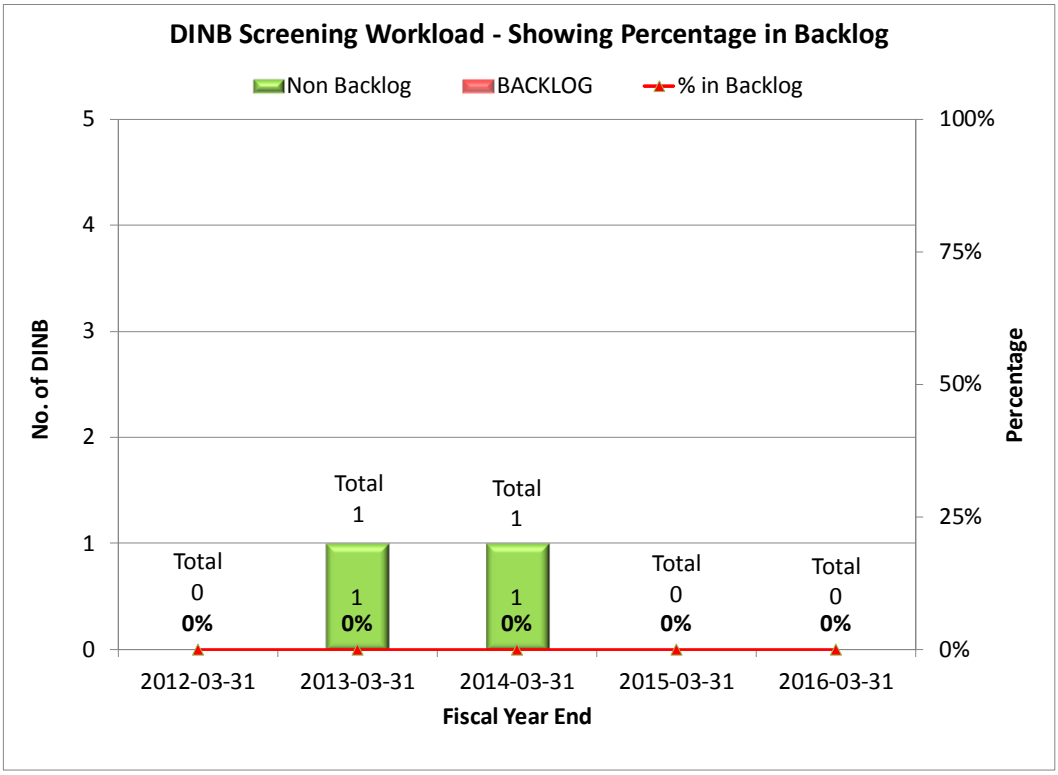


Review Workload by Class - DINB

DINB All REVIEW WORKLOAD BY FEE CATEGORY - BGTD (excluding administrative) and Fiscal Year End					
	2012-03-31	2013-03-31	2014-03-31	2015-03-31	2016-03-31
Form	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Form and Supporting Data	**1**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**4**	**3**	**1**	**5**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**5**	**3**	**1**	**5**	**1**
Non Backlog	**5**	**3**	**1**	**5**	**1**
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

DINB All SCREENING WORKLOAD BY FEE CATEGORY - BGTD (excluding dministrative) and Fiscal Year End					
	2012-03-31	2013-03-31	2014-03-31	2015-03-31	2016-03-31
Clinical or Non-Clin and C&M	**0**	**1**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**0**	**0**	**1**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**0**	**1**	**1**	**0**	**0**
Non Backlog	**0**	**1**	**1**	**0**	**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	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER	5				
SCREENING DEFICIENCY NOTICE					
NOTICE OF DEFICIENCY					
CANCELLED BY COMPANY		1			

DINB - FORM AND SUPPORTING DATA					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER	9				
NOTIFICATION FORM DIN SUB	3				
NOT SATISFACTORY NOTICE					
NOTICE OF DEFICIENCY	1				
NOD WITHDRAWAL LETTER	1				
REJECTION LETTER (SCR)					
REFUSAL LETTER					
SCREENING DEFICIENCY NOTICE					

DINB - CLIN ONLY					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER	1				

DINB - CHEMISTRY & MANUFACTURING					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
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	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NO OBJECTION LETTER			1		
SCREENING DEFICIENCY NOTICE				2	
CANCELLED BY COMPANY					1

DINB - ADMINISTRATIVE					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
NOTIFICATION FORM/DIN ISSUED	6	11		2	

DINB - UNASSIGNED					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
CANCELLED BY COMPANY		4			

DINB - COMPARATIVE STUDIES					
DOCUMENT TYPE	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
REJECTION LETTER (SCREENING)					1
SCREENING DEFICIENCY NOTICE					1

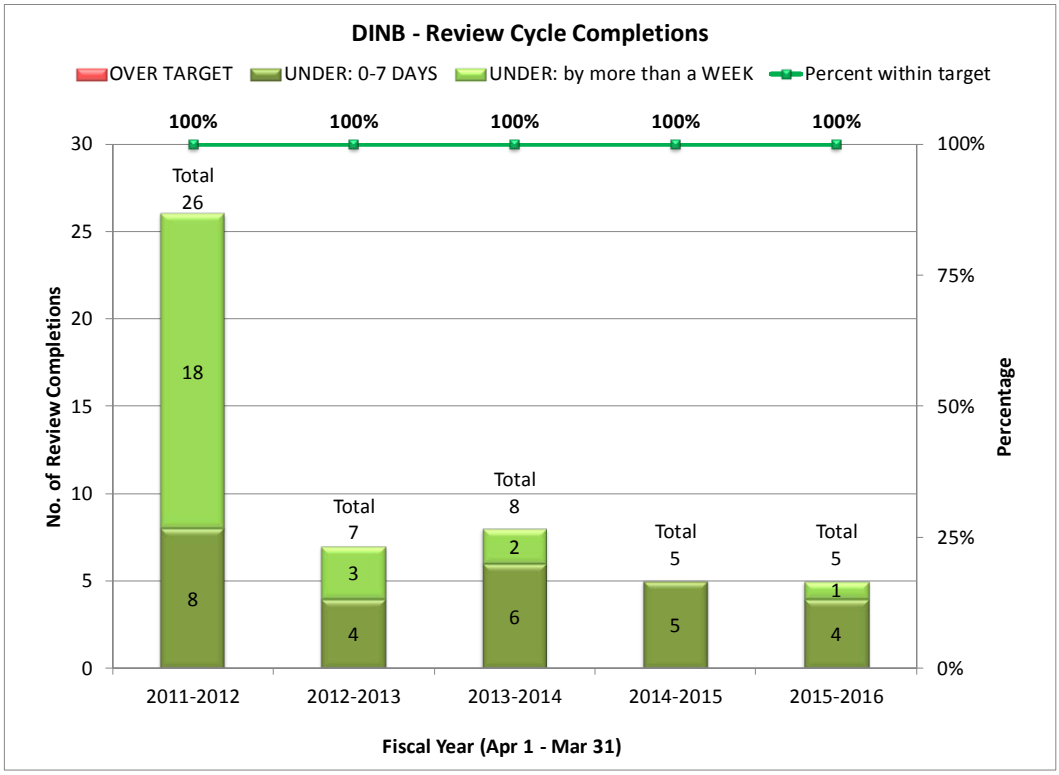
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – DINB

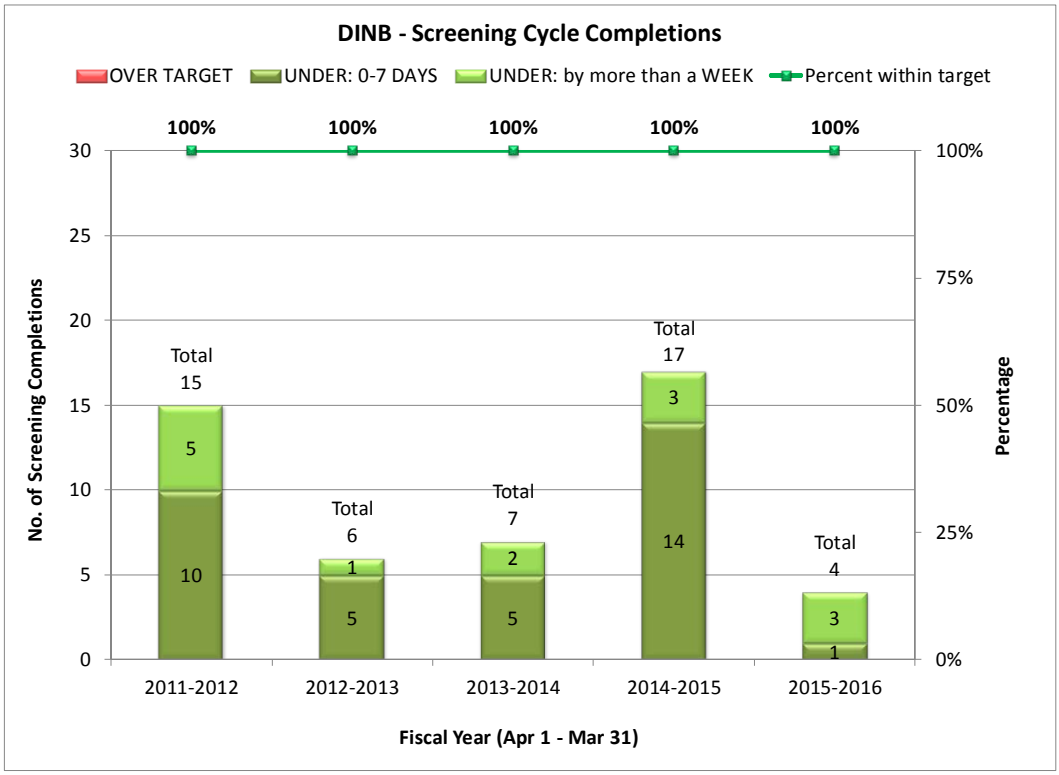
DINB					
Year of Reconsideration Request					
	11-12	**12-13**	**13-14**	**14-15**	**15-16**
Total	**0**	**0**	**0**	**0**	**0**

PERFORMANCE

Review Cycle Completions - DINB

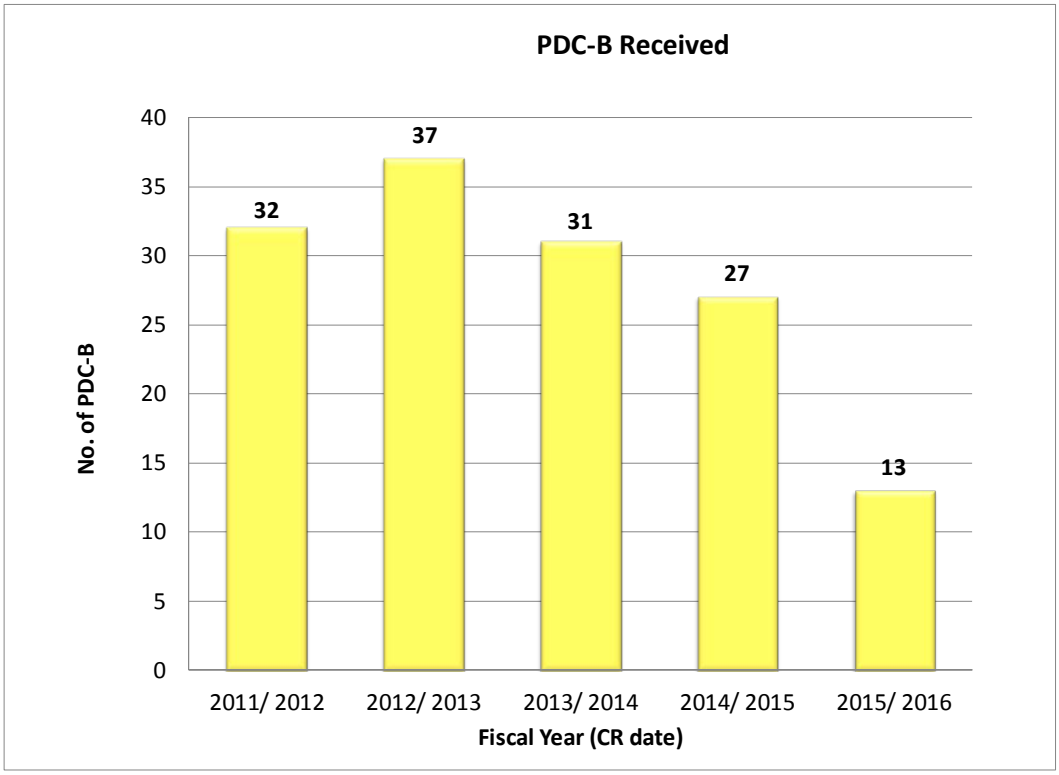


Screening Cycle Completions - DINB



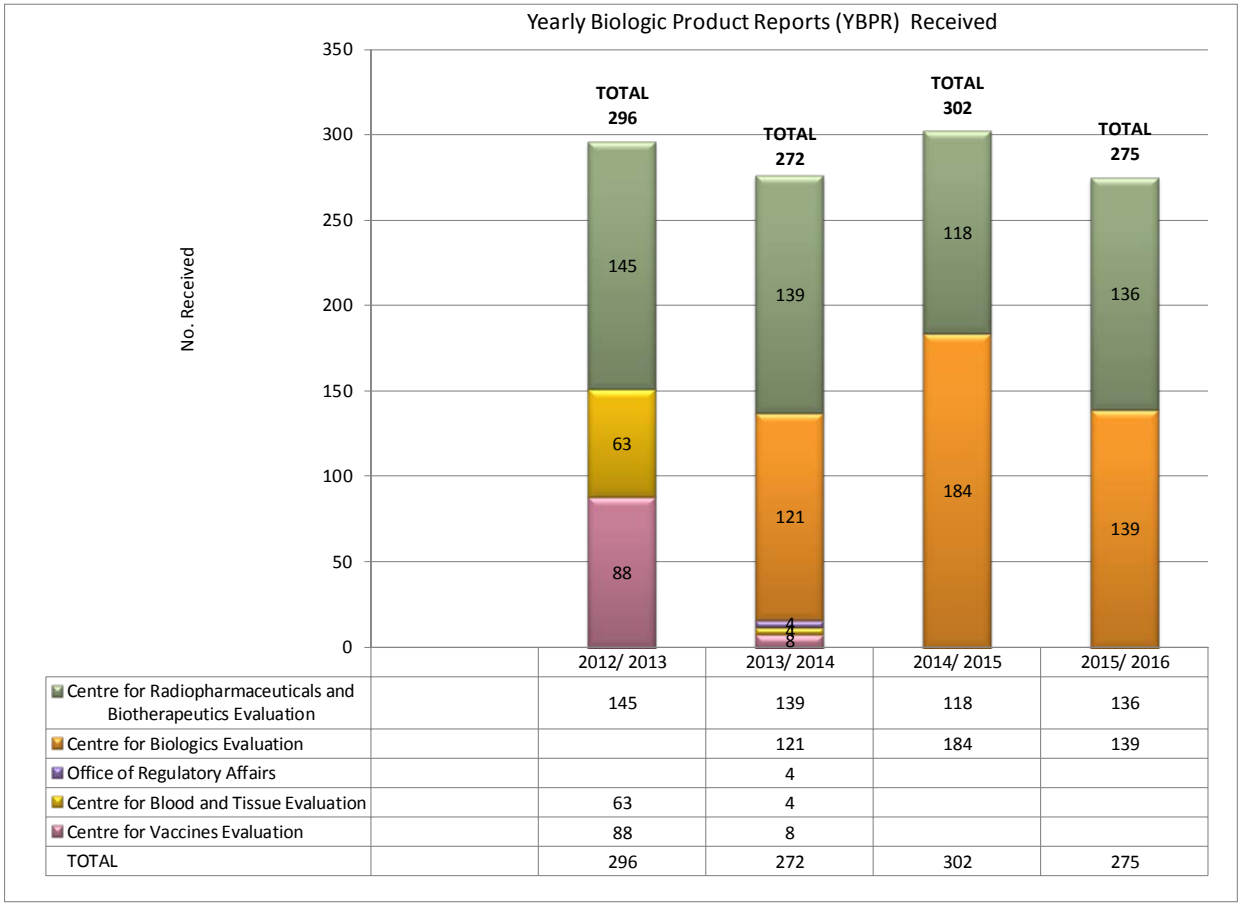
PDC-B: Post Authorization Division 1 Changes - Biologics

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



Yearly Biologic Product Reports[9] (YBPR)

Yearly Biologic Product Reports (YBPR) Received



		2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016
Centre for Radiopharmaceuticals and Biotherapeutics Evaluation		145	139	118	136
Centre for Biologics Evaluation			121	184	139
Office of Regulatory Affairs			4		
Centre for Blood and Tissue Evaluation		63	4		
Centre for Vaccines Evaluation		88	8		
TOTAL		296	272	302	275

[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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