Health Products and Food Branch

Drug Submission Performance Annual Reports

Fiscal Year

2016-2017

April 1 2016- March 31 2017

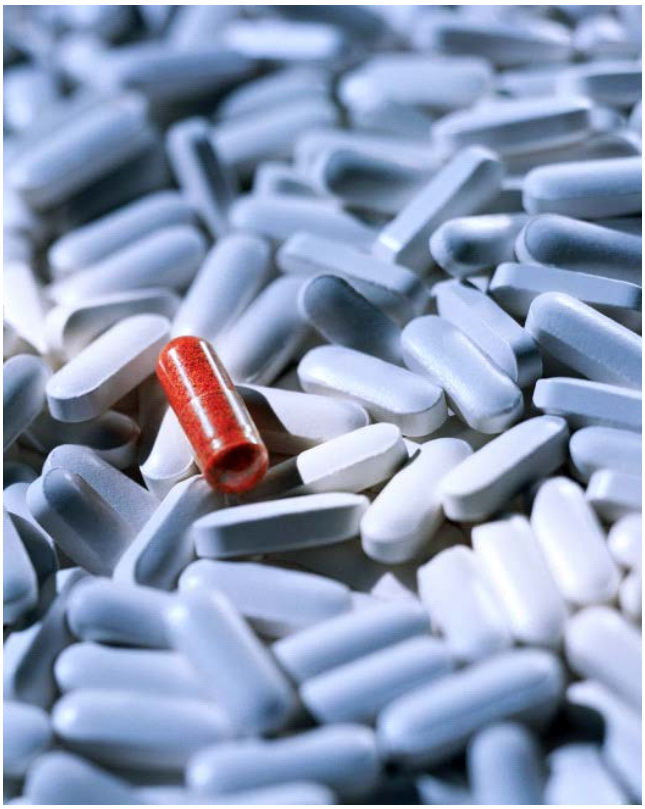
Therapeutic Products Directorate and
Biologics and Genetic Therapies Directorate
Natural and Non-Prescription Health Products Directorate

Canada

Biologics and Genetic Therapies Directorate
Drug Submission Performance Annual Report

Fiscal Year
2016 – 2017

April 1 2016 – March 31 2017



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 2012-2013 to 2016-2017.

Statistics are provided by submission type and show the number received, the number in workload, the number of decisions, the number of approvals and approval times. The report lists details of Priority Submissions and New Active Substances approved during the fiscal year Apr 1 2016 to March 31 2017.

General Information

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

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

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

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

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

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

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

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

A **review cycle completion**[2] is counted upon the conclusion of an in-depth scientific review that then results in a decision of approval or non-approval. The time taken is compared to a set performance standard[2] which is based on the type of submission, class and cycle (status). For example, in the case of a Priority NDS, the performance standard is 180 days for Review1 and 90 days for Review2. Health Canada has set a goal of 90% of review cycle completions to be rendered within performance standards.

"First Cycle Review" Approvals are those submissions approved without having to go through several review cycles to resolve submission deficiencies or non-compliance issues, and exclude "refiled"[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

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	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

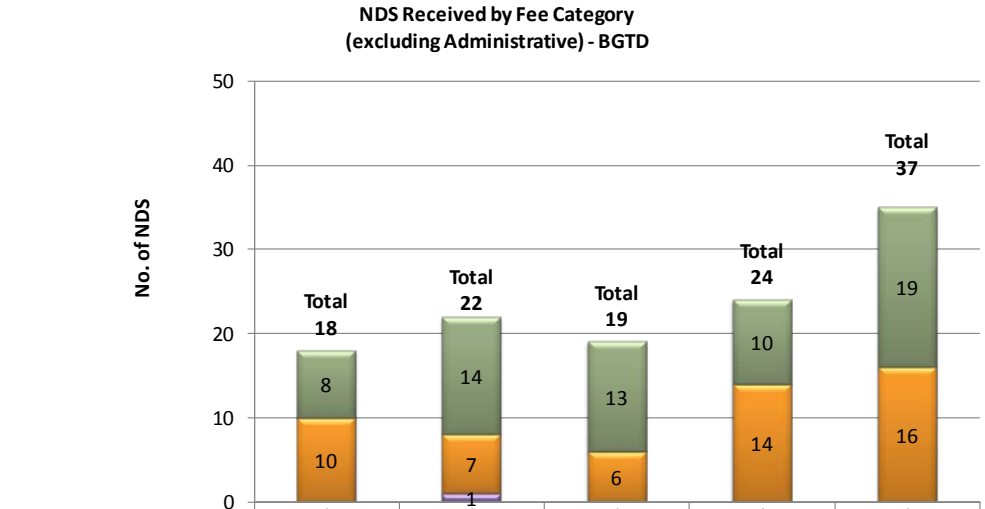
New Drug Submission (NDS)

&

Supplemental New Drug Submission (SNDS)

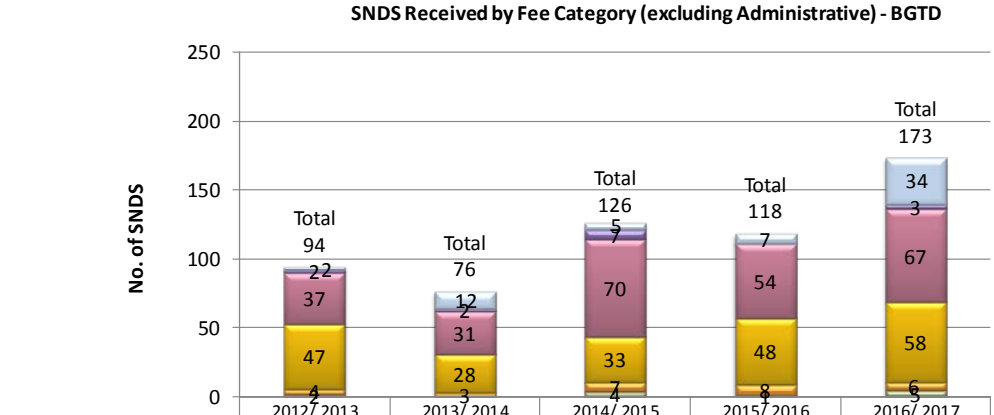
SUBMISSIONS RECEIVED

New Drug Submissions (NDS) Received by Fee Category



	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
New Active Substance	8	14	13	10	19
Clinical or Non-Clin and C&M	10	7	6	14	16
Comparative Studies	0	1	0	0	0
Total	18	22	19	24	37
Priority (subset)	3	1	3	2	2
Emergency Use NDS	0	0	0	1	2
Biosimilar	4	1	2	4	7

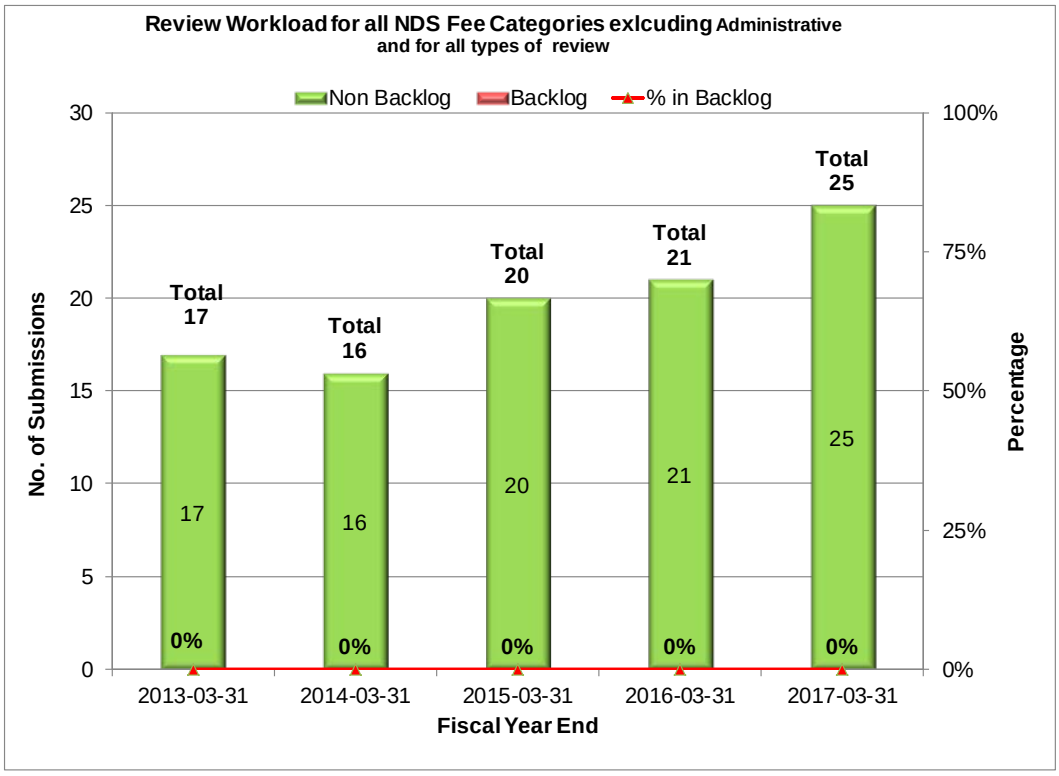
Supplemental New Drug Submissions (SNDS) Received by Fee Category



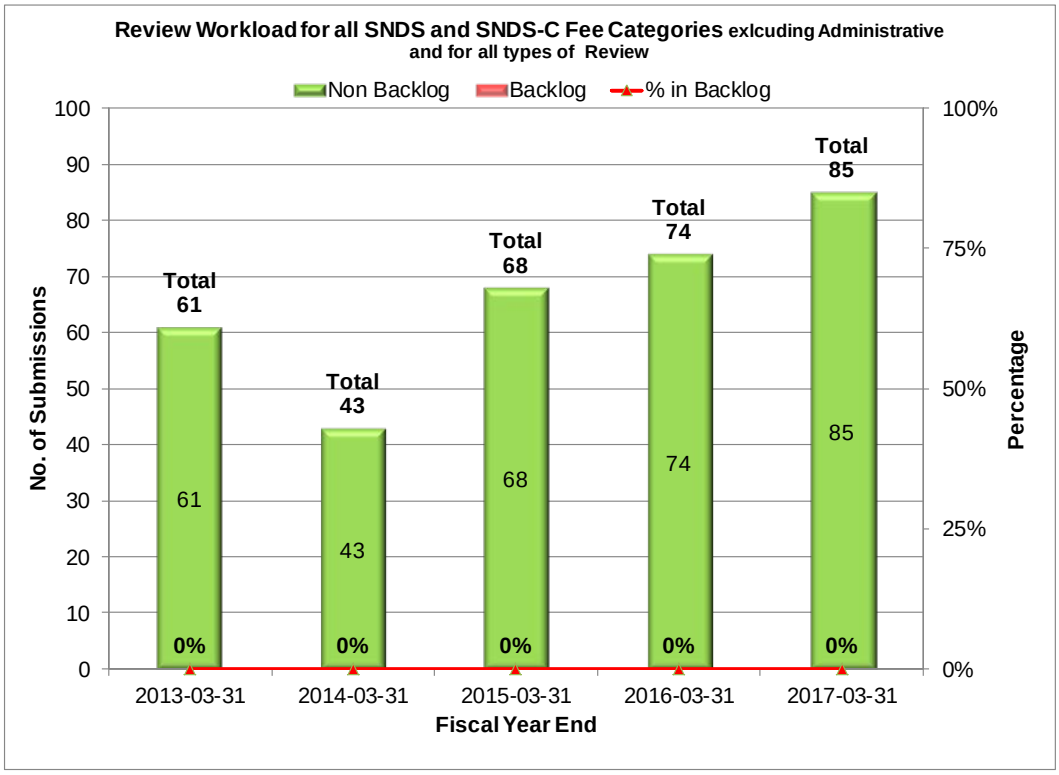
	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Labelling Only	2	12	5	7	34
Comparative Studies	2	2	7	0	3
Chemistry & Manufacturing	37	31	70	54	67
Clinical or Non-Clin Only	47	28	33	48	58
Clinical or Non-Clin and C&M	4	3	7	8	6
Published Data Only	2	0	4	1	5
Total	94	76	126	118	173
Priority (subset)	0	1	0	2	5
SNDS Confirmatory	4	1	2	4	5
Biosimilar			1	* Revised 17 June 2016 3	1

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

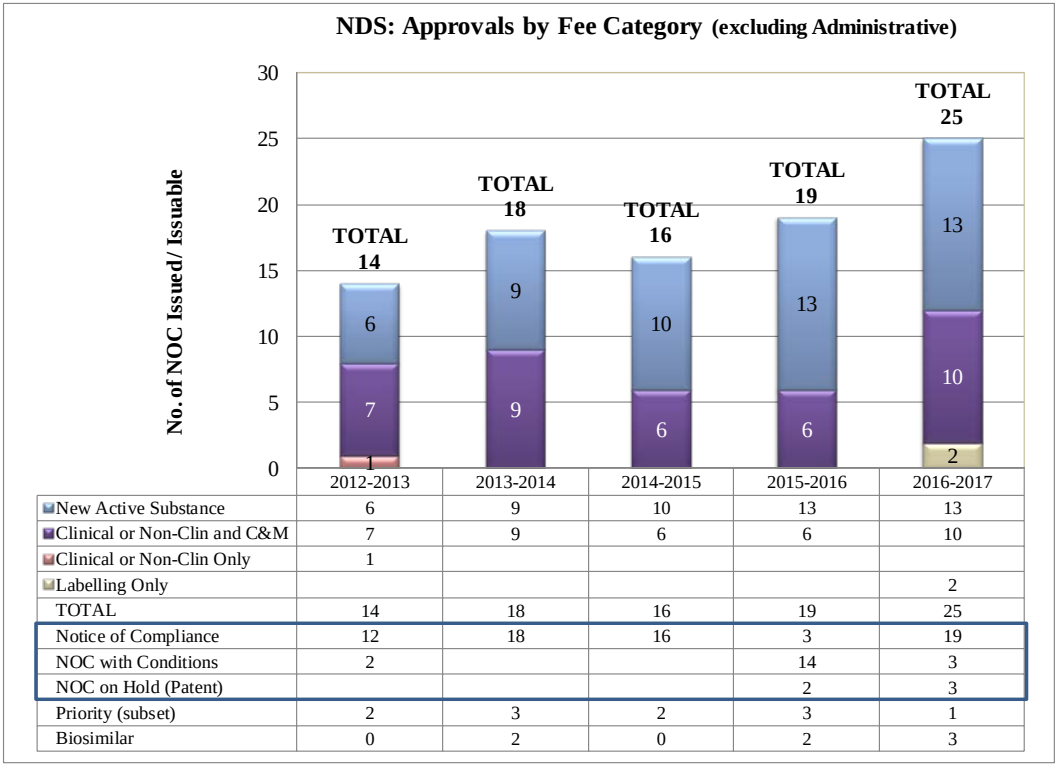
NDS All REVIEW WORKLOAD BY FEE CATEGORY - BGTD (excluding administrative) and Fiscal Year End					
	2013-03-31	2014-03-31	2015-03-31	2016-03-31	2017-03-31
Clinical or Non-Clin and C&M	**10**	**6**	**8**	**11**	**11**
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	**7**	**10**	**12**	**10**	**14**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**17**	**16**	**20**	**21**	**25**
Non Backlog	**17**	**16**	**20**	**21**	**25**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**3**	**1**	**2**	**1**	**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					
	2013-03-31	2014-03-31	2015-03-31	2016-03-31	2017-03-31
Comparative Studies	**0**	**0**	**3**	**0**	**1**
Backlog	0	0	0	0	0
Chemistry & Manufacturing	**18**	**15**	**32**	**25**	**28**
Backlog	0	0	0	0	0
Clinical or Non-Clin Only	**38**	**23**	**25**	**37**	**44**
Backlog	0	0	0	0	0
Published Data	**1**	**0**	**3**	**1**	**3**
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	**4**	**2**	**5**	**10**	**4**
Backlog	0	0	0	0	0
Labelling Only	**0**	**3**	**0**	**1**	**5**
Backlog	0	0	0	0	0
Total	**61**	**43**	**68**	**74**	**85**
Non Backlog	**61**	**43**	**68**	**74**	**85**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**0**	**0**	**0**	**2**	**3**
Backlog	*0*	*0*	*0*	*0*	*0*

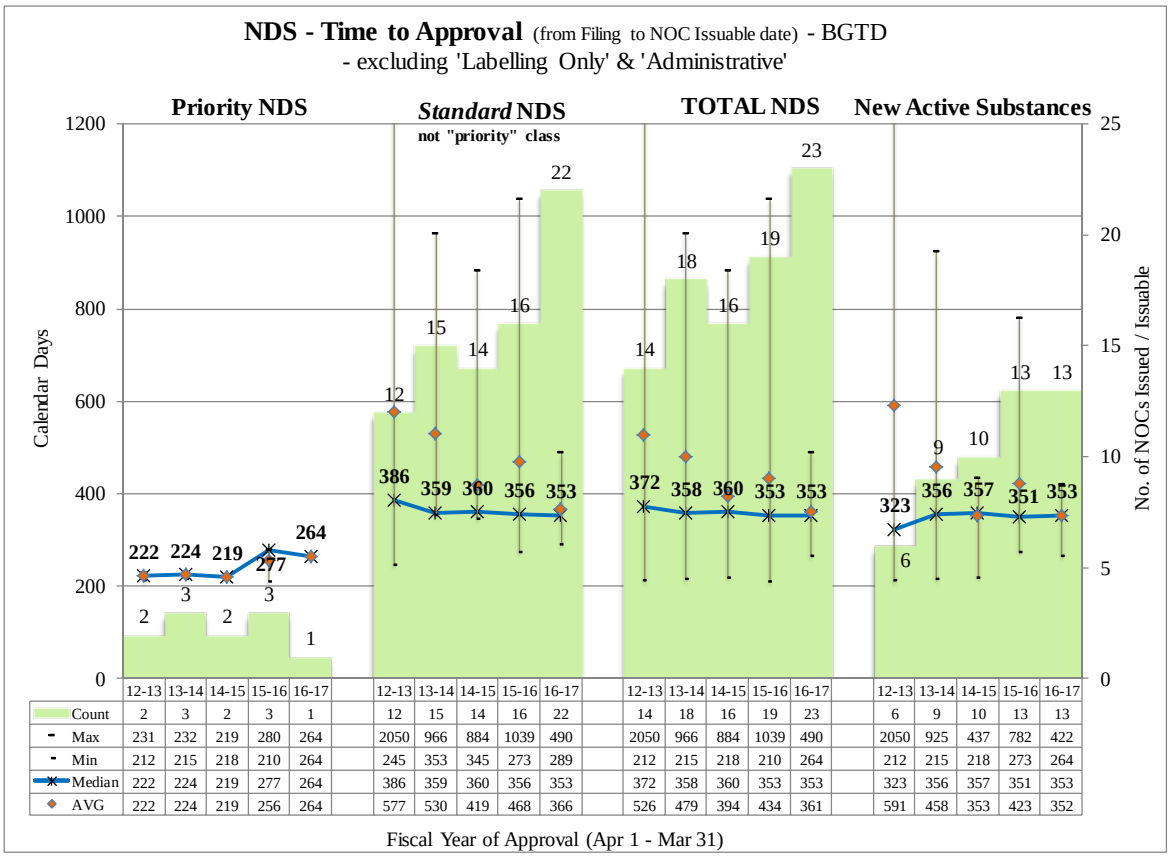
APPROVALS

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



	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
New Active Substance	6	9	10	13	13
Clinical or Non-Clin and C&M	7	9	6	6	10
Clinical or Non-Clin Only	1				
Labelling Only					2
TOTAL	14	18	16	19	25
Notice of Compliance	12	18	16	3	19
NOC with Conditions	2			14	3
NOC on Hold (Patent)				2	3
Priority (subset)	2	3	2	3	1
Biosimilar	0	2	0	2	3

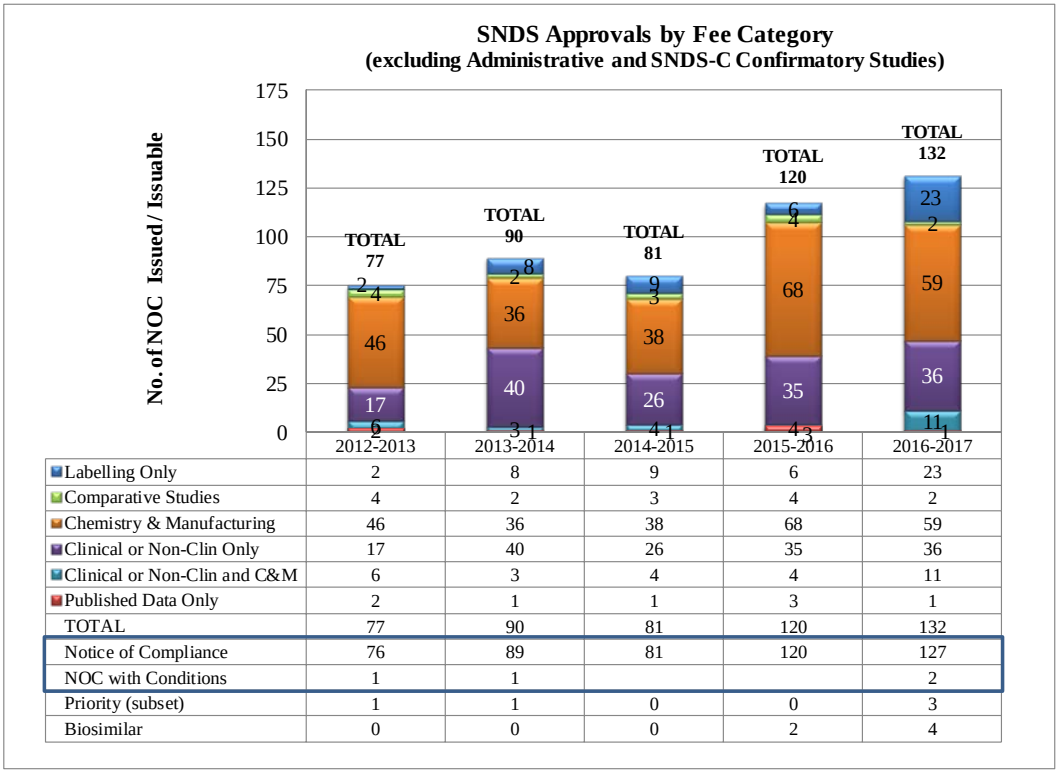
NDS Approval Times



	Priority NDS					Standard NDS (not "priority" class)					TOTAL NDS					New Active Substances				
	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17
Count	2	3	2	3	1	12	15	14	16	22	14	18	16	19	23	6	9	10	13	13
Max	231	232	219	280	264	2050	966	884	1039	490	2050	966	884	1039	490	2050	925	437	782	422
Min	212	215	218	210	264	245	353	345	273	289	212	215	218	210	264	212	215	218	273	264
Median	222	224	219	277	264	386	359	360	356	353	372	358	360	353	353	323	356	357	351	353
AVG	222	224	219	256	264	577	530	419	468	366	526	479	394	434	361	591	458	353	423	352

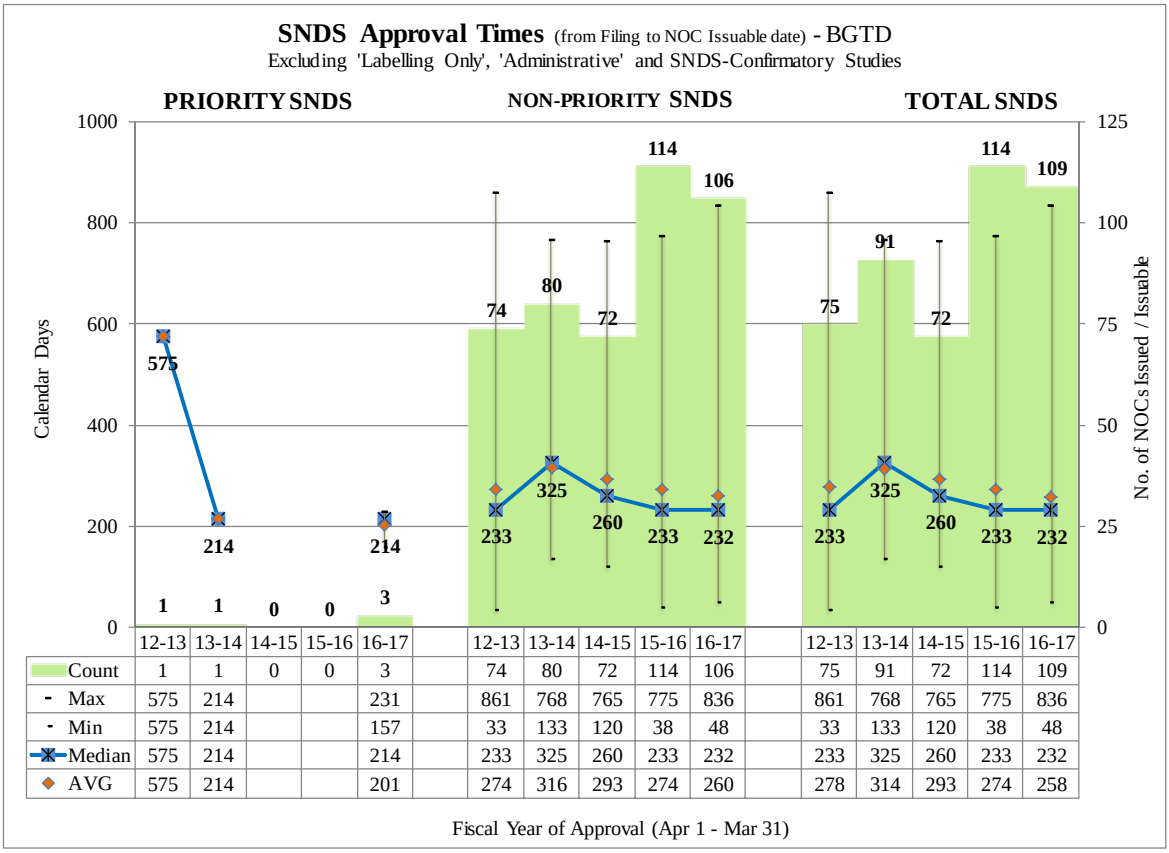
Approval Time is the total number of calendar days between the date a submission is filed (CR date) and the date it is approved (NOC Issuable). This includes time in processing, screening, review and any time taken by the company to respond to notices of deficiency or non-compliance.

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



	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
Labelling Only	2	8	9	6	23
Comparative Studies	4	2	3	4	2
Chemistry & Manufacturing	46	36	38	68	59
Clinical or Non-Clin Only	17	40	26	35	36
Clinical or Non-Clin and C&M	6	3	4	4	11
Published Data Only	2	1	1	3	1
TOTAL	77	90	81	120	132
Notice of Compliance	76	89	81	120	127
NOC with Conditions	1	1			2
Priority (subset)	1	1	0	0	3
Biosimilar	0	0	0	2	4

SNDS Approval Times



	PRIORITY SNDS					NON-PRIORITY SNDS					TOTAL SNDS				
	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17	12-13	13-14	14-15	15-16	16-17
Count	1	1	0	0	3	74	80	72	114	106	75	91	72	114	109
Max	575	214			231	861	768	765	775	836	861	768	765	775	836
Min	575	214			157	33	133	120	38	48	33	133	120	38	48
Median	575	214			214	233	325	260	233	232	233	325	260	233	232
AVG	575	214			201	274	316	293	274	260	278	314	293	274	258

Approval Time is the total number of calendar days between the date a submission is filed (CR date) and the date it is approved (NOC Issuable). This includes time in processing, screening, review and any time taken by the company to respond to notices of deficiency or non-compliance.

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

New Active Substance Approvals (NAS) – BGTD Fiscal Year 2016-2017 (April 1 2016 to March 31 2017)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[4])**	**Approval Date (dd-mon-yy)**
ADYNOVATE (Antihemophilic Factor (Recombinant), PEGylated) - is a pegylated recombinant antihemophilic factor (ADVATE) and is indicated in patients (≥12 years) with hemophilia A (congenital factor VIII deficiency) for: control and prevention of bleeding episodes, for prophylaxis to prevent or reduce the frequency of bleeding episodes and for perioperative management.	NAS	Baxalta Canada Corporation	2-Dec-15	17-Nov-16
AFSTYLA (Lonoctocog Alfa) - is a recombinant DNA-derived, antihemophilic factor indicated in adults and children with hemophilia A (congenital Factor VIII deficiency) for: control and prevention of bleeding episodes, for routine prophylaxis to prevent or reduce the frequency of bleeding episodes, and for perioperative management of bleeding (surgical prophylaxis).	NAS	CSL Behring Canada Inc.	23-Dec-15	12-Dec-16
BAT (Botulinum Antitoxin Serotypes A, B, C, D, E, F and G) - is a mixture of immune globulin fragments indicated for the treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in adults and pediatric patients.	NAS	Cangene Corporation	22-Dec-15	8-Dec-16
CINQAIR (Reslizumab) - is indicated as an add-on maintenance treatment of adult patients with severe eosinophilic asthma who: are inadequately controlled with medium-to-high-dose inhaled corticosteroids and an additional asthma controller(s) (eg, LABA) and have a blood eosinophil count of ≥400 cells/μL at initiation of the treatment.	NAS	Teva Canada Limited	3-Jul-15	20-Jul-16
DARZALEX (Daratumumab) - is indicated for: the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who are refractory to both a PI and an IMiD.	NOC-C NAS	Janssen Inc.	14-Sep-15	29-Jun-16 NOC-C
EMPLICITI (Elotuzumab) - in combination with lenalidomide and dexamethasone, is indicated for the treatment of patients with multiple myeloma who have received one to three prior therapies.	PRIORITY-NAS	Bristol-Myers Squibb Canada	1-Oct-15	21-Jun-16

[4] 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 2016-2017
(April 1 2016 to March 31 2017)

Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date[4])	Approval Date (dd-mon-yy)
KEVZARA (Sarilumab) - is indicated in the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more biologic or non-biologic Disease-Modifying Anti-Rheumatic Drugs (DMARDs).	NAS	Sanofi-Aventis Canada Inc.	29-Jan-16	12-Jan-17
NEURACEQ (Florbetaben (18F)) - is indicated for Positron Emission Tomography (PET) imaging of the brain to estimate β-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline.	NAS	Isologic Innovative Radiopharmaceuticals Ltd.	26-Feb-16	22-Feb-17
PORTRAZZA (Necitumumab) - is indicated, in combination with gemcitabine and cisplatin, for the treatment of patients with locally advanced or metastatic squamous non-small cell lung cancer who have not received prior chemotherapy for this condition. Patients with locally advanced disease should be considered surgically incurable or incurable by virtue of ineligibility to receive curative surgery.	NAS	Eli Lilly Canada Inc.	29-Mar-16	16-Mar-17
PRALUENT (Alirocumab) - is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C).	NAS	Sanofi-Aventis Canada Inc.	20-Mar-15	11-Apr-16
PRAXBIND (Idarucizumab) - is an antidote, specific for dabigatran, and is indicated for adult patients treated with Pradaxa® when rapid specific reversal of the anticoagulant effects of dabigatran is required for: emergency surgery/urgent procedures and life-threatening or uncontrolled bleeding.	NOC-C NAS	Boehringer Ingelheim (Canada) Ltd Ltée	4-Mar-15	29-Apr-16 NOC-C
TALTZ (Ixekizumab) - is indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.	NAS	Eli Lilly Canada Inc.	5-Jun-15	25-May-16
ZINBRYTA (Daclizumab Beta) - is indicated for the treatment of adult patients with active relapsing remitting multiple sclerosis (RRMS) who have had an inadequate response to, or who are unable to tolerate, one or more therapies indicated for the treatment of multiple sclerosis (MS).	NAS	Biogen Canada Inc.	21-Dec-15	8-Dec-16

Priority Submission Approvals – BGTD - Fiscal Year 2016-2017

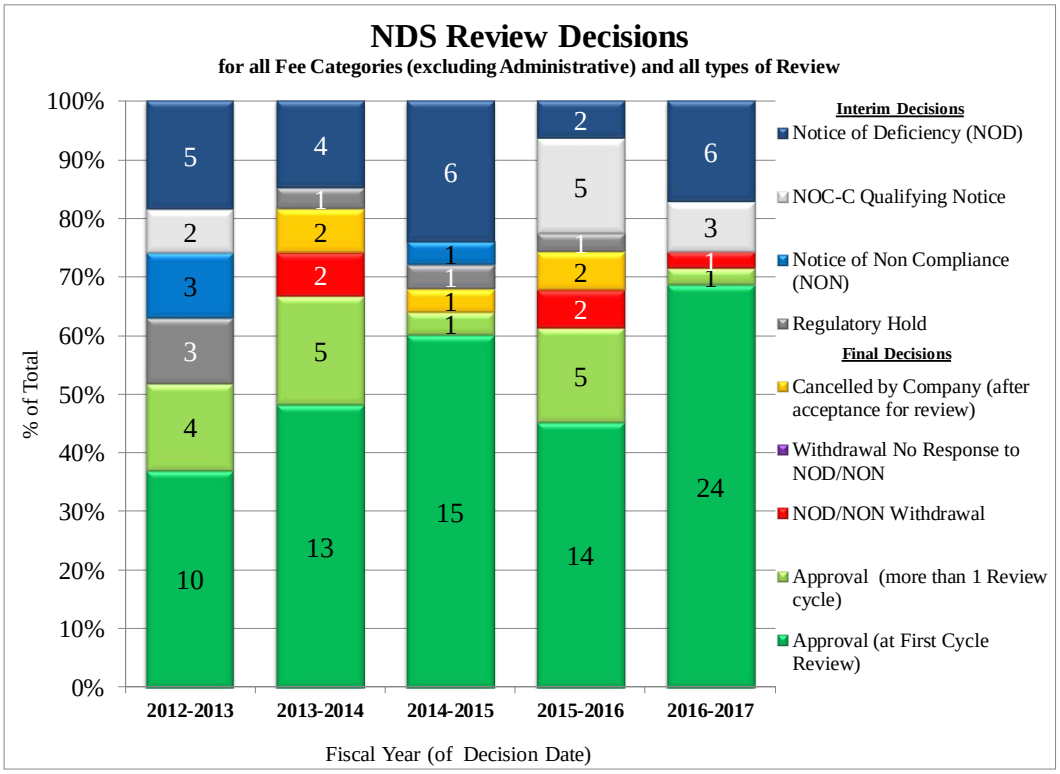
Priority Submission Approvals – BGTD Fiscal Year 2016-2017 (April 1 2016 to March 31 2017)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[5])**	**Approval Date (dd-mon-yy)**
EMPLICITI (Elotuzumab) - in combination with lenalidomide and dexamethasone, is indicated for the treatment of patients with multiple myeloma who have received one to three prior therapies.	PRIORITY-NAS	Bristol-Myers Squibb Canada	1-Oct-15	21-Jun-16
ILARIS (Canakinumab) - is an interleukin-1 beta (IL-1β) inhibitor indicated for the treatment of the following autoinflammatory Periodic Fever Syndromes. **Cryopyrin-Associated Periodic Syndromes (CAPS)** ILARIS® is indicated for the ongoing management of Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children aged 2 years and older, including: Familial Cold Autoinflammatory Syndrome (FCAS)/ Familial Cold Urticaria (FCU), Muckle-Wells Syndrome (MWS). ILARIS® may also be used in Neonatal-Onset Multisystem Inflammatory Disease (NOMID)/ Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA). Clinical data have not confirmed improvement in CNS symptoms in patients with this phenotype. **Tumor Necrosis Factor receptor Associated Periodic Syndrome (TRAPS)** ILARIS® is indicated for the treatment of Tumor Necrosis Factor (TNF) receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients. **Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)** ILARIS® is indicated for the treatment of Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients. **Familial Mediterranean Fever (FMF)** ILARIS® is indicated for the treatment of Familial Mediterranean Fever (FMF) in adult and pediatric patients. ILARIS® can be given as monotherapy or in combination with colchicine. ILARIS® is also indicated for the treatment of: **Systemic Juvenile Idiopathic Arthritis (SJIA)** ILARIS® is indicated for the treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older.	PRIORITY-CLIN/C&M	Novartis Pharmaceuticals Canada Inc.	6-Jun-16	6-Jan-17

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

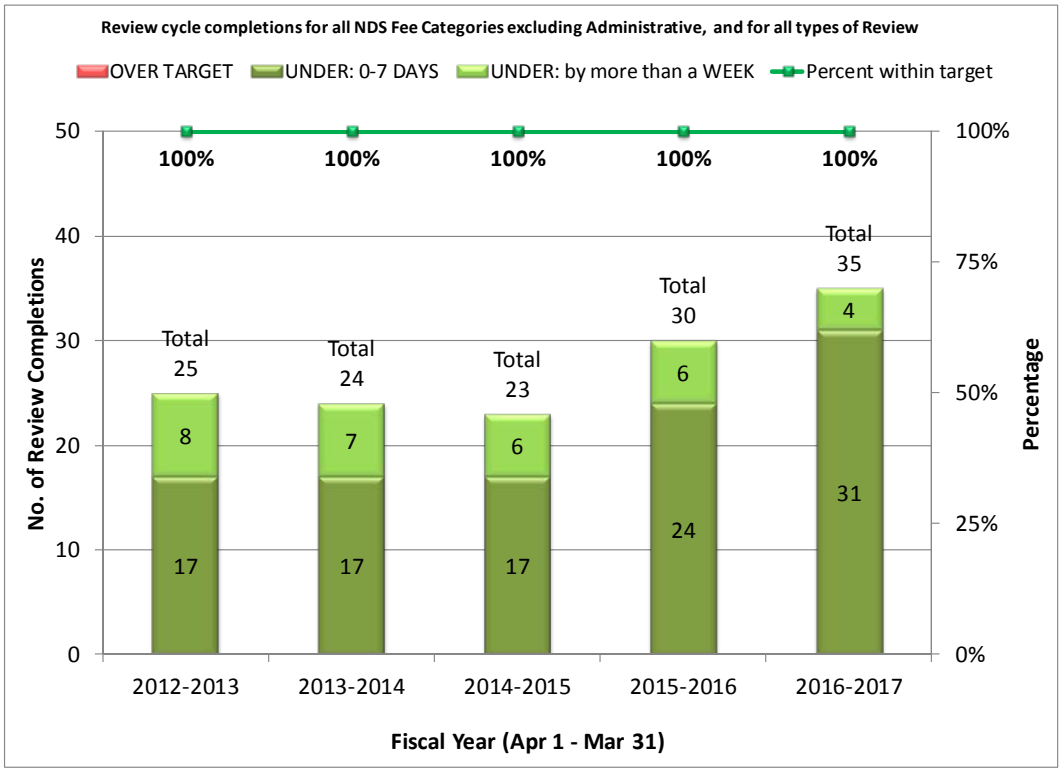
Priority Submission Approvals – BGTD Fiscal Year 2016-2017 (April 1 2016 to March 31 2017)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[5])**	**Approval Date (dd-mon-yy)**
KEYTRUDA (Pembrolizumab) - is indicated for the treatment of patients with unresectable or metastatic melanoma who have not received prior treatment with ipilimumab. Subjects with BRAF V600 mutant melanoma may have received prior BRAF inhibitor therapy.	PRIORITY-CLIN ONLY	Merck Canada Inc.	18-Sep-15	6-May-16
OPDIVO (Nivolumab) - is indicated for the treatment of adult patients with advanced or metastatic renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.	PRIORITY-CLIN ONLY	Bristol-Myers Squibb Canada	20-Nov-15	25-Apr-16

REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

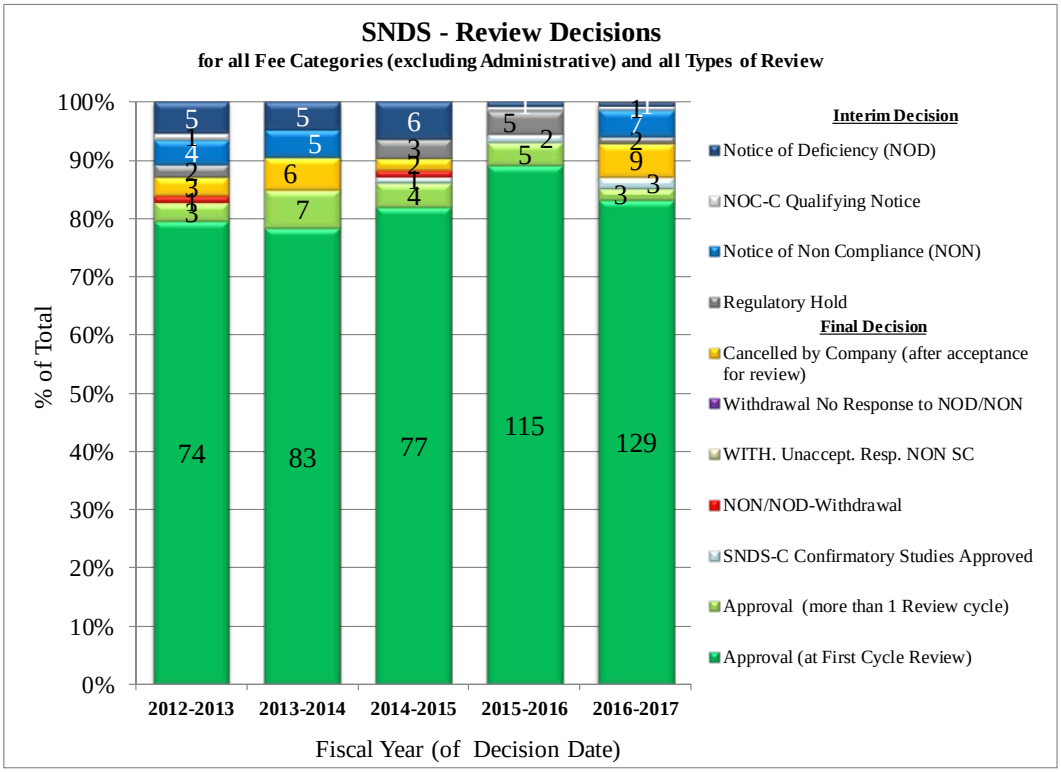


NDS: Review Cycle Completions Showing Percentage Within Target

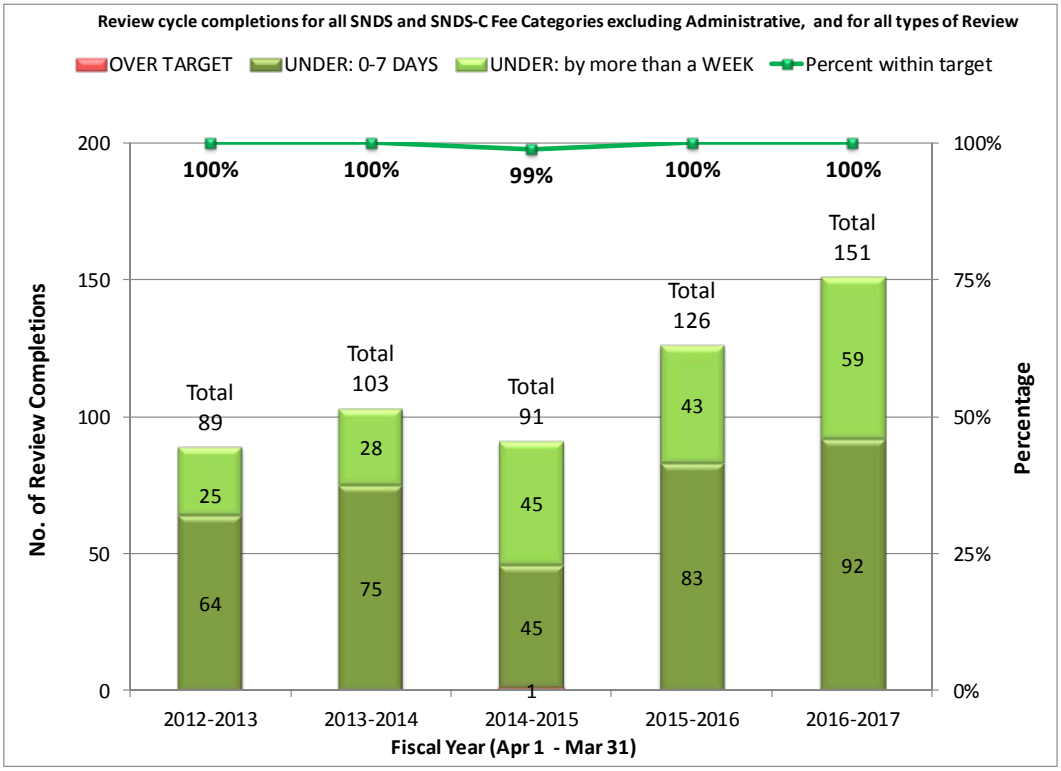


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

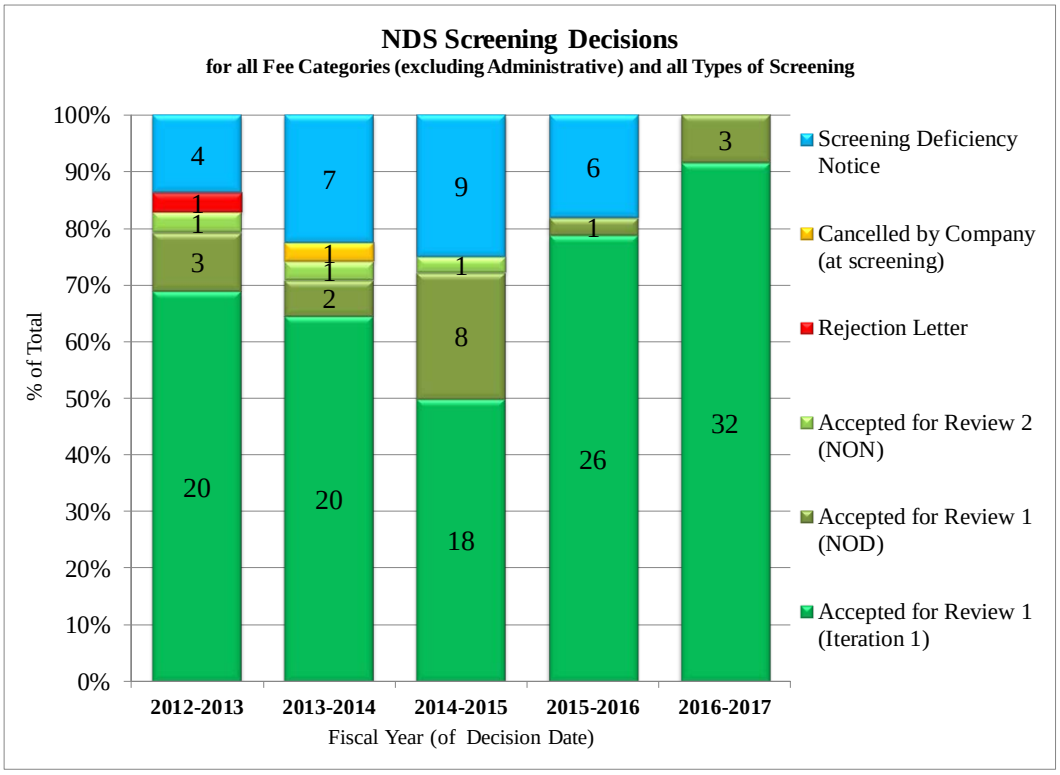


SNDS: Review Cycle Completions Showing Percentage Within Target

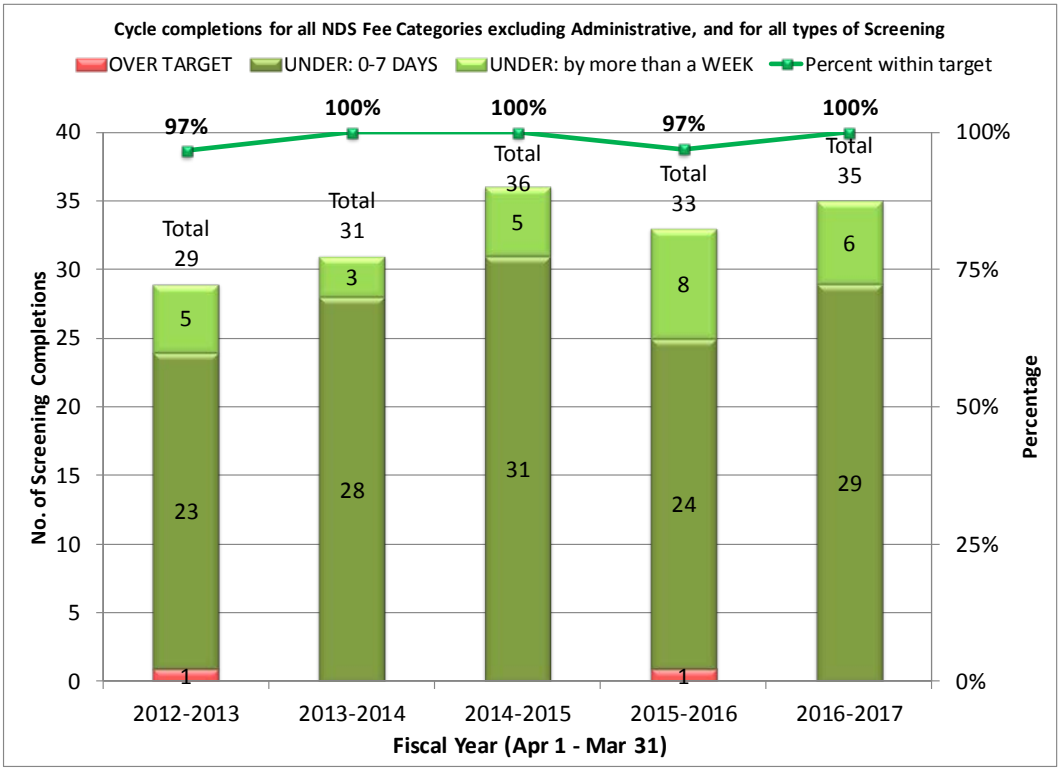


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

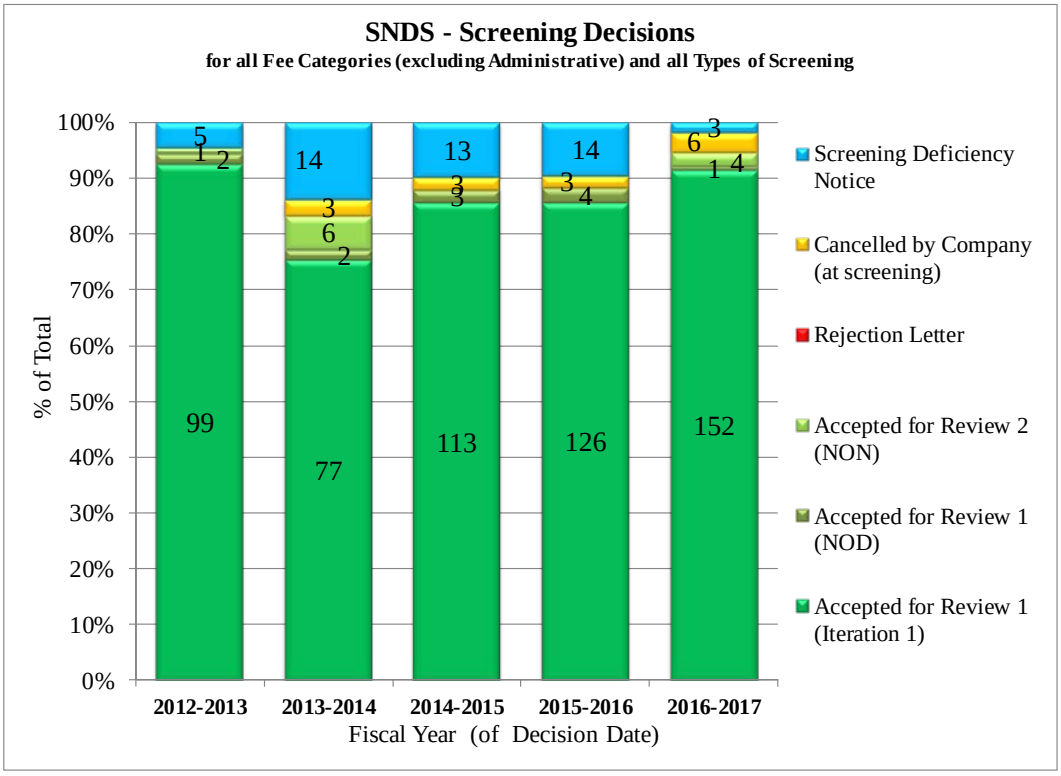


NDS: Screening Cycle Completions Showing Percentage Within Target

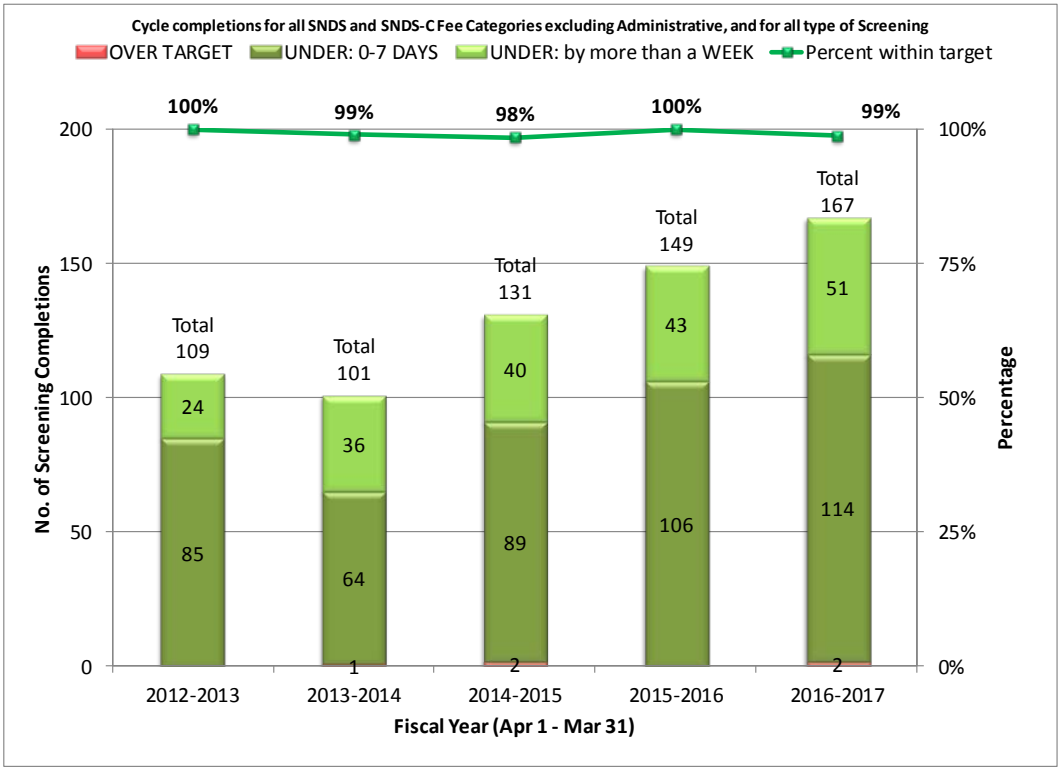


SCREENING CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Screening Decisions



SNDS: Screening Cycle Completions Showing Percentage Within Target



REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions –NDS, SNDS & ANDS

Reconsideration of Final Decisions Requests Received - NDS, SNDS & ANDS Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	**12-13**	**13-14**	**14-15**	**15-16**	**16-17**	**Final Decision in Dispute**	**Submission Status (as of May 12 2017)**
Total Received	**1**	**1**	**0**	**0**	**0**		
NDS	0	0	0	0	0		
Total Granted	***1***	***1***	***0***	***0***	***0***		
SNDS	1	0	0	0	0	NON Withdrawal	Withdrawn
ANDS	0	1	0	0	0	NO**N** Withdrawal	Withdrawn
Total Denied	***0***	***0***	***0***	***0***	***0***		

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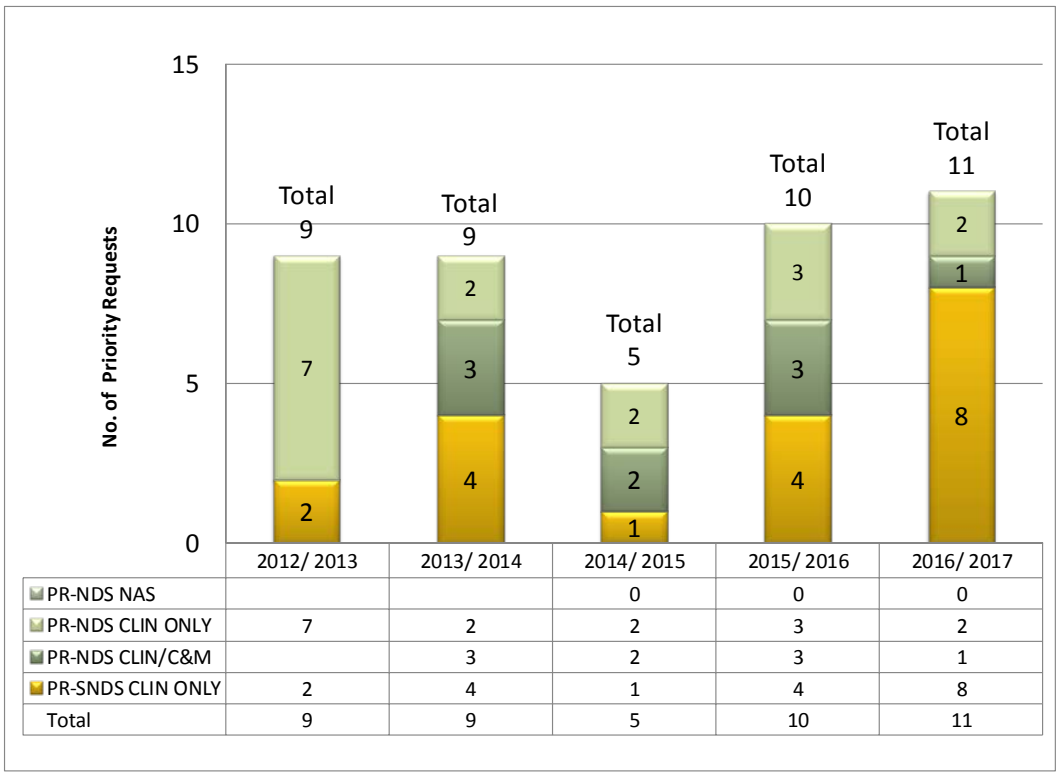
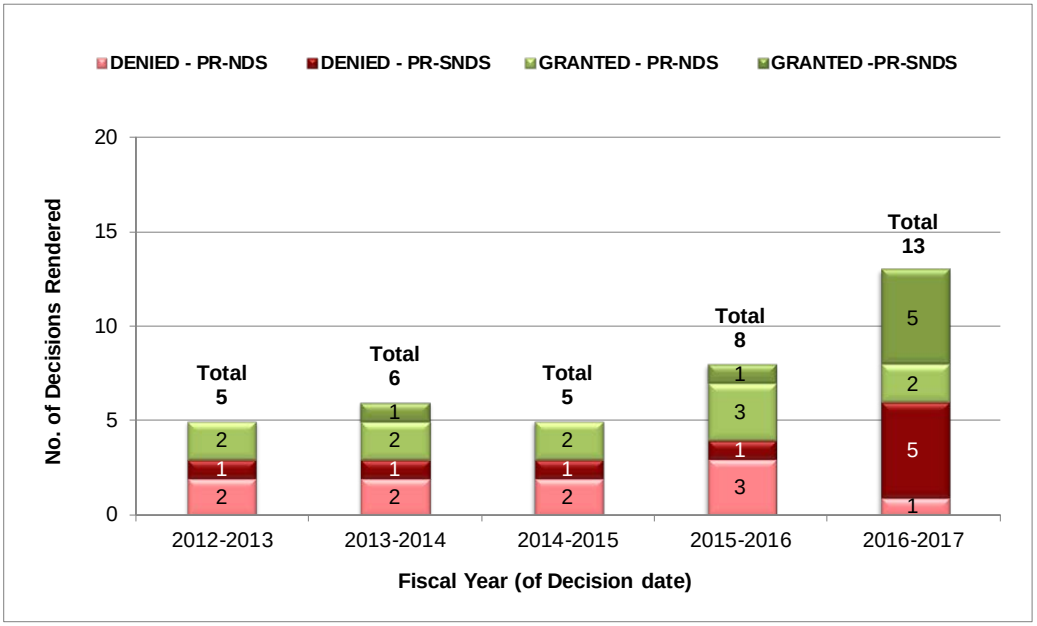
PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests Received



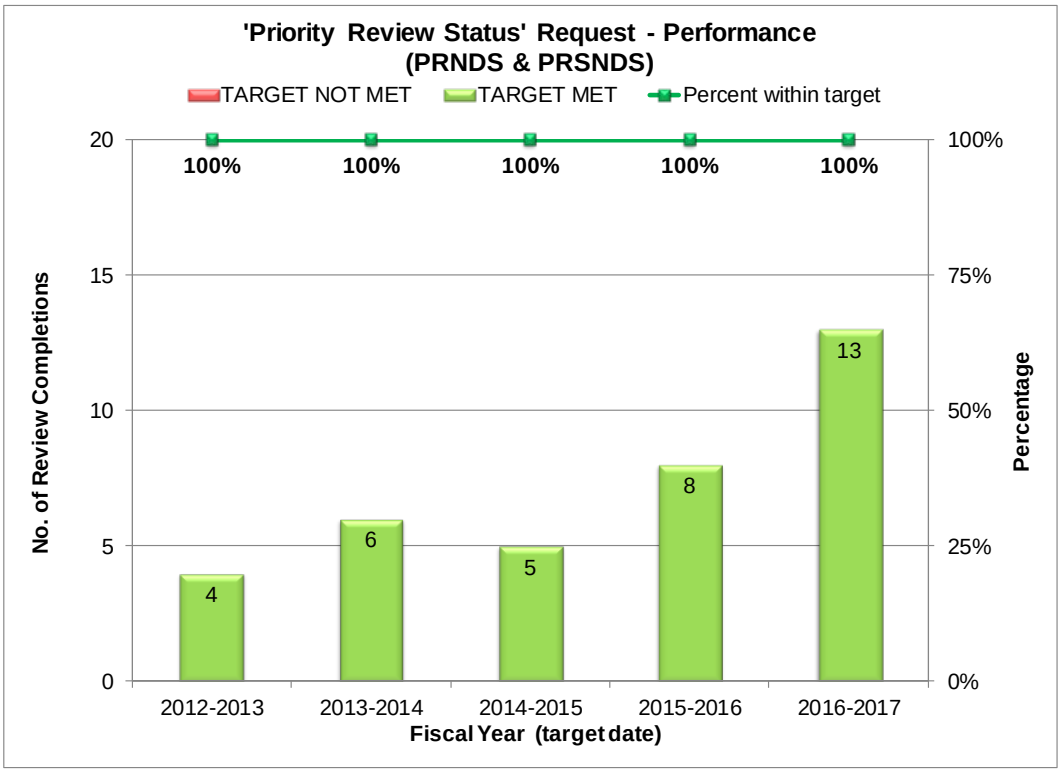
	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
PR-NDS NAS			0	0	0
PR-NDS CLIN ONLY	7	2	2	3	2
PR-NDS CLIN/C&M		3	2	3	1
PR-SNDS CLIN ONLY	2	4	1	4	8
Total	9	9	5	10	11

Priority Review Status Requests: Decisions Rendered



PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests: Performance



REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

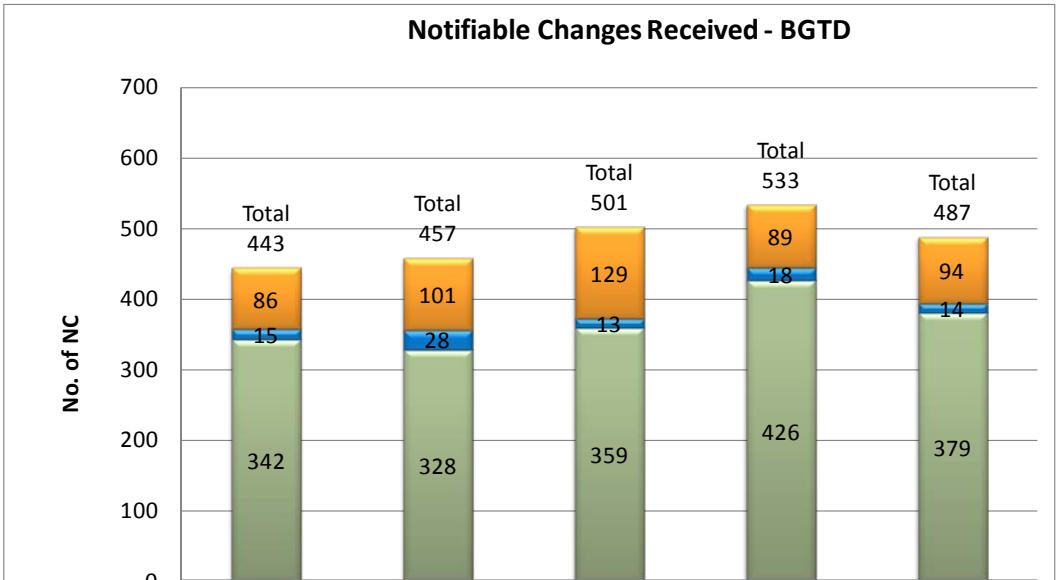
Requests for Reconsideration of Final Decisions – Priority Review Requests (for NDS and SNDS)

"Priority Review Request" - Requests for Reconsideration of Final Decisions Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	**12-13**	**13-14**	**14-15**	**15-16**	**16-17**	**Final Decision in Dispute**	**Submission Status (as of May 12 2017)**
Total Received	**1**	**0**	**0**	**0**	**1**		
Total Granted	***1***	***0***	***0***	***0***	***0***	PR-NDS: Priority Review Request Denied	CLEARED
Total Denied	***0***	***0***	***0***	***0***	***1***	PR-SNDS: Priority Review Request Denied	Rejected

NOTIFIABLE CHANGES (NC)

NOTIFIABLE CHANGES

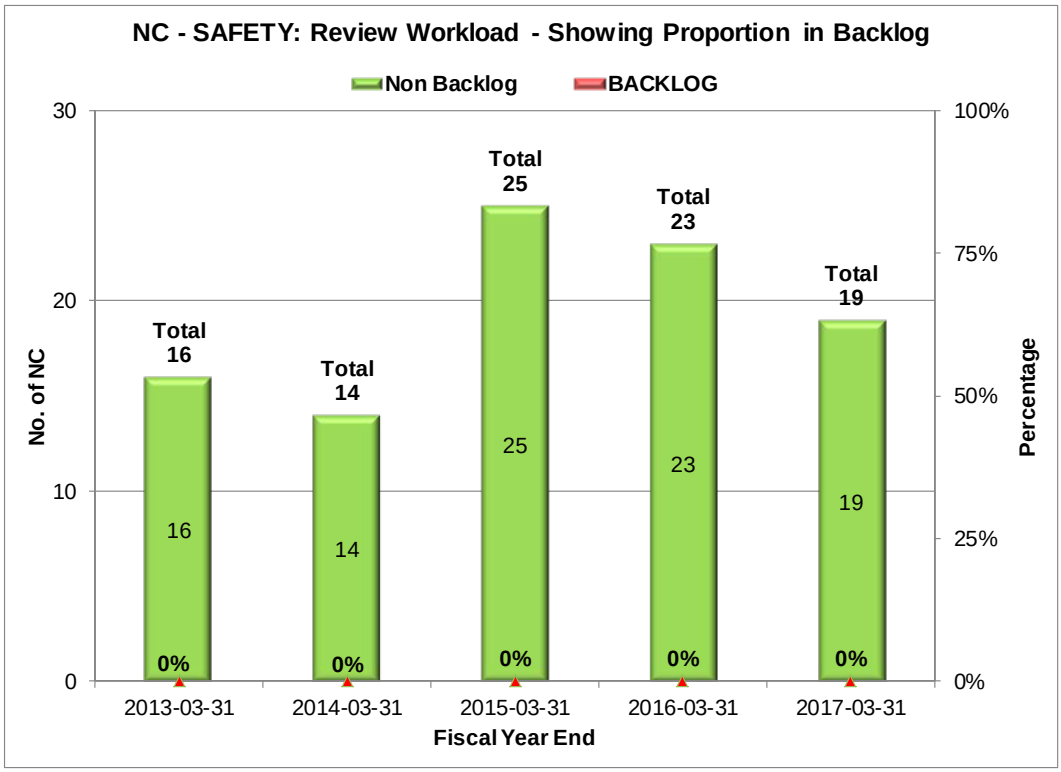
Number Received - Notifiable Changes (NC)



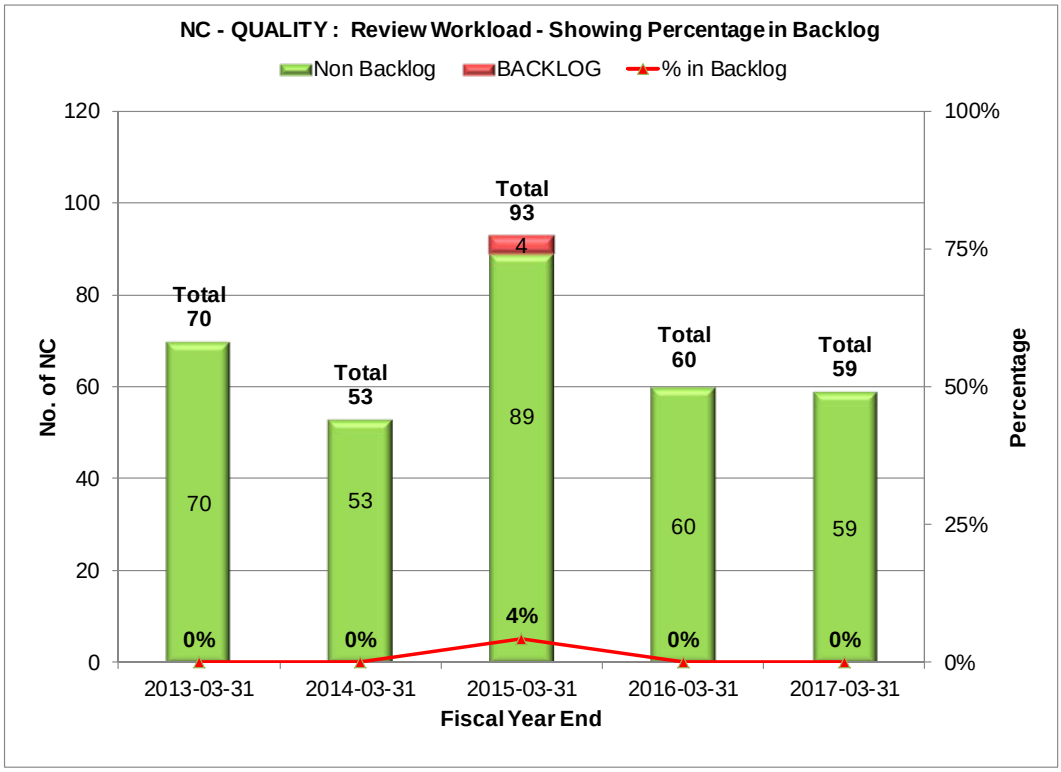
	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Safety (90)	86	101	129	89	94
Safety (120)	15	28	13	18	14
Quality (90)	342	328	359	426	379
Total	443	457	501	533	487

WORKLOAD

Notifiable Change (NC) SAFETY: Review Workload / Backlog



Notifiable Change (NC) QUALITY: Review Workload / Backlog



WORKLOAD

Notifiable Change (NC) SAFETY: Review Workload by Class

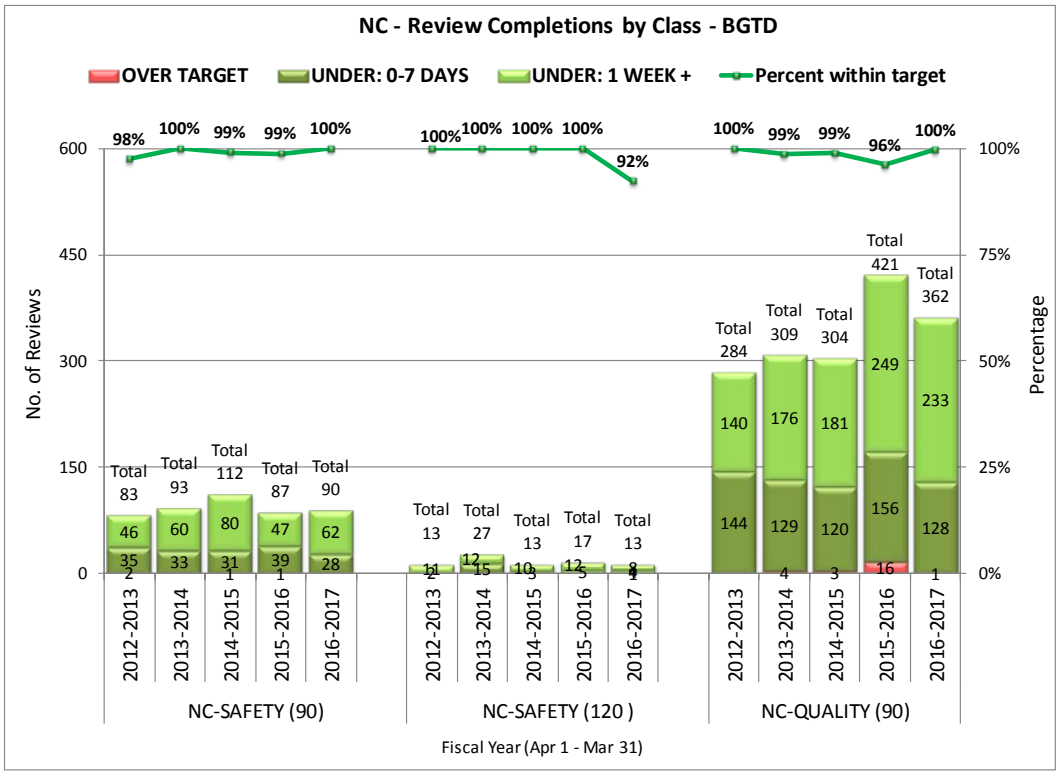
BGTD NC- SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2013-03-31	2014-03-31	2015-03-31	2016-03-31	2017-03-31
SAFETY - 90 day	13	11	22	20	15
Backlog	*0*	*0*	*0*	*0*	*0*
SAFETY - 120 day	3	3	3	3	4
Backlog	*0*	*0*	*0*	*0*	*0*
Total	16	14	25	23	19
Non Backlog	16	14	25	23	19
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

Notifiable Change (NC) QUALITY: Review Workload by Class

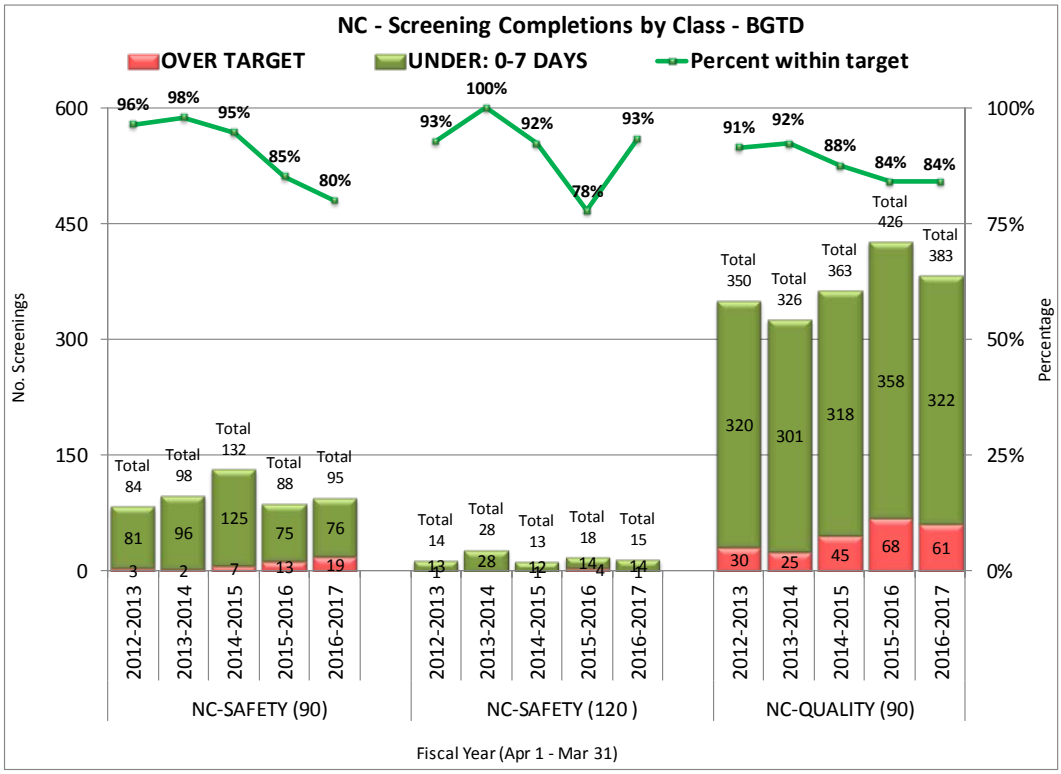
BGTD NC- QUALITY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2013-03-31	2014-03-31	2015-03-31	2016-03-31	2017-03-31
QUALITY - 90 day	70	53	93	60	59
Backlog	*0*	*0*	*4*	*0*	*0*
Total	70	53	93	60	59
Non Backlog	70	53	89	60	59
BACKLOG	0	0	4	0	0
% in Backlog	0%	0%	4%	0%	0%

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	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER	278	301	302	410	363
NOT SATISFACTORY NOTICE	4	4		3	1
REJECTION LETTER (SCR)	19	22	8	33	7
CANCELLED BY COMPANY	8	13	3	6	13
SCREENING DEFICIENCY NOTICE	3	6	12	7	5

NC - SAFETY (90)					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER	81	92	112	81	97
NOT SATISFACTORY NOTICE	2			2	
REJECTION LETTER (SCR)	6	1	5	1	
CANCELLED BY COMPANY	2	7	4	4	3
SCREENING DEFICIENCY NOTICE		1	1	1	1
NC - HOLD (PATENT)				1	

NC - SAFETY (120)					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER	13	27	12	15	12
NOT SATISFACTORY NOTICE				2	1
REJECTION LETTER (SCR)					
SCREENING DEFICIENCY NOTICE					
CANCELLED BY COMPANY		1	1	1	1

REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

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

NC					
Year of Reconsideration Request					
	12-13	**13-14**	**14-15**	**15-16**	**16-17**
Total	**0**	**0**	**0**	**0**	**0**

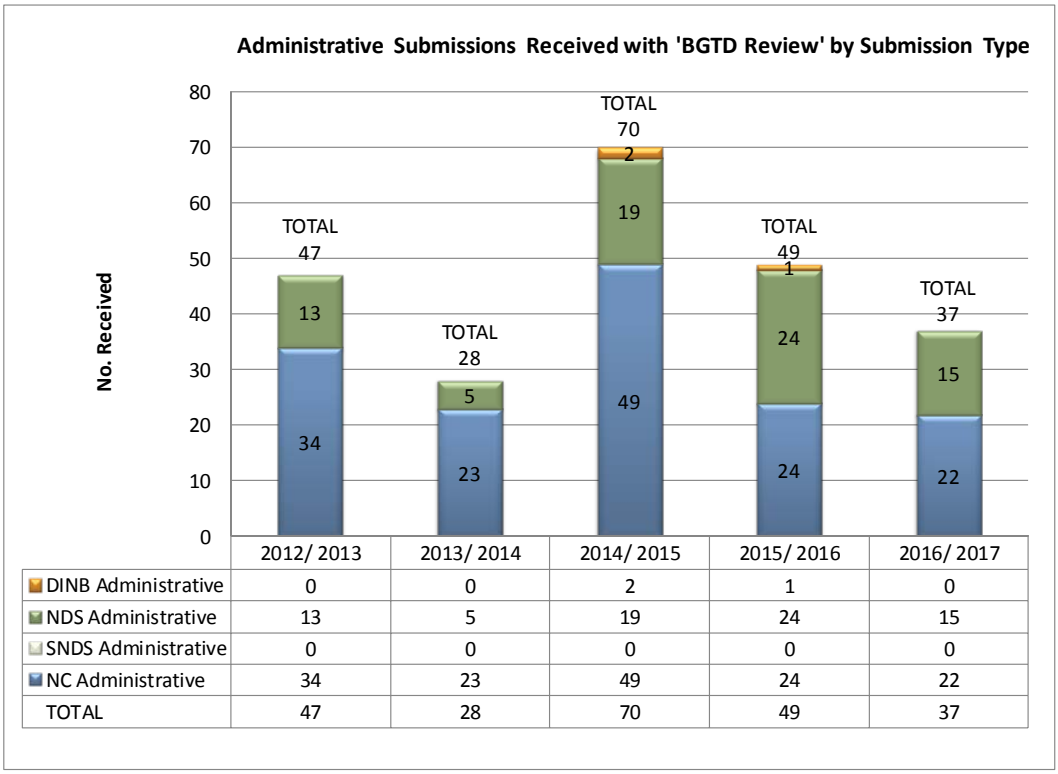
Administrative Submissions

Submissions in support of a manufacturer or product name change.

ADMINISTRATIVE SUBMISSIONS with BGTD review

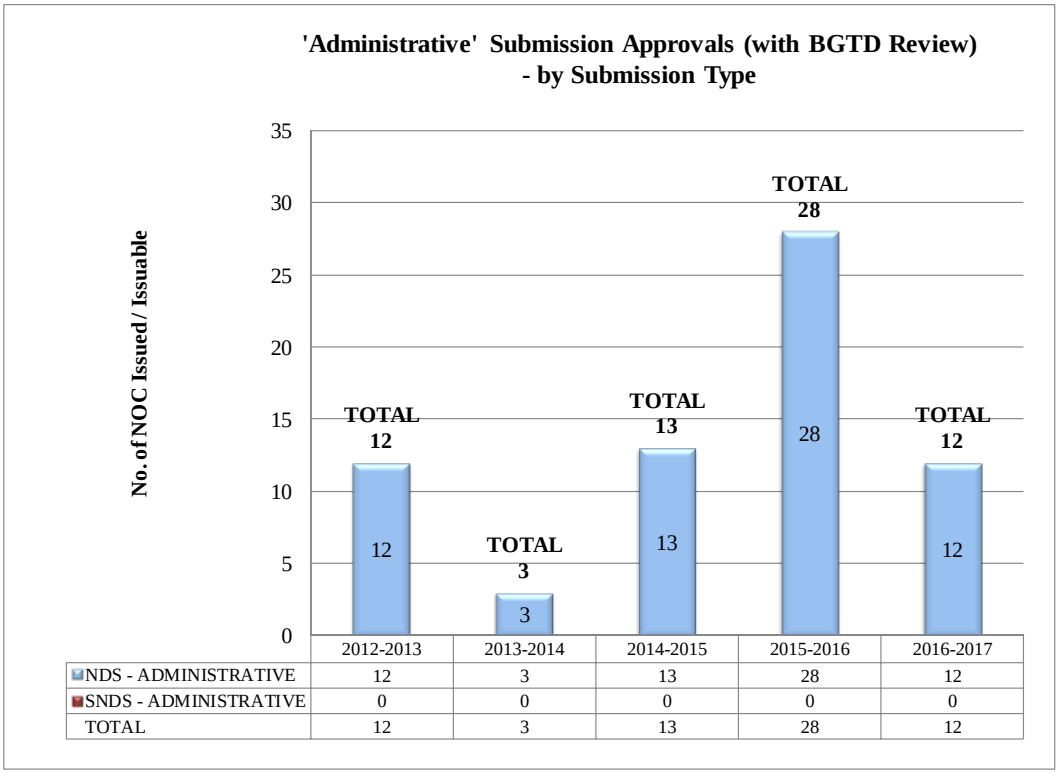
(such as product name change that requires a drug name review)

Administrative Submissions Received (with BGTD review)



	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
DINB Administrative	0	0	2	1	0
NDS Administrative	13	5	19	24	15
SNDS Administrative	0	0	0	0	0
NC Administrative	34	23	49	24	22
TOTAL	47	28	70	49	37

Administrative Submission Approvals (with BGTD Review)

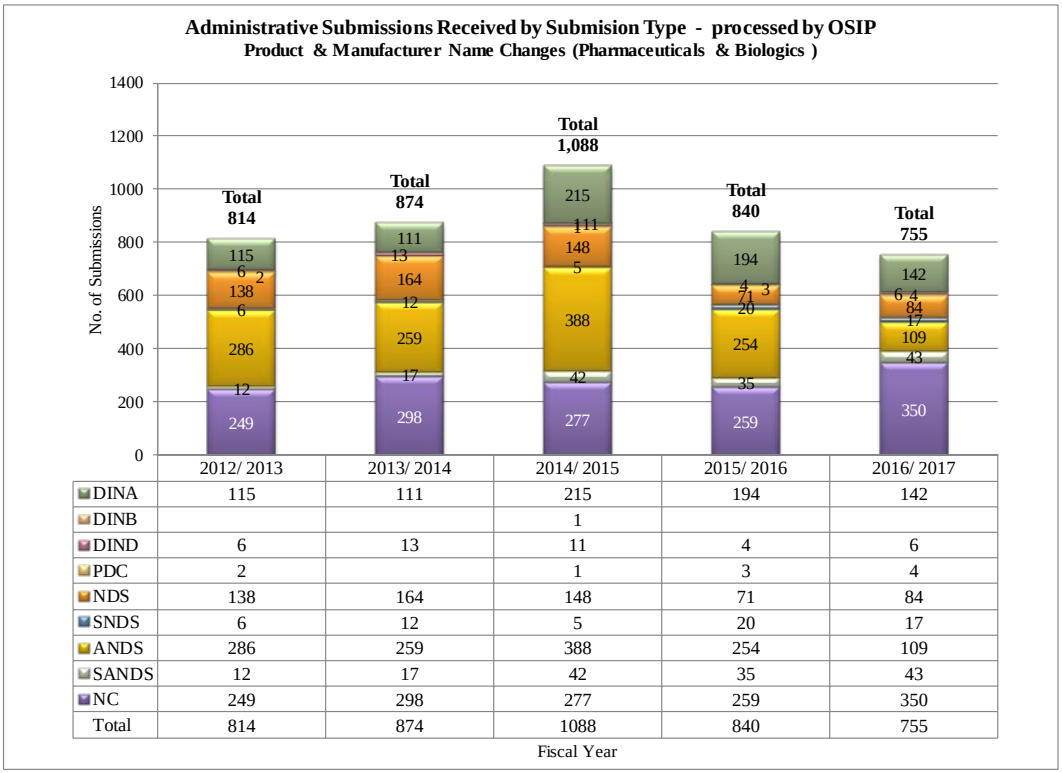


	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
NDS - ADMINISTRATIVE	12	3	13	28	12
SNDS - ADMINISTRATIVE	0	0	0	0	0
TOTAL	12	3	13	28	12

ADMINISTRATIVE SUBMISSIONS (Processed by OSIP)

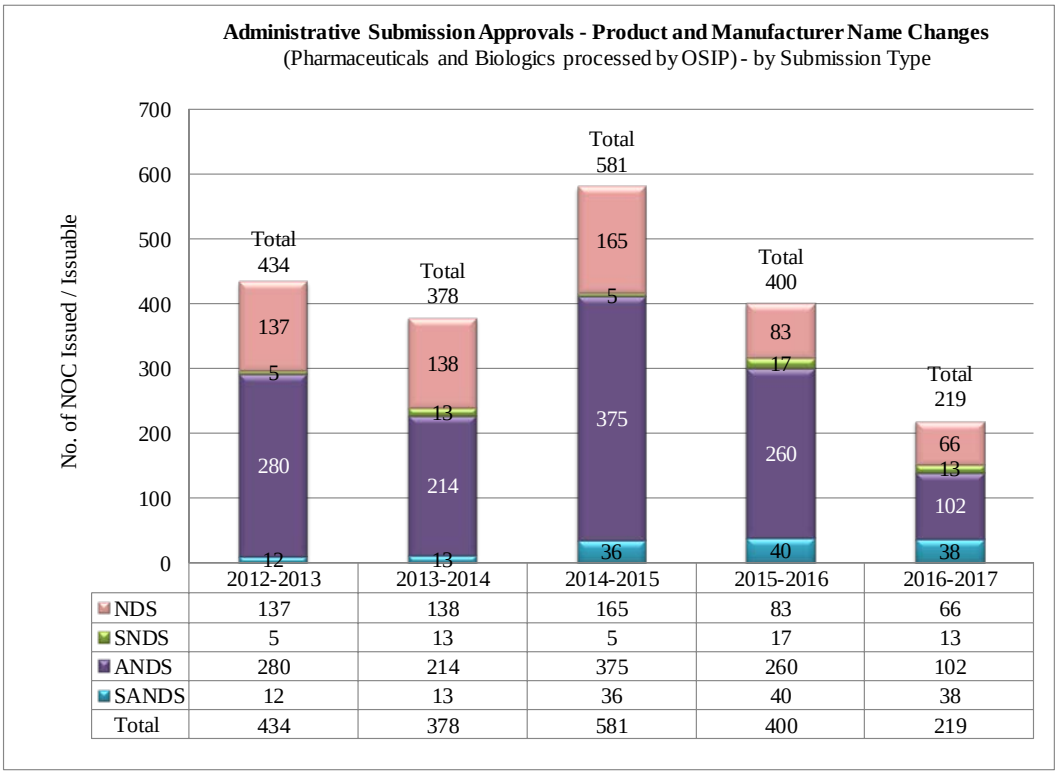
(Product & Manufacturer Name Changes)
(Admin NCs are for cross-referenced changes)

Administrative Submissions Received by Submission Type (OSIP)



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

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



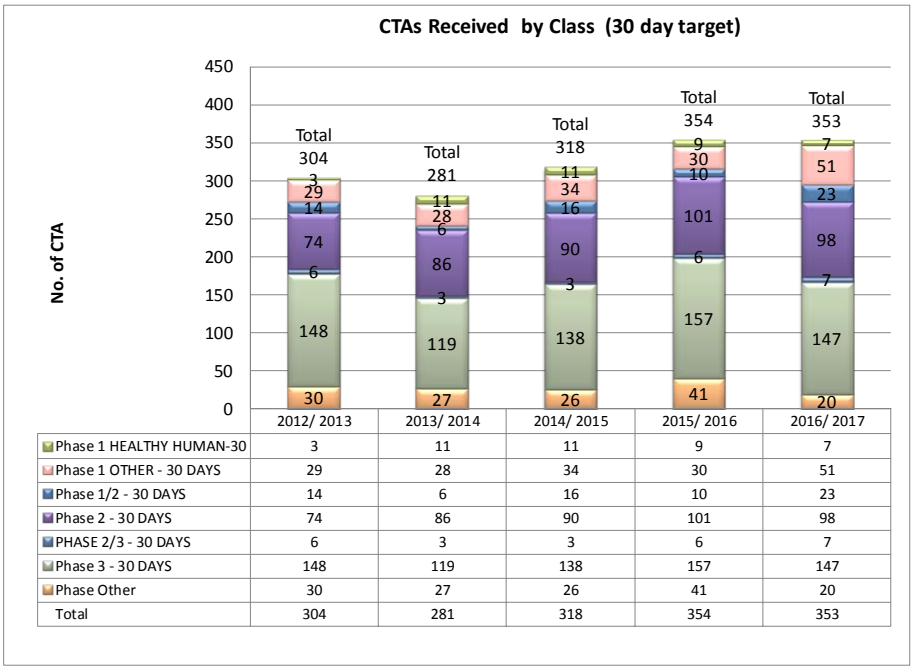
	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
NDS	137	138	165	83	66
SNDS	5	13	5	17	13
ANDS	280	214	375	260	102
SANDS	12	13	36	40	38
Total	434	378	581	400	219

Clinical Trial Applications and Amendments

(CTA & CTA-A)

CLINICAL TRIAL APPLICATIONS

Number Received - Clinical Trial Application (CTA)

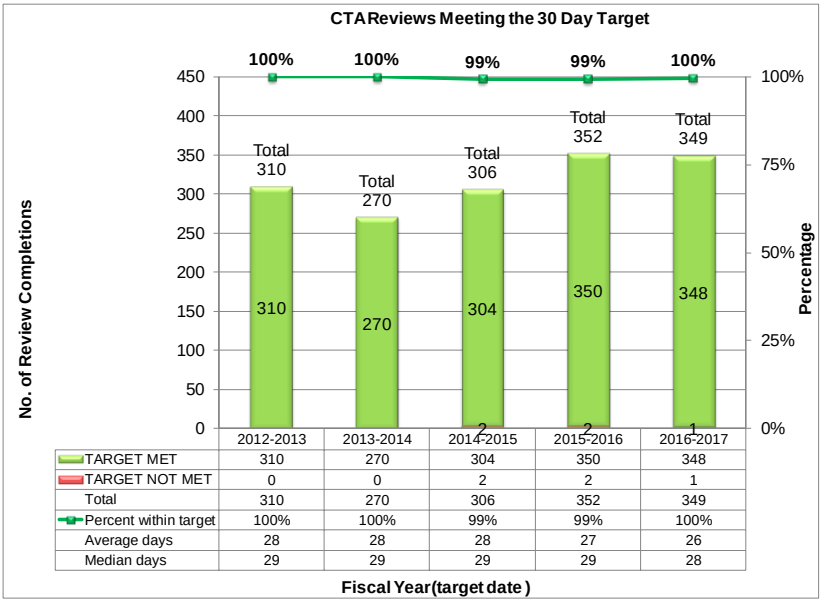


	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Phase 1 HEALTHY HUMAN-30	3	11	11	9	7
Phase 1 OTHER - 30 DAYS	29	28	34	30	51
Phase 1/2 - 30 DAYS	14	6	16	10	23
Phase 2 - 30 DAYS	74	86	90	101	98
PHASE 2/3 - 30 DAYS	6	3	3	6	7
Phase 3 - 30 DAYS	148	119	138	157	147
Phase Other	30	27	26	41	20
Total	304	281	318	354	353

Decision Documents - Clinical Trial Application (CTA)

CTA (30 day target)					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER	302	255	283	336	328
CANCELLED BY COMPANY DURING REVIEW	7	7	18	10	21
CANCELLED BY COMPANY AT PROCESSING	4	0	5	2	10
NOT SATISFACTORY NOTICE	1	6	4	3	
REFUSAL LETTER	0	0	0	0	
REJECTION LETTER (SCR)	1	0	1	1	1
SCREENING DEFICIENCY NOTICE	0	0	0	3	

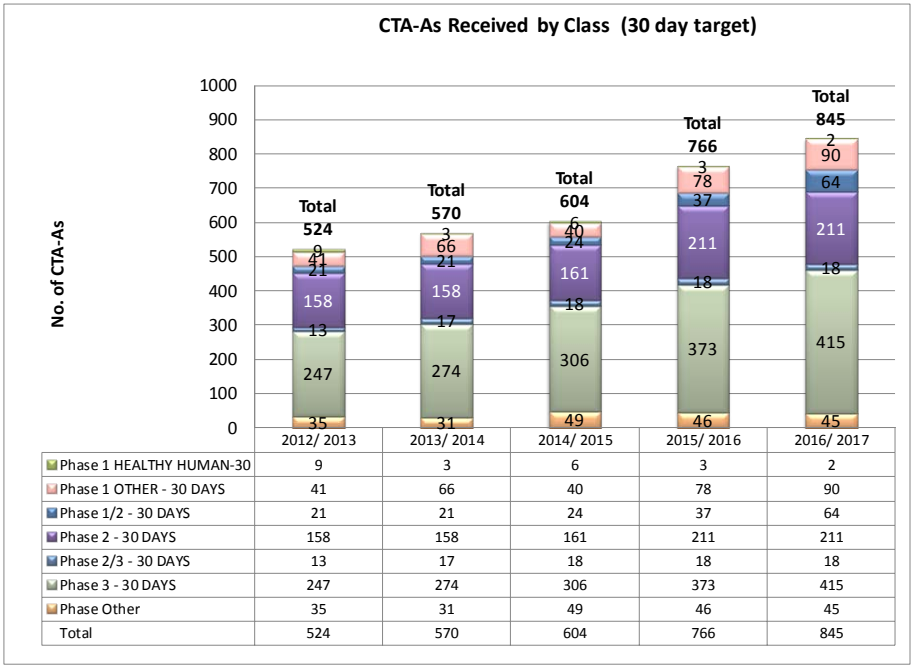
Performance - Clinical Trials Applications (CTA) Reviews Meeting the 30 Day Target



	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
TARGET MET	310	270	304	350	348
TARGET NOT MET	0	0	2	2	1
Total	310	270	306	352	349
Percent within target	100%	100%	99%	99%	100%
Average days	28	28	28	27	26
Median days	29	29	29	29	28

CLINICAL TRIAL APPLICATION-AMENDMENTS

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

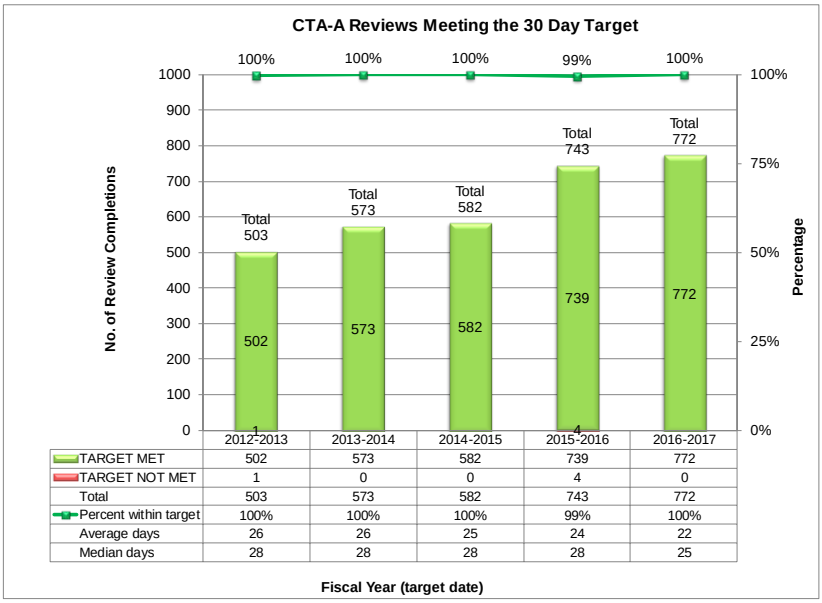


	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Phase 1 HEALTHY HUMAN-30	9	3	6	3	2
Phase 1 OTHER - 30 DAYS	41	66	40	78	90
Phase 1/2 - 30 DAYS	21	21	24	37	64
Phase 2 - 30 DAYS	158	158	161	211	211
Phase 2/3 - 30 DAYS	13	17	18	18	18
Phase 3 - 30 DAYS	247	274	306	373	415
Phase Other	35	31	49	46	45
Total	524	570	604	766	845

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

CTA-A (30 day target)					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER	491	572	574	747	794
CANCELLED BY COMPANY DURING REVIEW	9	3	8	5	7
CANCELLED BY COMPANY AT PROCESSING	3	0	6	2	10
NOT SATISFACTORY NOTICE	3	0	0	2	
REJECTION LETTER (SCR)	8	3	5	10	15

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



	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017
TARGET MET	502	573	582	739	772
TARGET NOT MET	1	0	0	4	0
Total	503	573	582	743	772
Percent within target	100%	100%	100%	99%	100%
Average days	26	26	25	24	22
Median days	28	28	28	28	25

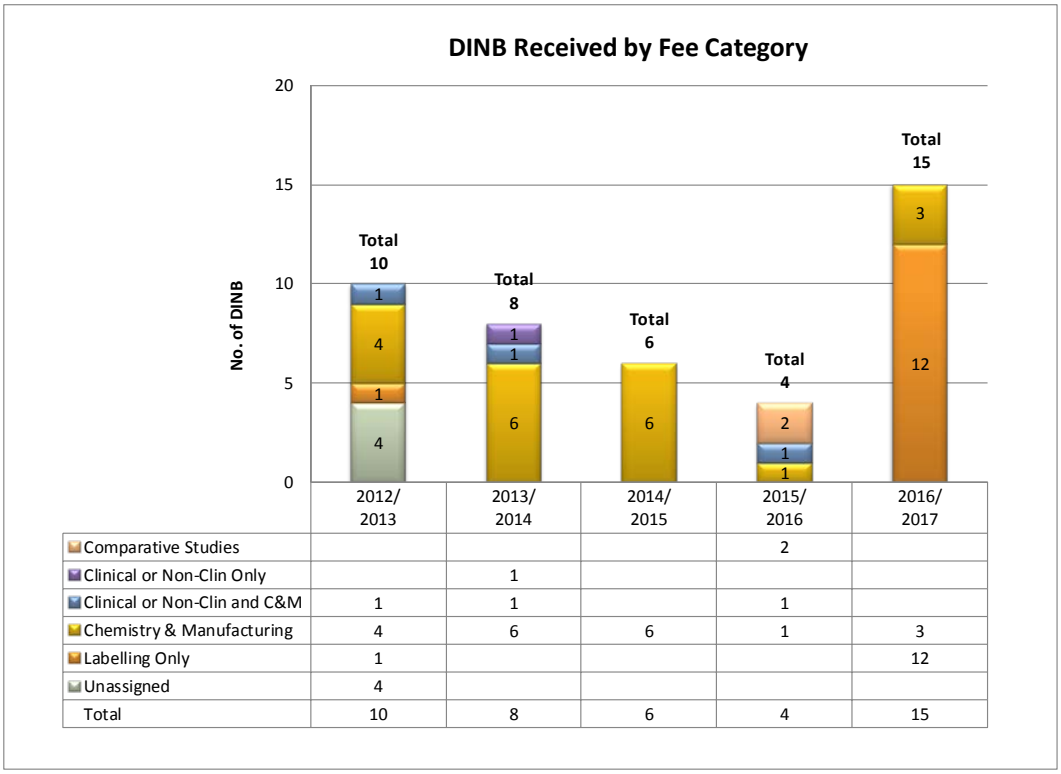
Application for a Drug Identification Number

DINB

Biological Products

DINB: Application for a Drug Identification Number – BIOLOGICAL Products

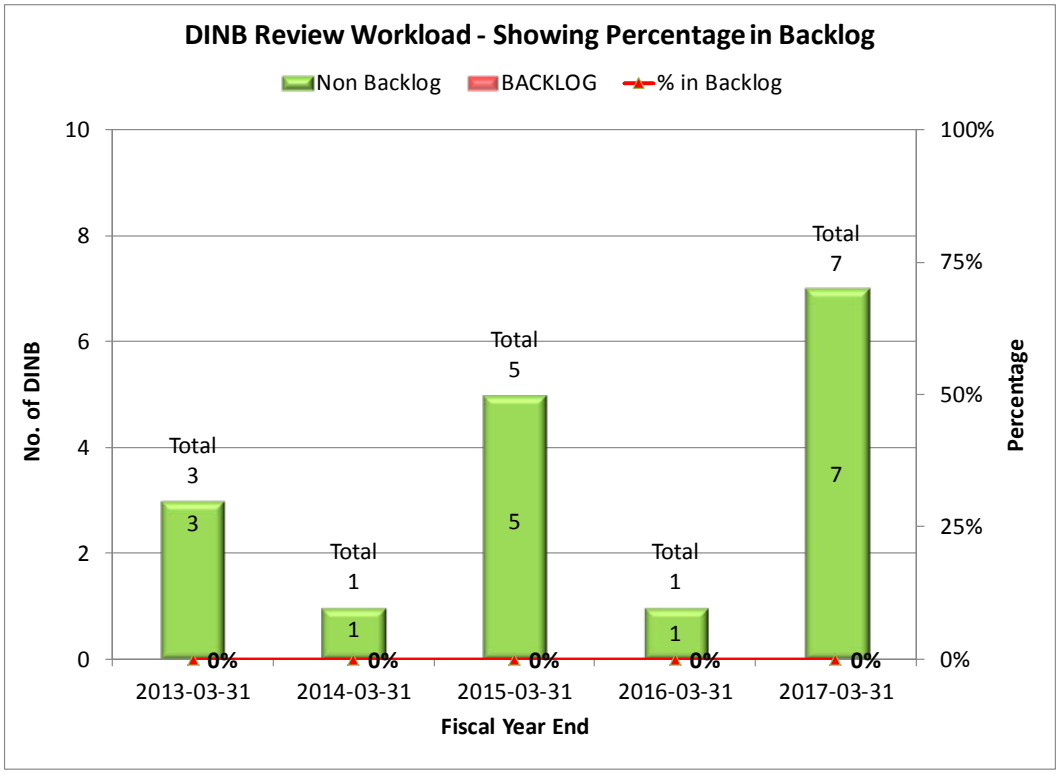
DINB: Number Received



	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Comparative Studies				2	
Clinical or Non-Clin Only		1			
Clinical or Non-Clin and C&M	1	1		1	
Chemistry & Manufacturing	4	6	6	1	3
Labelling Only	1				12
Unassigned	4				
Total	10	8	6	4	15

REVIEW WORKLOAD

DINB: Review Workload Showing Percentage in Backlog

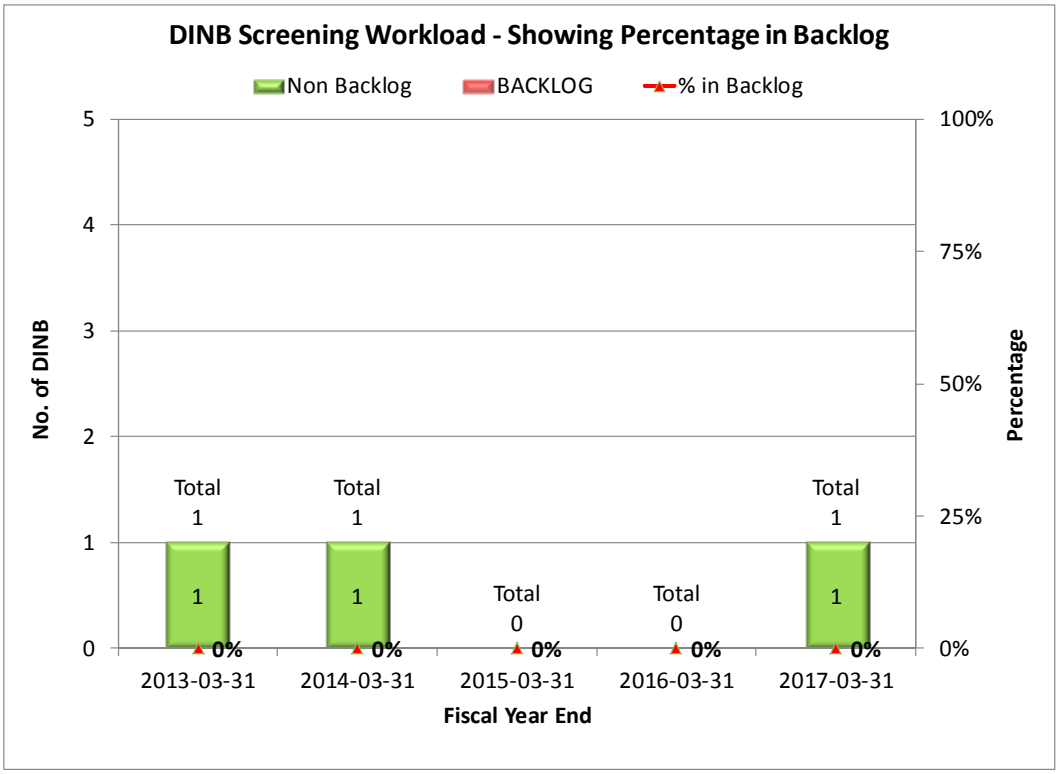


DINB: Review Workload by Class

DINB All REVIEW WORKLOAD BY FEE CATEGORY - BGTD (excluding administrative) and Fiscal Year End					
	2013-03-31	2014-03-31	2015-03-31	2016-03-31	2017-03-31
Labelling Only	**0**	**0**	**0**	**0**	**6**
Backlog	*0*	*0*	*0*	*0*	*0*
Form and Supporting Data	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**3**	**1**	**5**	**1**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**3**	**1**	**5**	**1**	**7**
Non Backlog	**3**	**1**	**5**	**1**	**7**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

SCREENING WORKLOAD

DINB: Screening Workload Showing Percentage in Backlog



DINB: Screening Workload by Class

DINB All SCREENING WORKLOAD BY FEE CATEGORY - BGTD (excluding dministrative) and Fiscal Year End					
	2013-03-31	2014-03-31	2015-03-31	2016-03-31	2017-03-31
Clinical or Non-Clin and C&M	**1**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**0**	**1**	**0**	**0**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**1**	**1**	**0**	**0**	**1**
Non Backlog	**1**	**1**	**0**	**0**	**1**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

DECISION DOCUMENTS

DINB: Decision Documents by Class

DINB - LABELLING ONLY					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER					
SCREENING DEFICIENCY NOTICE					
NOTICE OF DEFICIENCY					
CANCELLED BY COMPANY	1				6

DINB - CLIN ONLY					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER					

DINB - CHEMISTRY & MANUFACTURING					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER	1	4			
NOTICE OF DEFICIENCY					
NOTIFICATION FORM DIN SUB			1		
SCREENING DEFICIENCY NOTICE		1	6		
CANCELLED BY COMPANY					

DINB - CLIN/C&M					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NO OBJECTION LETTER		1			
SCREENING DEFICIENCY NOTICE			2		
CANCELLED BY COMPANY				1	

DINB - CLIN/C&M					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
NOTIFICATION FORM/DIN ISSUED	11		2		

DINB - UNASSIGNED					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
CANCELLED BY COMPANY	4				

DINB - COMPARATIVE STUDIES					
DOCUMENT TYPE	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**
REJECTION LETTER (SCREENING)				1	
SCREENING DEFICIENCY NOTICE				1	

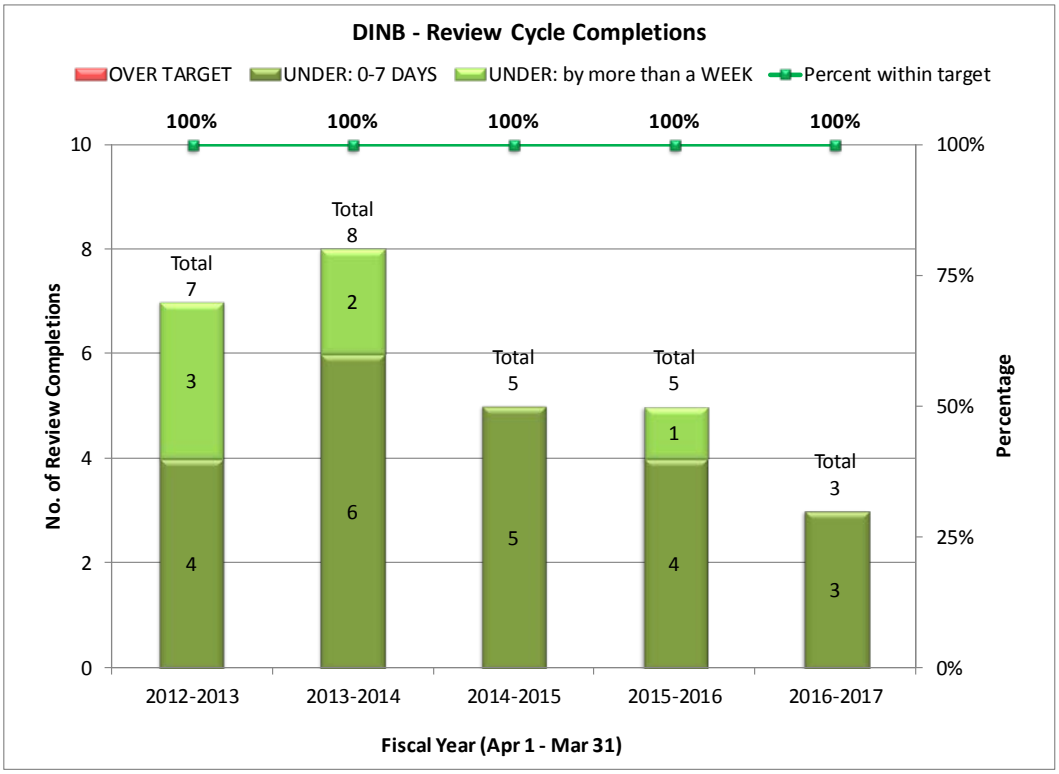
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

DINB: Requests for Reconsideration of Final Decisions

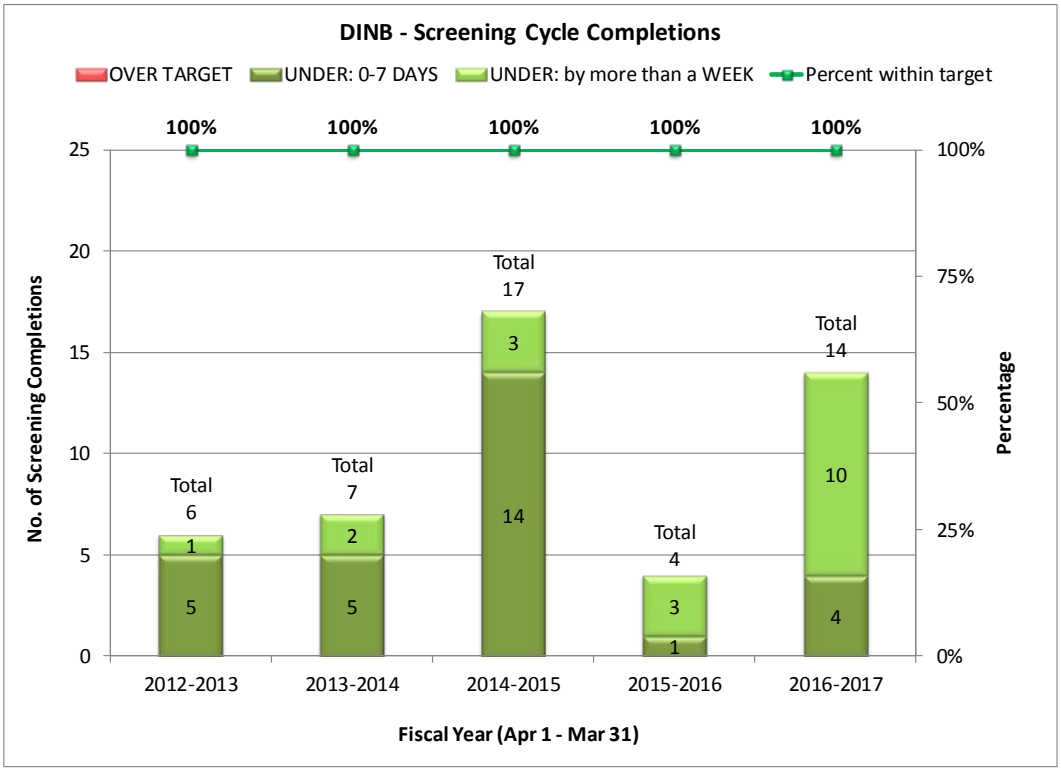
Year of Reconsideration Request					
	12-13	**13-14**	**14-15**	**15-16**	**16-17**
Total	**0**	**0**	**0**	**0**	**0**

PERFORMANCE

DINB: Review Cycle Completions

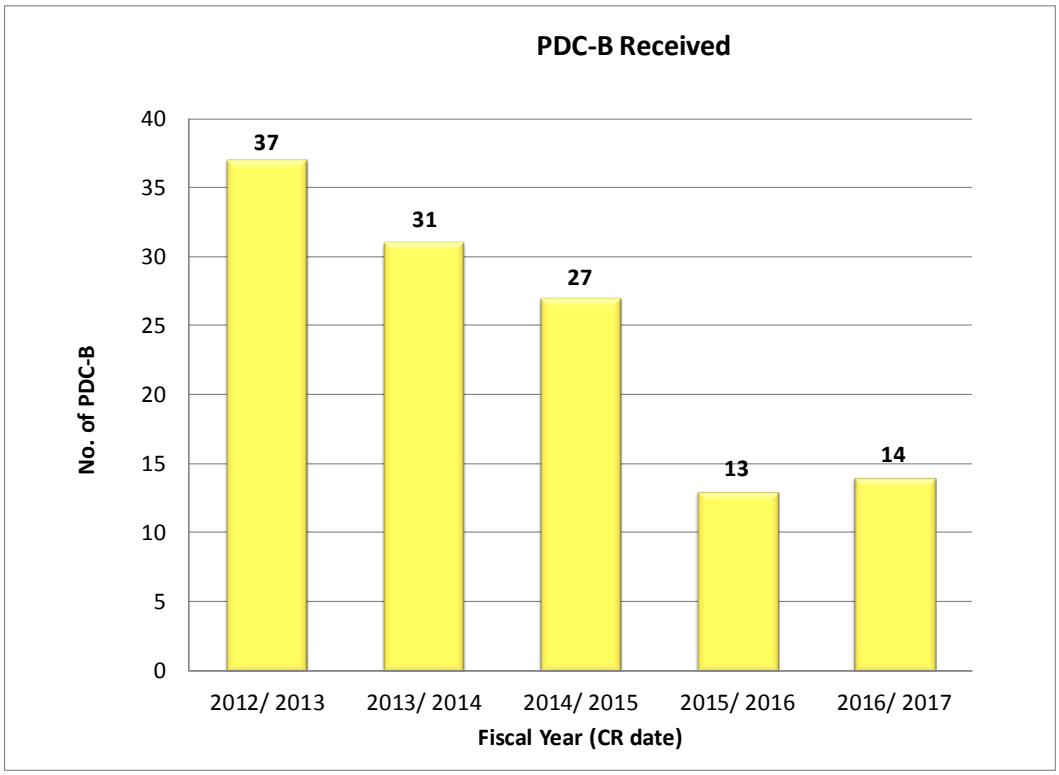


DINB: Screening Cycle Completions



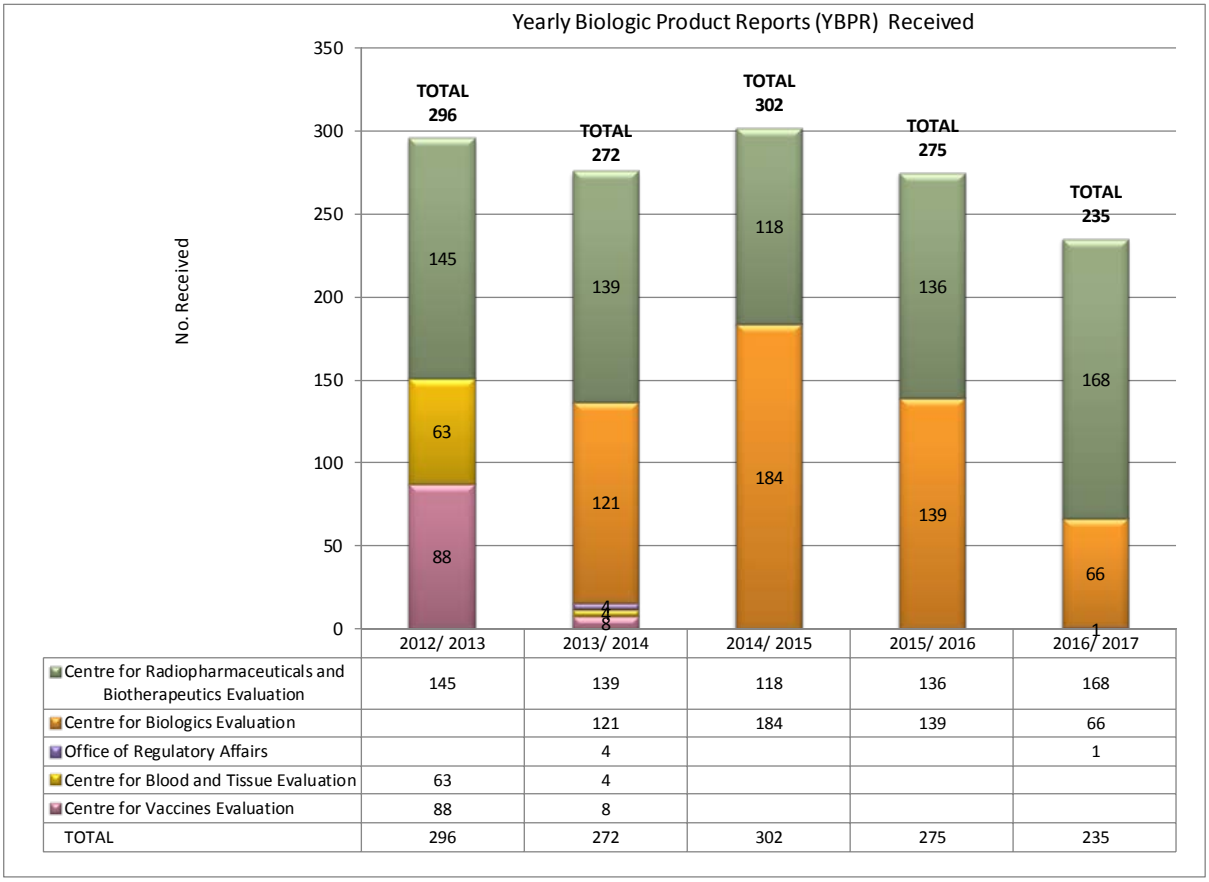
PDC-B: Post Authorization Division 1 Changes - Biologics

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



YBPR: Yearly Biologic Product Reports[6]

Yearly Biologic Product Reports (YBPR) Received



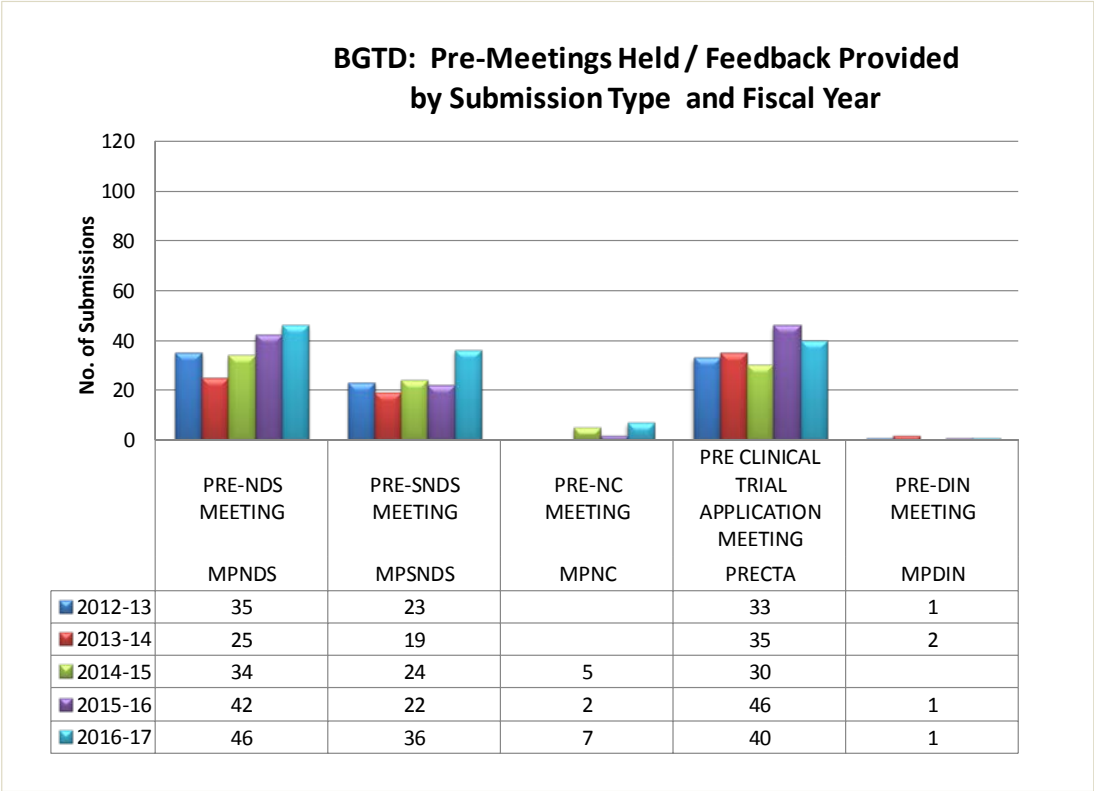
	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Centre for Radiopharmaceuticals and Biotherapeutics Evaluation	145	139	118	136	168
Centre for Biologics Evaluation		121	184	139	66
Office of Regulatory Affairs		4			1
Centre for Blood and Tissue Evaluation	63	4			
Centre for Vaccines Evaluation	88	8			
TOTAL	296	272	302	275	235

[6] 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.

Appendix A: Pre-submission Meetings

[7]

Pre-submission Meetings Held / Feedback Provided



	PRE-NDS MEETING MPNDS	PRE-SNDS MEETING MPSNDS	PRE-NC MEETING MPNC	PRE CLINICAL TRIAL APPLICATION MEETING PRECTA	PRE-DIN MEETING MPDIN
2012-13	35	23		33	1
2013-14	25	19		35	2
2014-15	34	24	5	30	
2015-16	42	22	2	46	1
2016-17	46	36	7	40	1

[7] Prior to filing a submission, the sponsor may request a pre-submission meeting to discuss the presentation of data in support of the submission: For further information, refer to the Guidance for Industry: Management of Drug Submissions