Santé Canada Health Canada

Biologics and Genetic Therapies Directorate

Drug Submission Performance Annual Report

Fiscal Year

2017-2018

April 1 2017 – March 31 2018

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

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Direction des produits biologiques et des thérapies génétiques – Rapport annuel du rendement des présentations de drogue – Exercice financier 2017-2018

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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 2013-2014 to 2017-2018.

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 2017 to March 31 2018.

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 (CR date) which is the date the submission is considered administratively complete by Health Canada.

Workload is the number of submissions "under active review" on the last day of the quarter. **"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[2] 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.

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

[2] Final results from confirmatory trials submitted in the form of an SNDS-C are now included in the SNDS Received, Workload and Performance figures. SNDS-C are not included in the SNDS Approval figures. For further Clarification refer to the Guidance Document: Notice of Compliance with Conditions (NOC/c).

A **review cycle completion**[3] 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[4] 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"[5] submissions.

Any questions or comments on this report should be forwarded to:

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[3] 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.

[4] Performance continues to be measured against performance standards for Submission Type/Submission Class/ Status combinations as set out in Appendix 3 of the Guidance for Industry: Management of Drug Submissions. This is not to be confused with the 'UF Review 1 (iteration 1)' performance standards that are employed to measure performance to meet the *User Fees Act* reporting Requirements in the 'Health Canada Departmental Performance Report (DPR).

[5] 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)	Submission 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 medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. For biologics, this submission class does not include an NDS in support of a subsequent entry biologic or an SNDS in support of changes to the manufacturing process of biologics.
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 NAS.
Clinical or Non-Clinical Data Only	Submissions based only on clinical or non-clinical data for a drug that does not include a NAS.
Comparative Studies	Submissions based on comparative studies with or without chemistry and manufacturing data for a drug that does not include a NAS. It excludes superiority and non-inferiority studies since they are clinical studies. It also excludes pharmaceutical equivalence studies since they are captured by the chemistry and manufacturing fee.
Chemistry and Manufacturing Data Only	Submissions based only on chemistry and manufacturing data for a drug that does not include a NAS.
Published Data Only	Submissions based only on published clinical or non-clinical data for a drug that does not include a NAS.
Switch from Prescription to Nonprescription Status	Submissions based only on data that support the modification or removal of a medicinal ingredient on the Prescription Drug List. This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug.
Labelling Only[6]	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
Administrative Submission[7]	Submissions in support of a manufacturer or product name change.
Disinfectants[8]	Submissions and applications that include data in support of a disinfectant.
Drug Identification Number (DIN) - Labelling Standards	Applications attesting to compliance with a labelling standard or Category IV Monograph (DINF) for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data.

For further information, please refer to the Guidance Document - Fees for the Review of Drug Submissions and Applications

[6] For more information, please consult the Guidance Document: Question and Answers about Plain Language Labelling
[7] For additional information, please consult the "Changes in Manufacturer and/or Product Name Policy" (2015)
[8] The non-prescription (or over-the-counter) and disinfectant drug review functions were moved from TPD to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013. These products are reported on in a separate NNHPD Drug Submission Performance Report.

New Drug Submission (NDS)

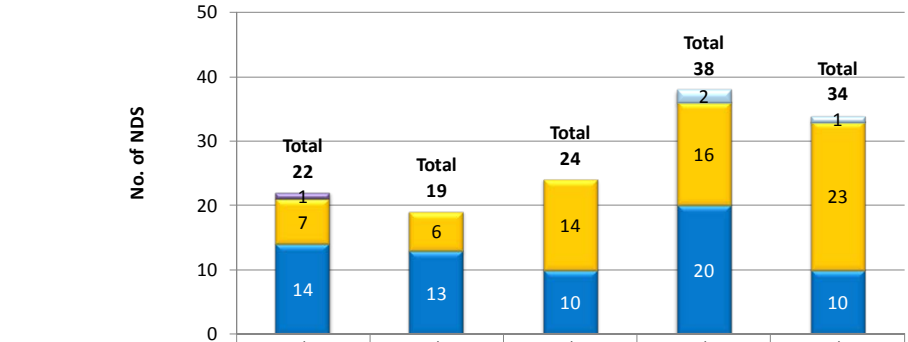
&

Supplemental New Drug Submission (SNDS)

SUBMISSIONS RECEIVED

[9] [10]

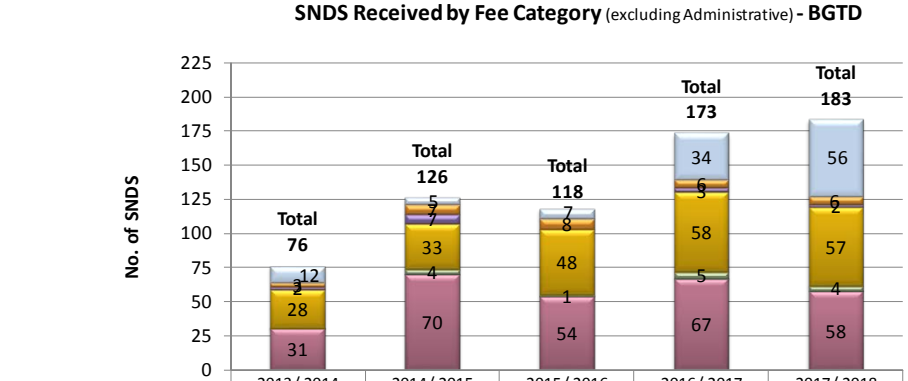
New Drug Submissions (NDS) Received by Fee Category



	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Labelling Only	0	0	0	2	1
Comparative Studies	1	0	0	0	0
Clinical or Non-Clin and C&M	7	6	14	16	23
New Active Substance	14	13	10	20*	10
Total	22	19	24	38	34
Priority (subset)	1	3	2	2	5
NOC/c Class	0	4	1	4	2
Emergency Use NDS	0	0	1	2	1
Biosimilar	0 *	2	4	7	14

*revised May 2018

Supplemental New Drug Submissions (SNDS) Received by Fee Category



	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Labelling Only	12	5	7	34	56
Clinical or Non-Clin and C&M	3	7	8	6	6
Comparative Studies	2	7	0	3	2
Clinical or Non-Clin Only	28	33	48	58	57
Published Data Only	0	4	1	5	4
Chemistry & Manufacturing	31	70	54	67	58
Total	76	126	118	173	183
Priority (subset)	1	0	2	5	2
NOC/c Class	0	0	2	3	3
SNDS Confirmatory	1	2	4	5	5
Biosimilar	0	2 *	4 *	3 *	11

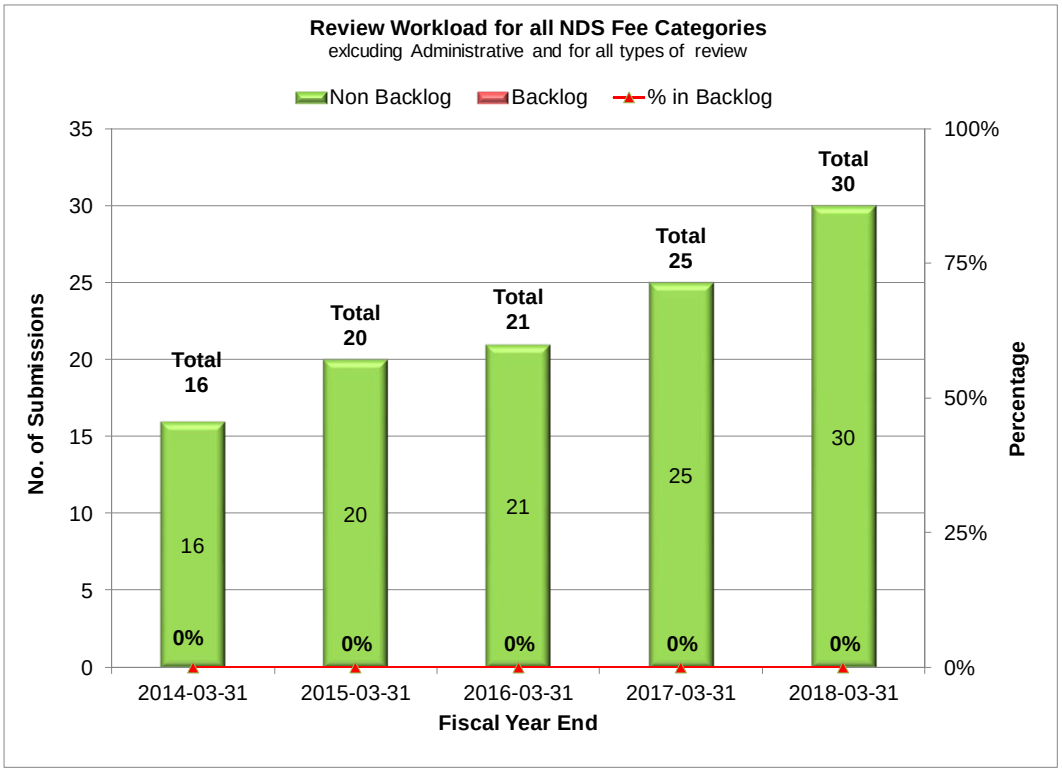
* revised May 2018

[9] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance with conditions (NOC/c) Guidance and the Management of Drug Submissions Guidance .

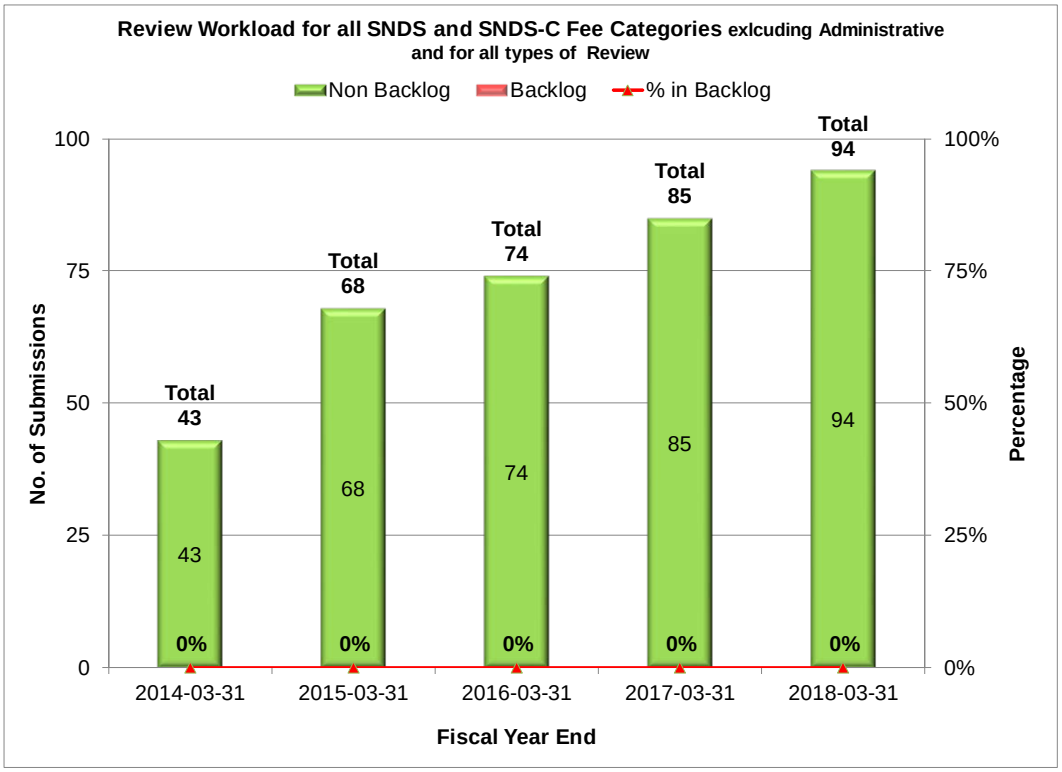
[10] **Biosimilar**: A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required.

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

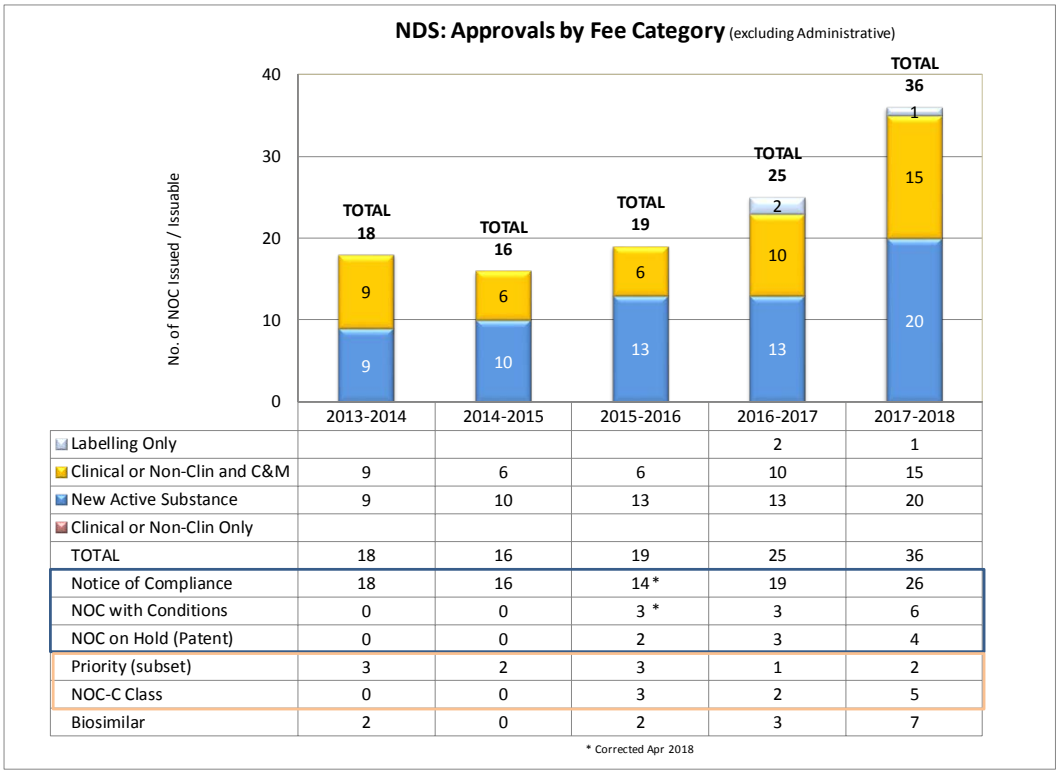
NDS All REVIEW WORKLOAD BY FEE CATEGORY - BGTD (excluding administrative) and Fiscal Year End					
	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Clinical or Non-Clin and C&M	**6**	**8**	**11**	**11**	**21**
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	**10**	**12**	**10**	**14**	**9**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**16**	**20**	**21**	**25**	**30**
Non Backlog	**16**	**20**	**21**	**25**	**30**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**1**	**2**	**1**	**1**	**5**
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					
	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Comparative Studies	**0**	**3**	**0**	**1**	**1**
Backlog	0	0	0	0	0
Chemistry & Manufacturing	**15**	**32**	**25**	**28**	**26**
Backlog	0	0	0	0	0
Clinical or Non-Clin Only	**23**	**25**	**37**	**44**	**54**
Backlog	0	0	0	0	0
Published Data	**0**	**3**	**1**	**3**	**2**
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	**2**	**5**	**10**	**4**	**4**
Backlog	0	0	0	0	0
Labelling Only	**3**	**0**	**1**	**5**	**7**
Backlog	0	0	0	0	0
Total	**43**	**68**	**74**	**85**	**94**
Non Backlog	**43**	**68**	**74**	**85**	**94**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**0**	**0**	**2**	**3**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*
SNDS-C (Confirmatory)	**0**	**2**	**3**	**3**	**5**
Backlog	*0*	*0*	*0*	*0*	*0*

APPROVALS

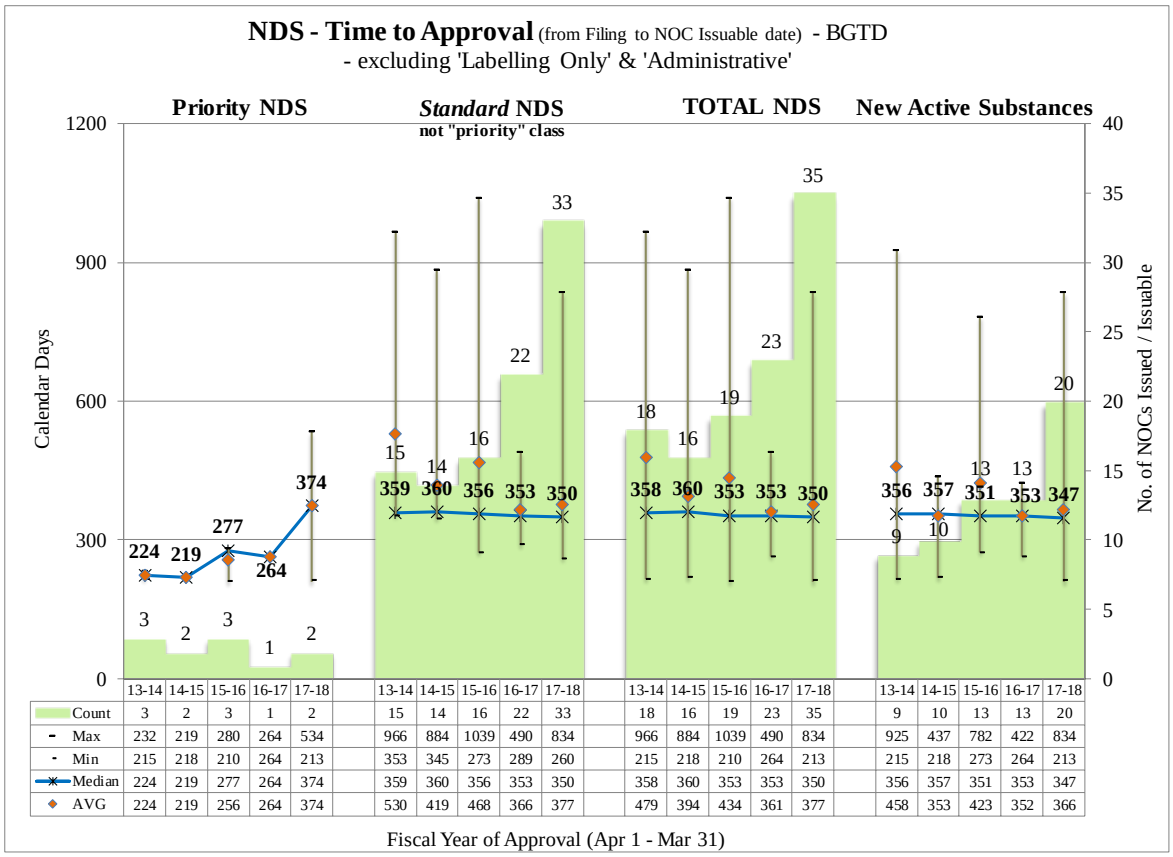
New Drug Submission (NDS) Approvals by Fee Category and by NOC Type



	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
Labelling Only				2	1
Clinical or Non-Clin and C&M	9	6	6	10	15
New Active Substance	9	10	13	13	20
Clinical or Non-Clin Only					
TOTAL	18	16	19	25	36
Notice of Compliance	18	16	14*	19	26
NOC with Conditions	0	0	3 *	3	6
NOC on Hold (Patent)	0	0	2	3	4
Priority (subset)	3	2	3	1	2
NOC-C Class	0	0	3	2	5
Biosimilar	2	0	2	3	7

* Corrected Apr 2018

NDS Approval Times

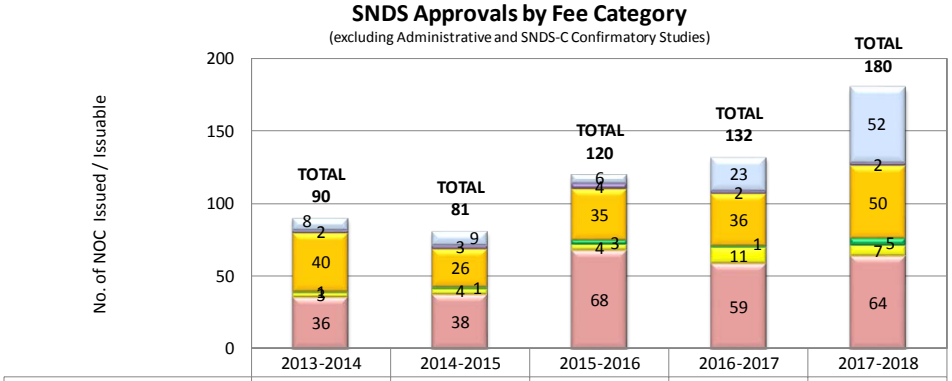


	Priority NDS					*Standard* NDS not "priority" class					TOTAL NDS					New Active Substances				
	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18
Count	3	2	3	1	2	15	14	16	22	33	18	16	19	23	35	9	10	13	13	20
Max	232	219	280	264	534	966	884	1039	490	834	966	884	1039	490	834	925	437	782	422	834
Min	215	218	210	264	213	353	345	273	289	260	215	218	210	264	213	215	218	273	264	213
Median	224	219	277	264	374	359	360	356	353	350	358	360	353	353	350	356	357	351	353	347
AVG	224	219	256	264	374	530	419	468	366	377	479	394	434	361	377	458	353	423	352	366

Fiscal Year of Approval (Apr 1 - Mar 31)

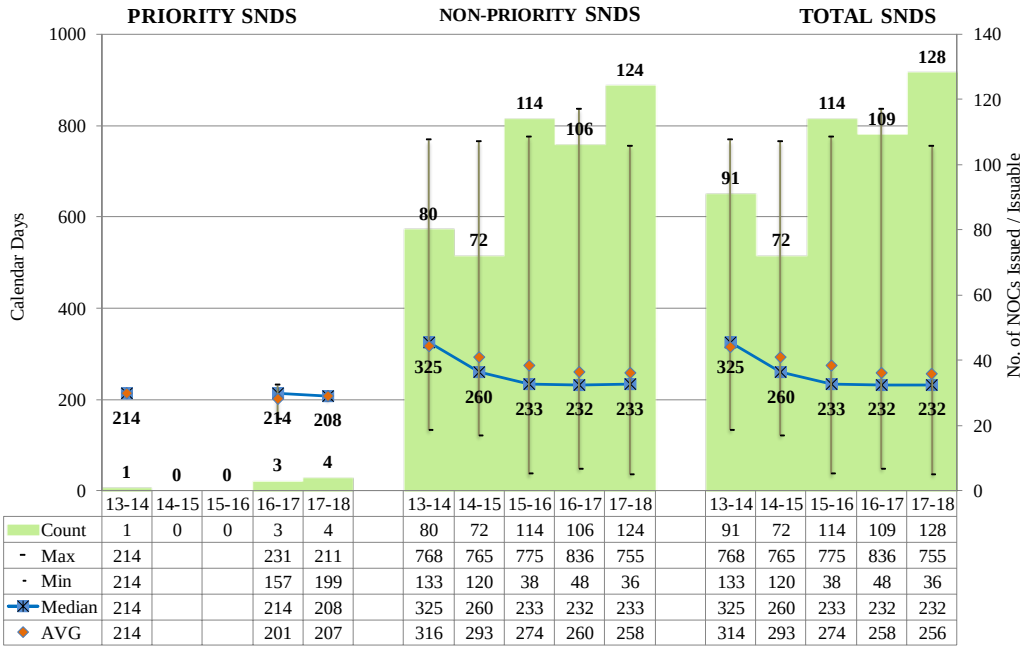
Approval Time is the total number of calendar days between the date a submission is filed (CR date) and the date it is approved (NOC Issuable). This includes time in processing, screening, review and any time taken by the company to respond to notices of deficiency or non-compliance.

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



	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
Labelling Only	8	9	6	23	52
Comparative Studies	2	3	4	2	2
Clinical or Non-Clin Only	40	26	35	36	50
Published Data Only	1	1	3	1	5
Clinical or Non-Clin and C&M	3	4	4	11	7
Chemistry & Manufacturing	36	38	68	59	64
TOTAL	90	81	120	132	180
Notice of Compliance	89	81	120	127	175
NOC with Conditions	1	0	0	2	4
Priority (subset)	1	0	0	3	4
NOC-C Class	0	0	0	2	4
Biosimilar	0	0	2	4	5

SNDS Approval Times



	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18
Count	1	0	0	3	4	80	72	114	106	124	91	72	114	109	128
Max	214			231	211	768	765	775	836	755	768	765	775	836	755
Min	214			157	199	133	120	38	48	36	133	120	38	48	36
Median	214			214	208	325	260	233	232	233	325	260	233	232	232
AVG	214			201	207	316	293	274	260	258	314	293	274	258	256

Fiscal Year of Approval (Apr 1 - Mar 31)

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

Biosimilar: A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required..

New Active Substance Approvals (NAS) – BGTD - Fiscal Year 2017-2018

New Active Substance Approvals (NAS) – BGTD Fiscal Year 2017-2018 (April 1 2017 to March 31 2018)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[11])**	**Approval Date (dd-mon-yy)**
ANTHRASIL (Anthrax Immune Globuline (Human) - is indicated for the treatment of adult and pediatric patients with toxemia associated with inhalational anthrax. ANTHRASIL is beneficial in combination with appropriate antibacterial drugs.	NAS	Emergent Biosolutions Canada Inc.	24-Nov-16	6-Nov-17
BAVENCIO (Avelumab) - is indicated for the treatment of metastatic Merkel cell carcinoma (MCC) in previously treated adults.	NOC-C NAS	EMD Serono a Division of EMD Inc. Canada	23-Mar-17	18-Dec-17 NOC-C
BESPONSA (Inotuzumab Ozogamicin) - is indicated as a monotherapy for the treatment of adults with relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL).	NAS	Pfizer Canada Inc.	30-Mar-17	15-Mar-18
DATSCAN (Ioflupane (123I) - is indicated for visualization of functional striatal dopamine transporter using single photon emission computed tomography (SPECT) brain imaging.	NAS	GE Healthcare Canada Inc.	22-Dec-16	7-Dec-17
DEFITELIO (Defibrotide) - solution for intravenous infusion is indicated for the treatment of adult and pediatric patients with hepatic veno-occlusive disease (VOD) also known as sinusoidal obstruction syndrome (SOS), with renal or pulmonary dysfunction following haematopoietic stem-cell transplantation (HSCT) therapy.	PRIORITY-NAS	Jazz Pharmaceuticals Ireland Limited	9-Dec-16	10-Jul-17
DUPIXENT (Dupilumab) - is indicated for the treatment of adult patients with moderate-tosevere atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.	NAS	Sanofi-Aventis Canada Inc.	16-Dec-16	30-Nov-17
FASENRA (Benralizumab) - is indicated as an add-on maintenance treatment of adult patients with severe eosinophilic asthma.	NAS	Astrazeneca Canada Inc.	21-Mar-17	22-Feb-18
IMFINZI (Durvalumab) - is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who: have disease progression during or following platinum-containing chemotherapy and who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy**.**	NOC-C NAS	Astrazeneca Canada Inc.	16-Feb-17	3-Nov-17 NOC-C

[11] 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 2017-2018
(April 1 2017 to March 31 2018)

Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date[11])	Approval Date (dd-mon-yy)
KANUMA (Sebelipase Alfa) - is indicated for the treatment of infants, children and adults diagnosed with lysosomal acid lipase (LAL) deficiency.	NOC-C NAS	Alexion Pharma GMBH	23-Mar-17	15-Dec-17 NOC-C
LARTRUVO (Olaratumab) - is indicated in combination with doxorubicin for the treatment of adult patients with advanced soft tissue sarcoma (STS) not amenable to curative treatment with radiotherapy or surgery and for whom treatment with an anthracycline-containing regimen is appropriate.	NOC-C NAS	Eli Lilly Canada Inc.	6 Mar-17	23-Nov-17 NOC-C
OCREVUS (Ocrelizumab) - is indicated for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease defined by clinical and imaging features.	NAS	Hoffmann-La Roche Limited	16-Sep-16	14-Aug-17
OZEMPIC (Semaglutide) - 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. Basal insulin with metformin, when diet and exercise plus basal insulin with metformin do not achieve adequate glycemic control (see CLINICAL TRIALS).	NAS	Novo Nordisk Canada Inc.	19-Jan-17	4-Jan-18
REKOVELLE (Follitropin Delta) - is indicated for controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies (ART) such as an in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) cycle.	NAS	Ferring Inc.	9-Dec-15	22-Mar-18
REBINYN (Coagulation Factor IX (Recombinant), pegylated) - is an anti- hemophilic factor indicated in adults and children with hemophilia B (congenital factor IX deficiency or Christmas disease) for: control and prevention of bleeding episodes and for control and prevention of bleeding in the perioperative setting REBINYN® is also indicated in patients 18 years and above with hemophilia B for routine prophylaxis to prevent or reduce the frequency of bleeding episodes.	NAS	Novo Nordisk Canada Inc.	12-Dec-16	29-Nov-17

New Active Substance Approvals (NAS) – BGTD Fiscal Year 2017-2018 (April 1 2017 to March 31 2018)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[11])**	**Approval Date (dd-mon-yy)**
SHINGRIX (Varicella-Zoster Virus Glycoprotein E (gE)) - is indicated for prevention of herpes zoster (HZ, or shingles) in adults 50 years of age or older.	NAS	GlaxoSmithKline Inc.	17-Nov-16	13-Oct-17
SILIQ (Brodalumab) - is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.	NAS	Valeant Canada LP Valeant Canada S.E.C.	24-May-16	6-Mar-18
TECENTRIQ (Atezolizumab) - is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who: have disease progression during or following platinum-containing chemotherapy and who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.	NOC-C NAS	Hoffmann-La Roche Limited	18-Jul-16	12-Apr-17 NOC-C
TREMFYA (Guselkumab) - is indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.	NAS	Janssen Inc.	25-Nov-16	10-Nov-17
TRESIBA (FLEXTOUCH) (Insuline Degludec) - is indicated for once-daily treatment of adults with diabetes mellitus to improve glycemic control.	NAS	Novo Nordisk Canada Inc.	13-Sep-16	25-Aug-17
TRUMENBA (Neisseria Meningitidis GRP B Recombinant Lipoprotein 2086 Subfamily A, Neisseria Meningitidis GRP B Recombinant Lipoprotein 2086 Subfamily B) - is indicated for active immunization to prevent invasive meningococcal disease (IMD) caused by Neisseria meningitidis serogroup B in individuals 10 through 25 years of age.	NAS	Pfizer Canada Inc.	31-May-16	5-Oct-17

Priority Submission Approvals – BGTD - Fiscal Year 2017-2018

Priority Submission Approvals – BGTD Fiscal Year 2017-2018 (April 1 2017 to March 31 2018)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[12])**	**Approval Date (dd-mon-yy)**
ACTEMRA (Tocilizumab) - new indication: for the treatment of giant cell arteritis (GCA) in adult patients.	PRIORITY-CLIN ONLY	Hoffmann-La Roche Limited	30-Mar-17	27-Oct-17
DARZALEX (Daratumumab) - indicated in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy.	PRIORITY-CLIN ONLY	Janssen Inc.	26-Sep-16	13-Apr-17
DEFITELIO (Defibrotide) - solution for intravenous infusion is indicated for the treatment of adult and pediatric patients with hepatic veno-occlusive disease (VOD) also known as sinusoidal obstruction syndrome (SOS), with renal or pulmonary dysfunction following haematopoietic stem-cell transplantation (HSCT) therapy.	PRIORITY-NAS	Jazz Pharmaceuticals Ireland Limited	9-Dec-16	10-Jul-17
KEYTRUDA (Pembrolizumab) - new indication: for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have received platinum-containing chemotherapy.	PRIORITY-CLIN ONLY	Merck Canada Inc.	22-Feb-17	20-Sep-17
OCREVUS (Ocrelizumab) - is indicated for the management of adult patients with early primary progressive multiple sclerosis (PPMS) as defined by disease duration and level of disability, in conjunction with imaging features characteristic of inflammatory activity.	PRIORITY-CLIN/C&M	Hoffmann-La Roche Limited	29-Aug-16	14-Feb-18 NOC-C
OPDIVO (Nivolumab) - new indication: Opdivo is indicated for the treatment of recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) in adults progressing on or after platinum-based therapy.	PRIORITY-CLIN ONLY	Bristol-Myers Squibb Canada	18-Oct-16	12-May-17

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

Biosimilars: NDS & SNDS Market Authorizations

Biosimilars: Number of NDS & SNDS that were issued an NOC by Fiscal Year

		Fiscal Year of Market Authorization				
Subm Type	**Class**	**2013-14**	**2014-15**	**2015-16**	**2016-17**	**2017-18**
NDS	CLIN/C&M	2	0	2	1	3
NDS Total		**2**	**0**	**2**	**1**	**3**
SNDS	C&M ONLY	0	0	1	2	1
	C&M/LABELLING	0	0	0	1	0
	CLIN/C&M	0	0	0	2	0
	COMP/C&M	0	0	0	1	0
	LABELLING ONLY	0	0	1	0	4
	PUBLISHED DATA ONLY	0	0	1	0	0
SNDS Total		**0**	**0**	**3**	**6**	**5**

Biosimilars: List of NDS & SNDS issued an NOC - Fiscal Year 2017-18

Subm Type	Brand Name	Class	Company	Active Ingredient(s)	Quarter FY 2017-18	Notice of Compliance (NOC) Date
NDS	ADMELOG	CLIN/C&M	SANOFI-AVENTIS CANADA INC	INSULIN LISPRO	Q3	2017-Nov-16
	ERELZI (SYRINGE), ERELZI (SENSOREADY PEN)	CLIN/C&M	SANDOZ CANADA INCORPORATED	ETANERCEPT	Q1	2017-Apr-06
	RENFLEXIS	CLIN/C&M	SAMSUNG BIOEPIS CO., LTD	INFLIXIMAB	Q3	2017-Dec-01
New Drug Submission Total						**3**
SNDS	BRENZYS	C&M ONLY	SAMSUNG BIOEPIS CO., LTD	ETANERCEPT	Q2	2017-Aug-28
	BRENZYS (PFS), BRENZYS (PFP)	LABELLING ONLY	SAMSUNG BIOEPIS CO., LTD	ETANERCEPT	Q2	2017-Aug-24
	GRASTOFIL	LABELLING ONLY	APOTEX INC	FILGRASTIM (R-METHUG-CSF)	Q3	2017-Oct-05
	GRASTOFIL	LABELLING ONLY	APOTEX INC	FILGRASTIM (R-METHUG-CSF)	Q4	2018-Feb-02
	INFLECTRA	LABELLING ONLY	CELLTRION HEALTHCARE CO LTD	INFLIXIMAB	Q3	2017-Nov-07
Supplemental New Drug Submission Total						**5**

Please note: Approved Biosimilars that remain on Intellectual Property HOLD are not included.

Biosimilar: A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required

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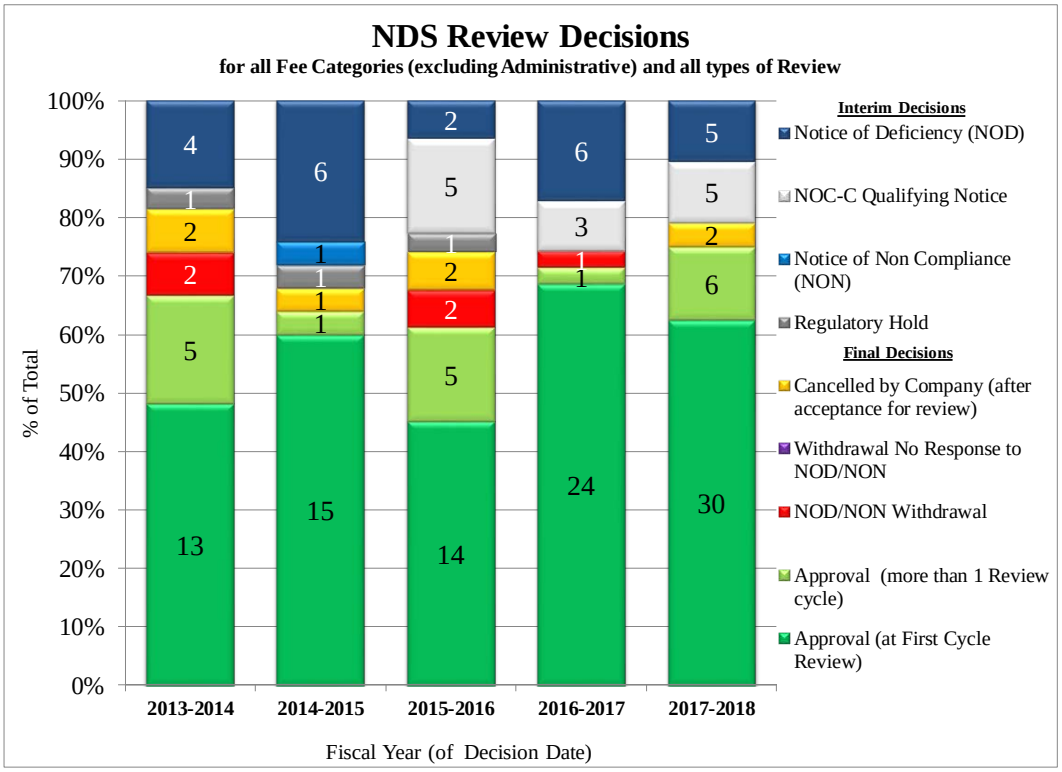
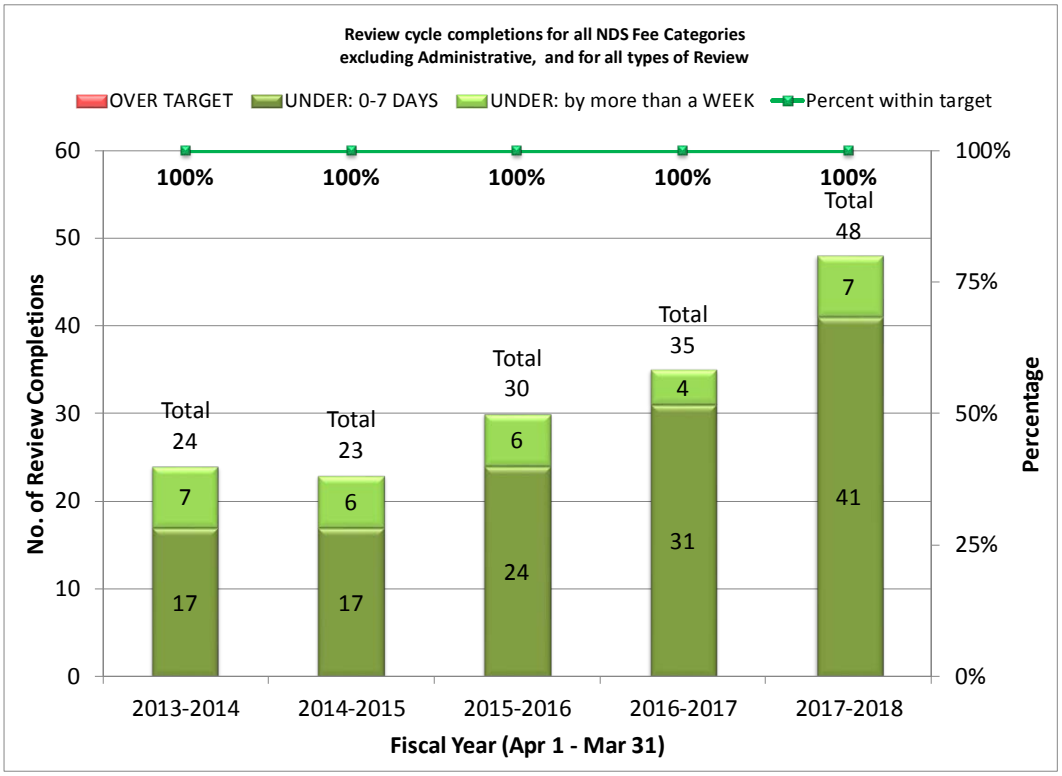
REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

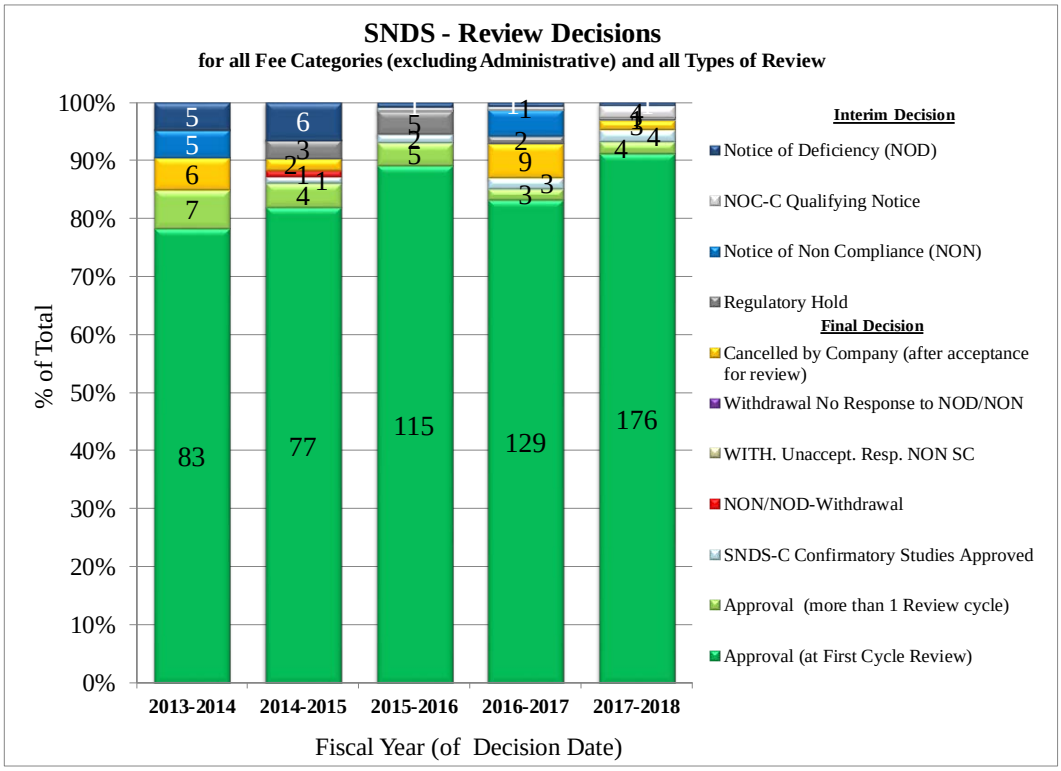


NDS: Review Cycle Completions Showing Percentage Within Target

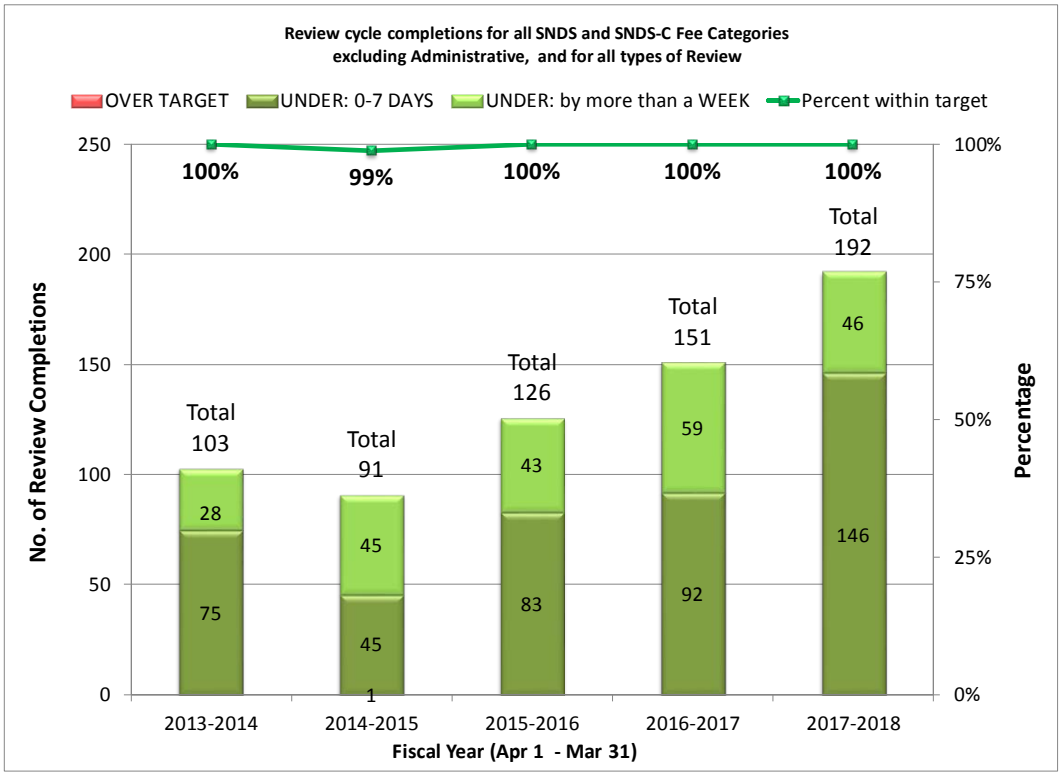


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

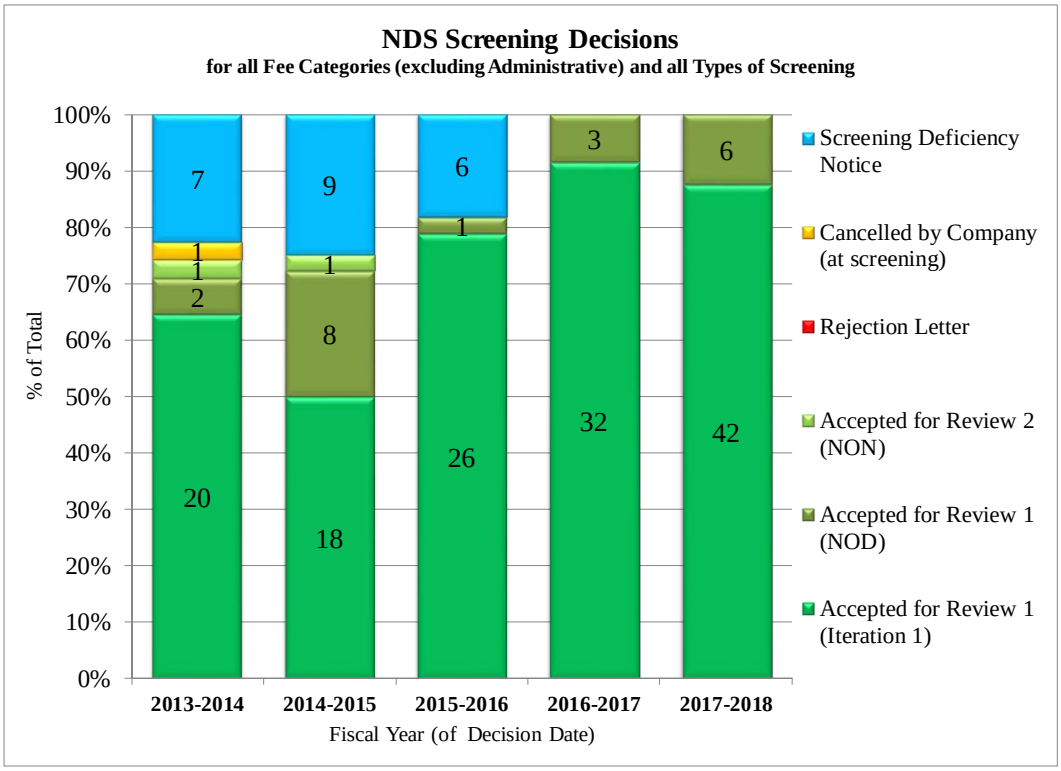


SNDS: Review Cycle Completions Showing Percentage Within Target

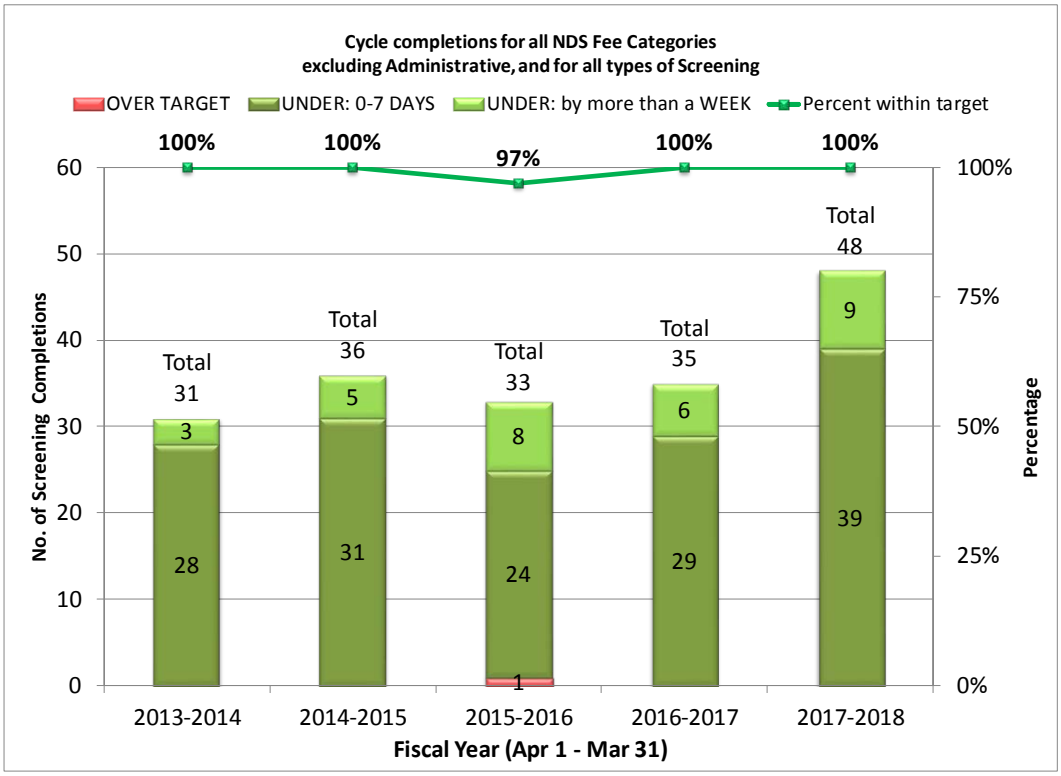


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

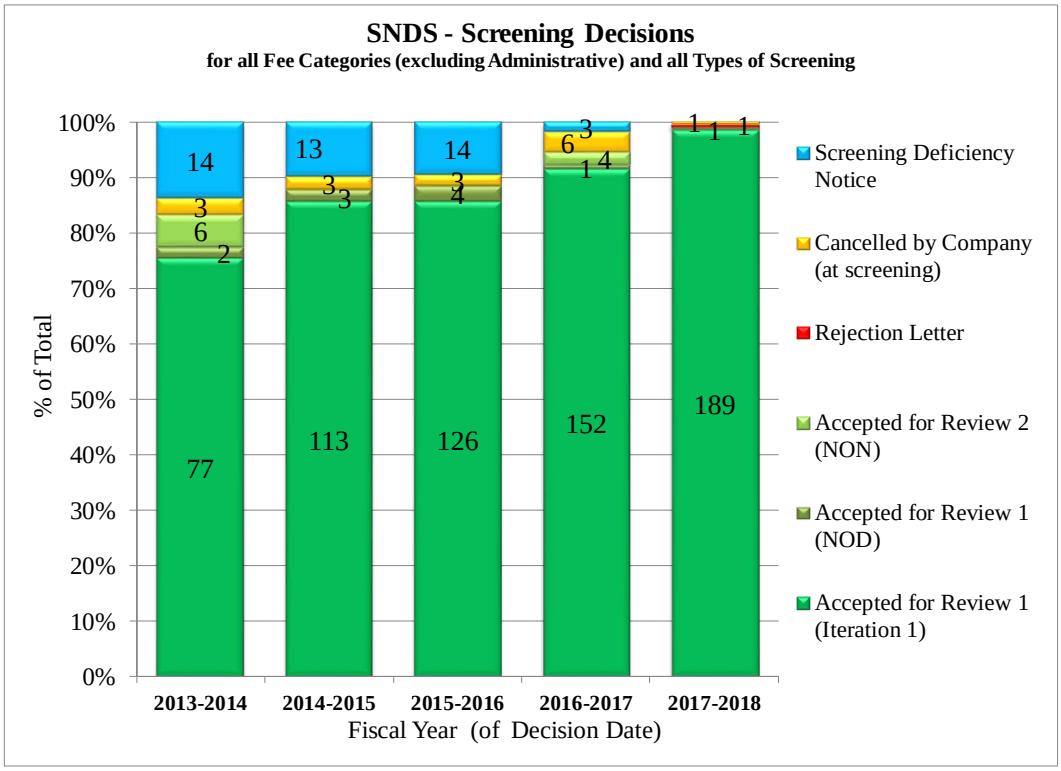


NDS: Screening Cycle Completions Showing Percentage Within Target

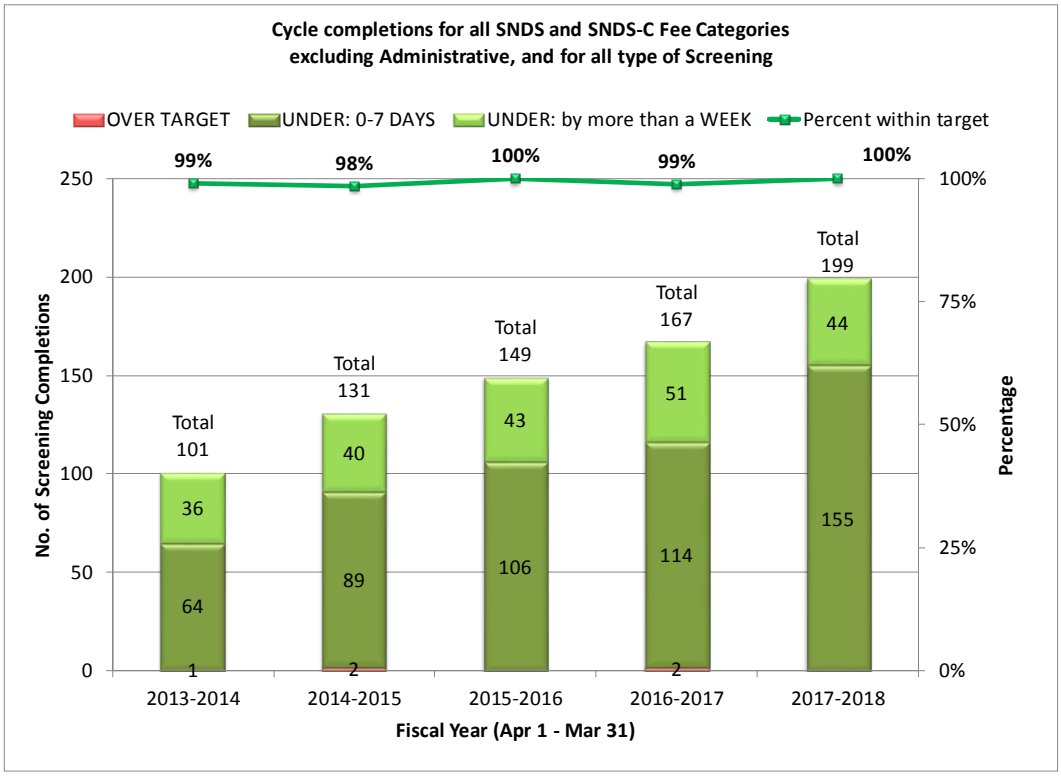


SCREENING CYCLE DECISIONS

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	**13-14**	**14-15**	**15-16**	**16-17**	**17-18**	**Final Decision in Dispute**	**Submission Status (as of April 2018)**
Total Received	**1**	**0**	**0**	**0**	**0**		
Total Granted	***1***	***0***	***0***	***0***	***0***		
ANDS	1	0	0	0	0	NON Withdrawal	Withdrawn
Total Denied	***0***	***0***	***0***	***0***	***0***		

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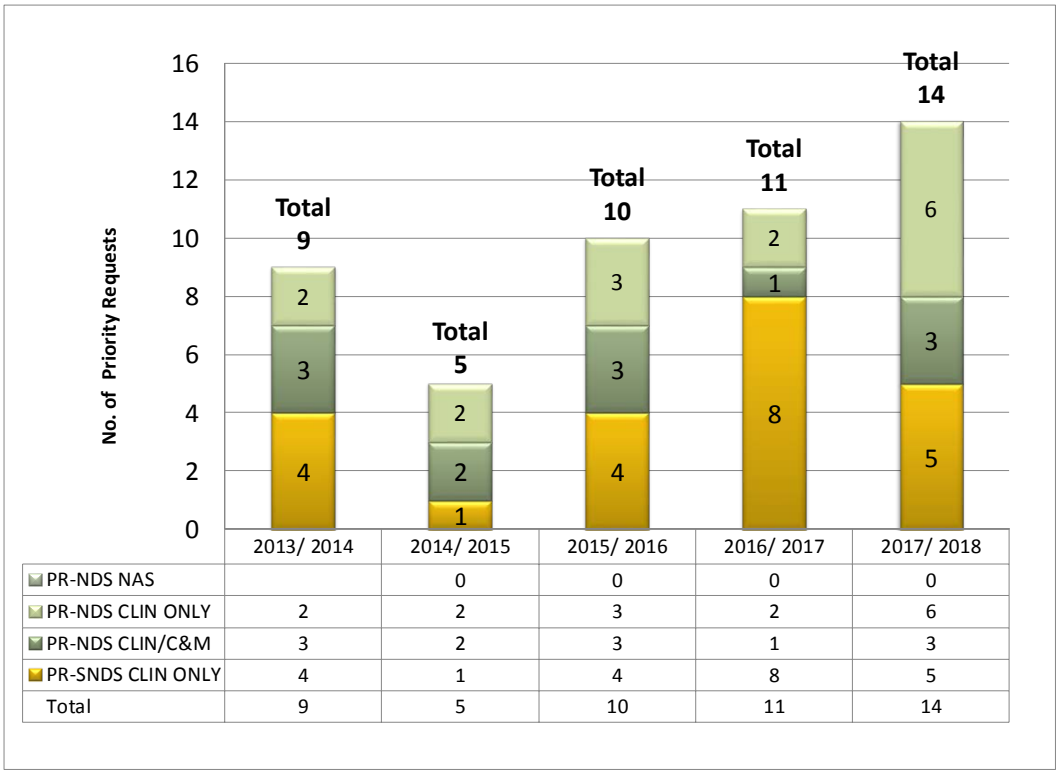
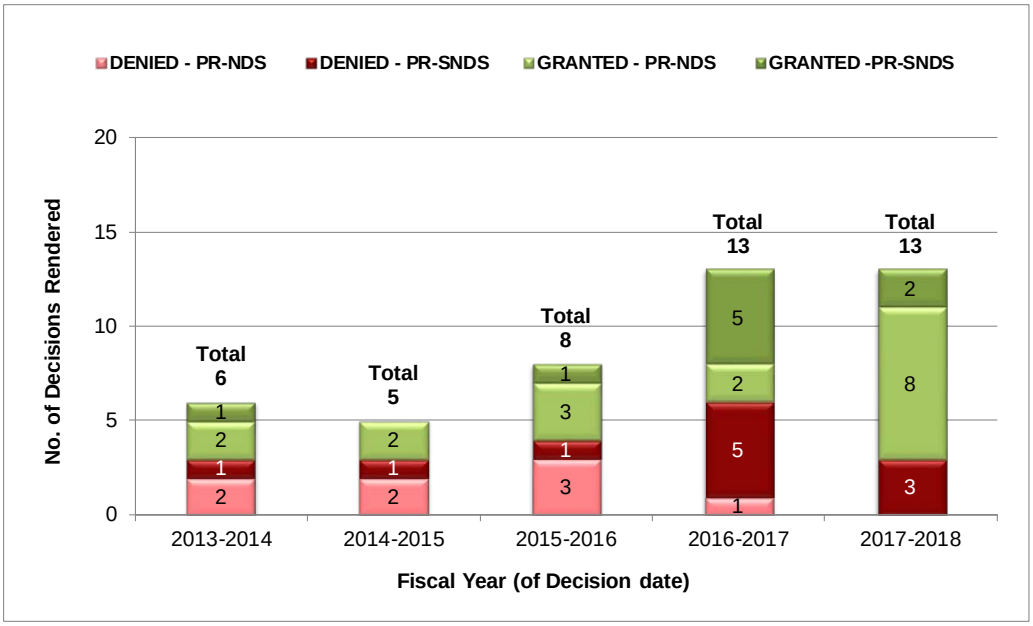
PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests Received



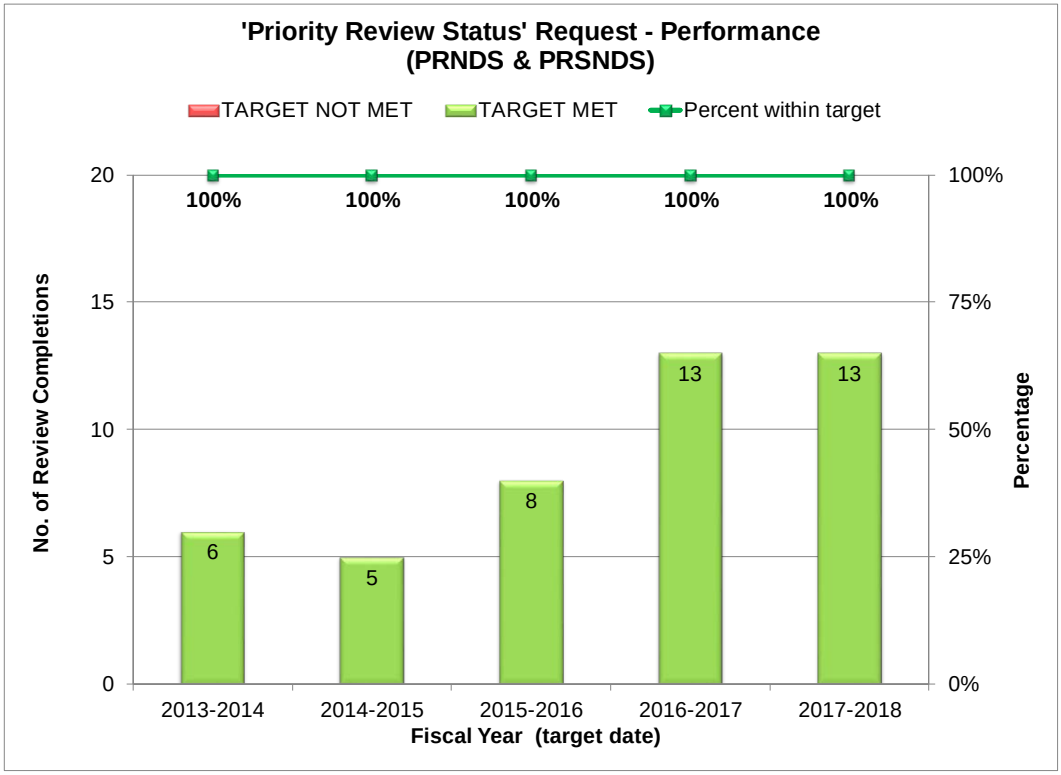
	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
PR-NDS NAS		0	0	0	0
PR-NDS CLIN ONLY	2	2	3	2	6
PR-NDS CLIN/C&M	3	2	3	1	3
PR-SNDS CLIN ONLY	4	1	4	8	5
Total	9	5	10	11	14

Priority Review Status Requests: Decisions Rendered



PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests: Performance



REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

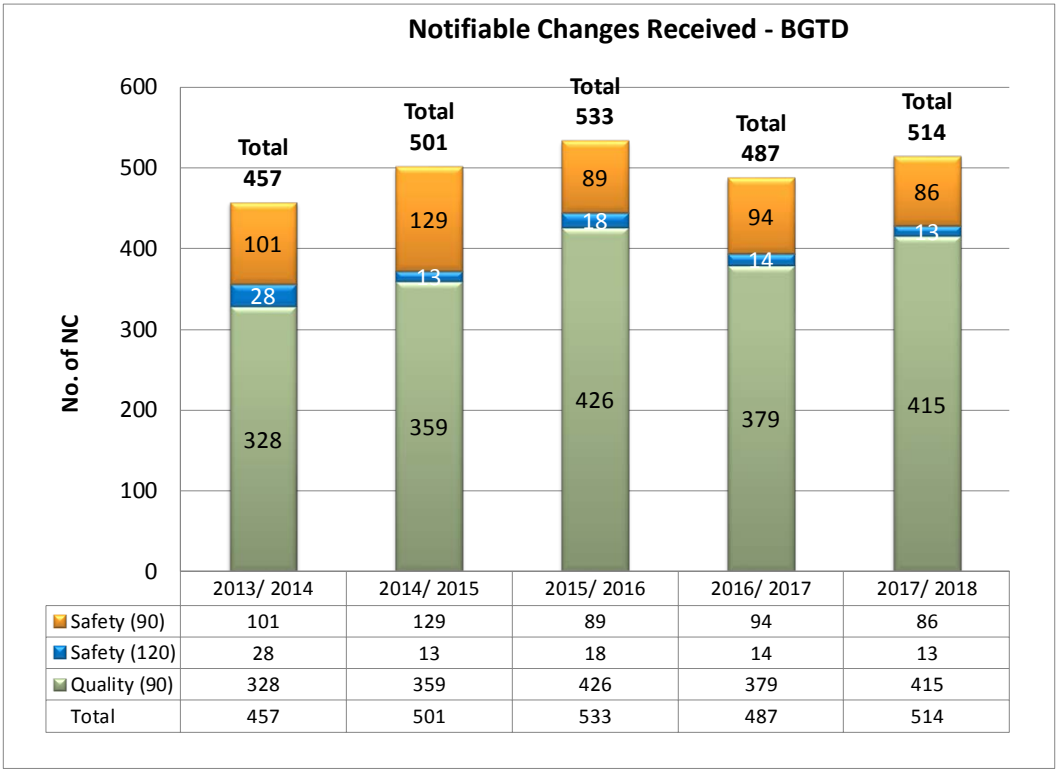
Requests for Reconsideration of Final Decisions – Priority Review Requests (for NDS and SNDS)

"Priority Review Request" - Requests for Reconsideration of Final Decisions Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	**13-14**	**14-15**	**15-16**	**16-17**	**17-18**	**Final Decision in Dispute**	**Submission Status (as of April 2018)**
Total Received	**0**	**0**	**0**	**1**	**0**		
Total Denied	***0***	***0***	***0***	***1***	***0***	PR-SNDS: Priority Review Request Denied	Rejected

NOTIFIABLE CHANGES (NC)

NOTIFIABLE CHANGES

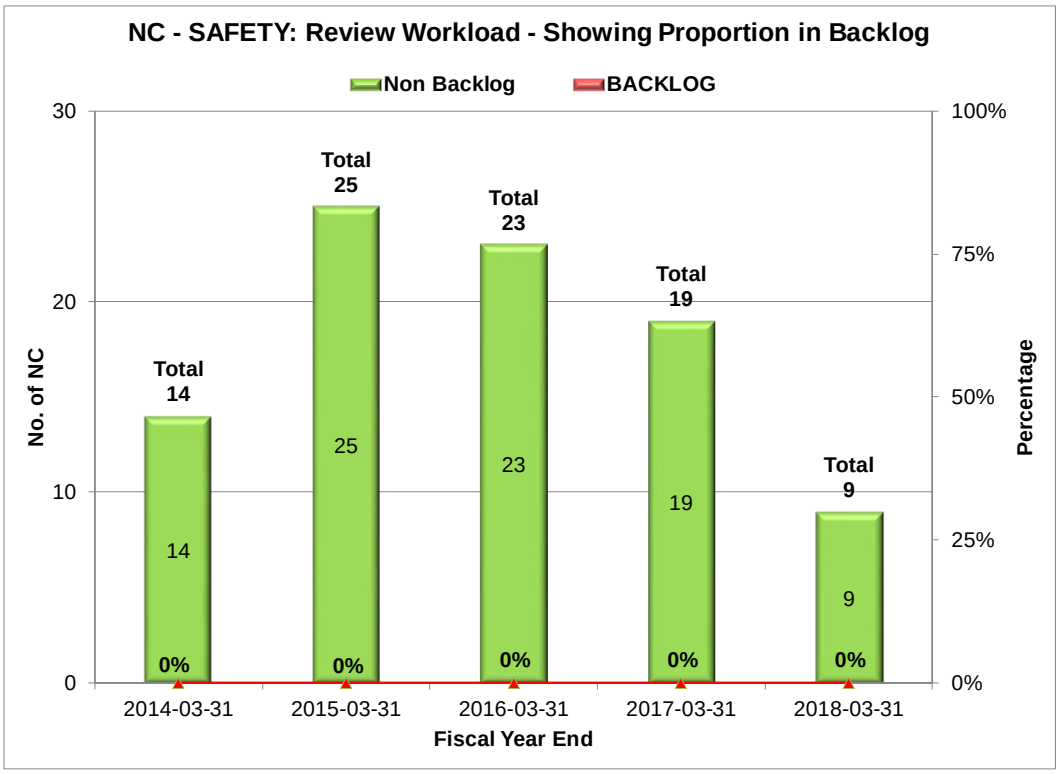
Number Received - Notifiable Changes (NC)



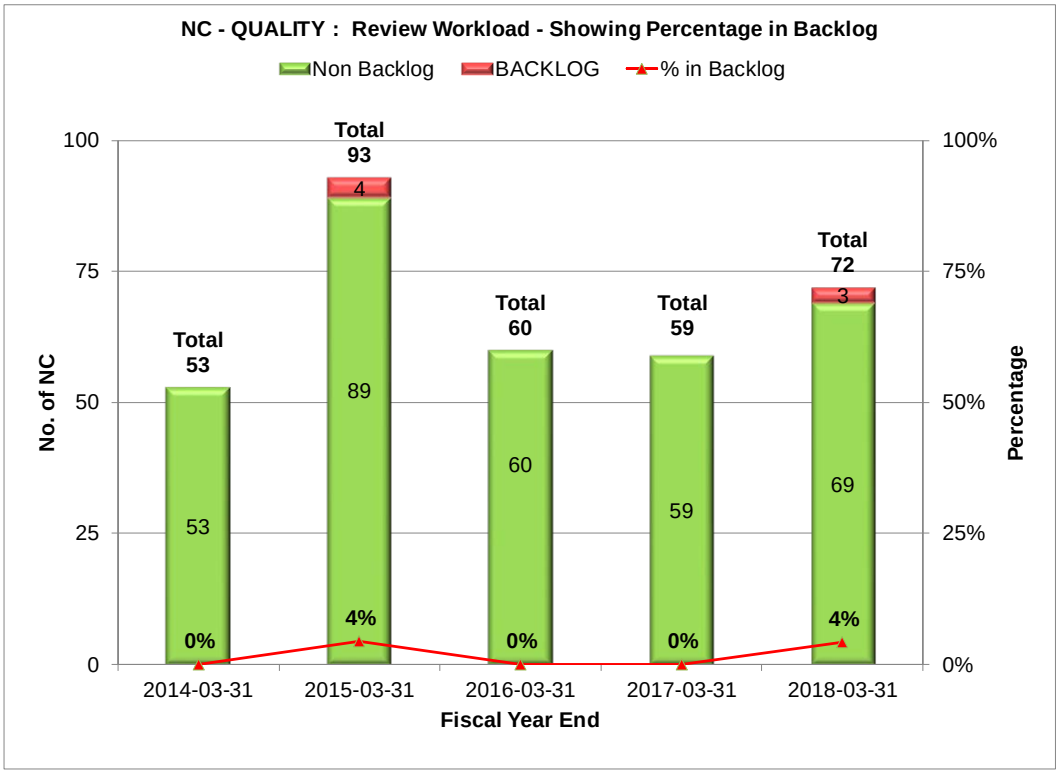
	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Safety (90)	101	129	89	94	86
Safety (120)	28	13	18	14	13
Quality (90)	328	359	426	379	415
Total	457	501	533	487	514

WORKLOAD

Notifiable Change (NC) SAFETY: Review Workload / Backlog



Notifiable Change (NC) QUALITY: Review Workload / Backlog



WORKLOAD

Notifiable Change (NC) SAFETY: Review Workload by Class

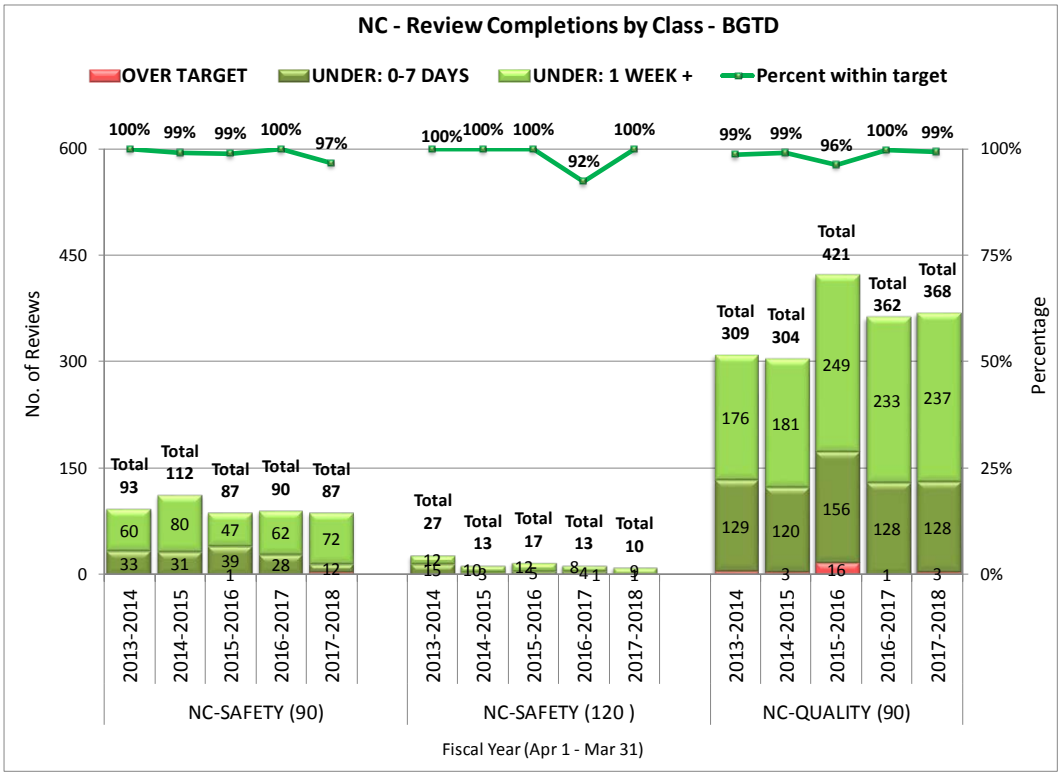
BGTD NC- SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
SAFETY - 90 day	11	22	20	15	8
Backlog	*0*	*0*	*0*	*0*	*0*
SAFETY - 120 day	3	3	3	4	1
Backlog	*0*	*0*	*0*	*0*	*0*
Total	14	25	23	19	9
Non Backlog	14	25	23	19	9
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

Notifiable Change (NC) QUALITY: Review Workload by Class

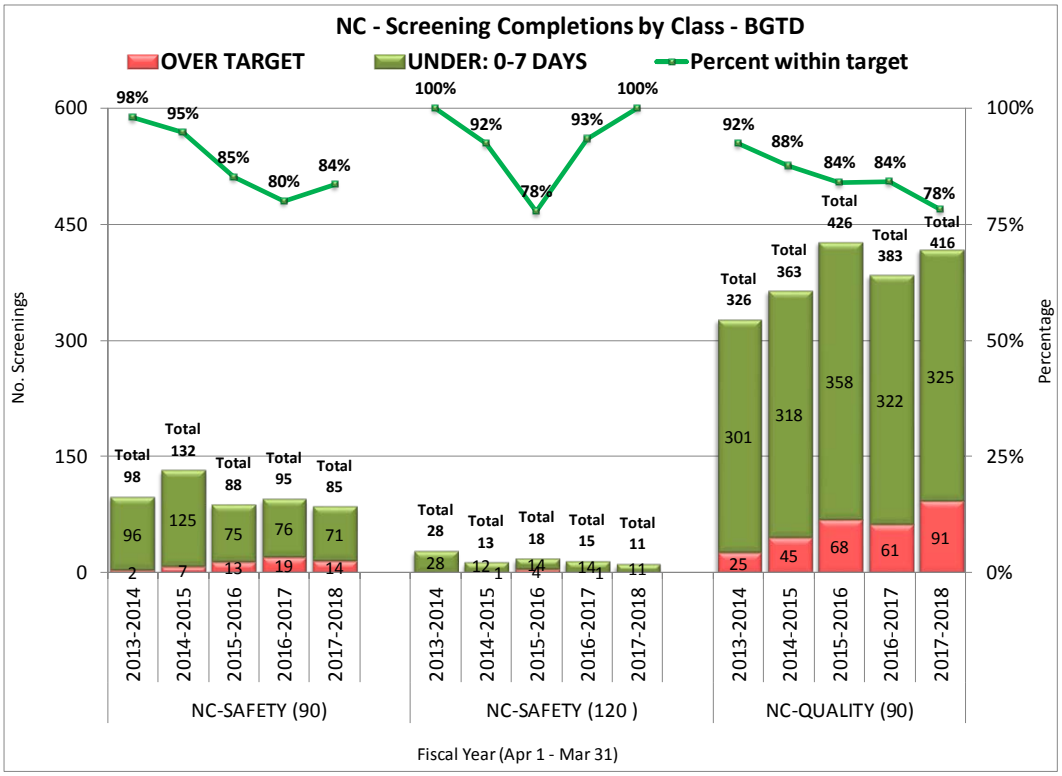
BGTD NC- QUALITY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
QUALITY - 90 day	53	93	60	59	72
Backlog	*0*	*4*	*0*	*0*	*3*
Total	53	93	60	59	72
Non Backlog	53	89	60	59	69
BACKLOG	0	4	0	0	3
% in Backlog	0%	4%	0%	0%	4%

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	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NO OBJECTION LETTER	301	302	410	363	381
NOT SATISFACTORY NOTICE	4	0	3	1	
REJECTION LETTER (SCR)	22	8	33	7	12
CANCELLED BY COMPANY	13	3	6	13	8
SCREENING DEFICIENCY NOTICE	6	12	7	5	2

NC - SAFETY (90)					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NO OBJECTION LETTER	92	112	81	97	88
NOT SATISFACTORY NOTICE			2		
REJECTION LETTER (SCR)	1	5	1		
CANCELLED BY COMPANY	7	4	4	3	6
SCREENING DEFICIENCY NOTICE	1	1	1	1	1
NC - HOLD (PATENT)			1		

NC - SAFETY (120)					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NO OBJECTION LETTER	27	12	15	12	12
NOT SATISFACTORY NOTICE			2	1	
REJECTION LETTER (SCR)					
SCREENING DEFICIENCY NOTICE					1
CANCELLED BY COMPANY	1	1	1	1	2

NC - ADMINISTRATIVE					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NO OBJECTION LETTER	23	43	30	22	9

REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

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

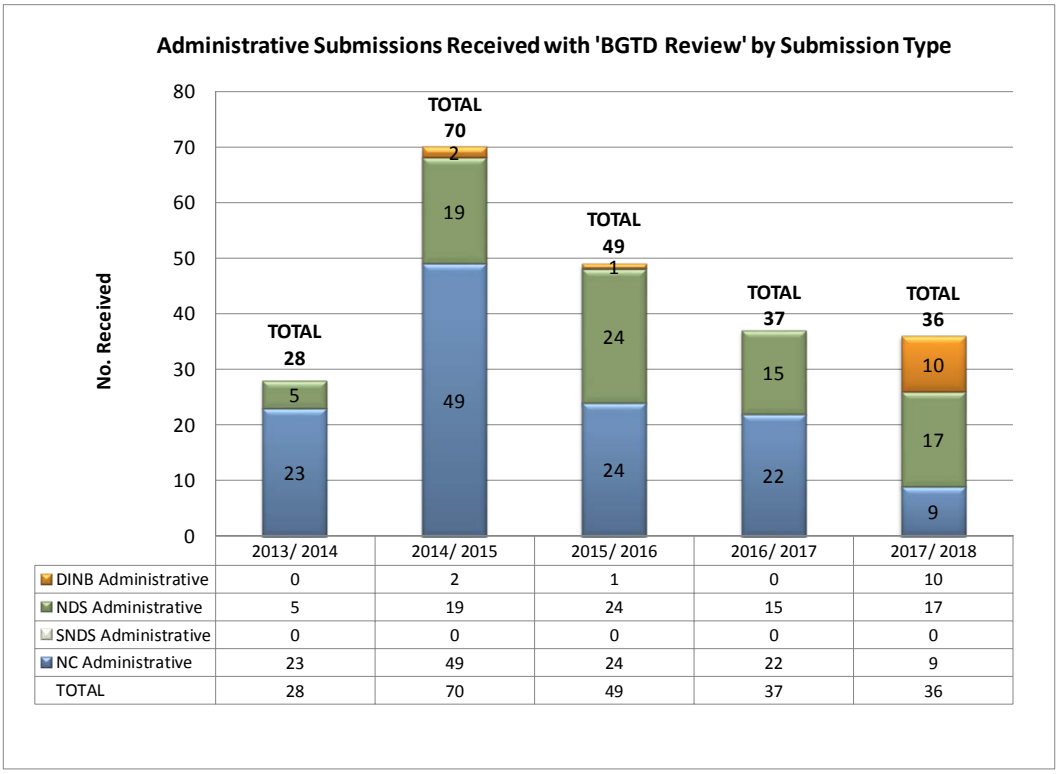
NC					
Year of Reconsideration Request					
	13-14	**14-15**	**15-16**	**16-17**	**17-18**
Total	**0**	**0**	**0**	**0**	**0**

Administrative Submissions

Submissions in support of a manufacturer or product name change.

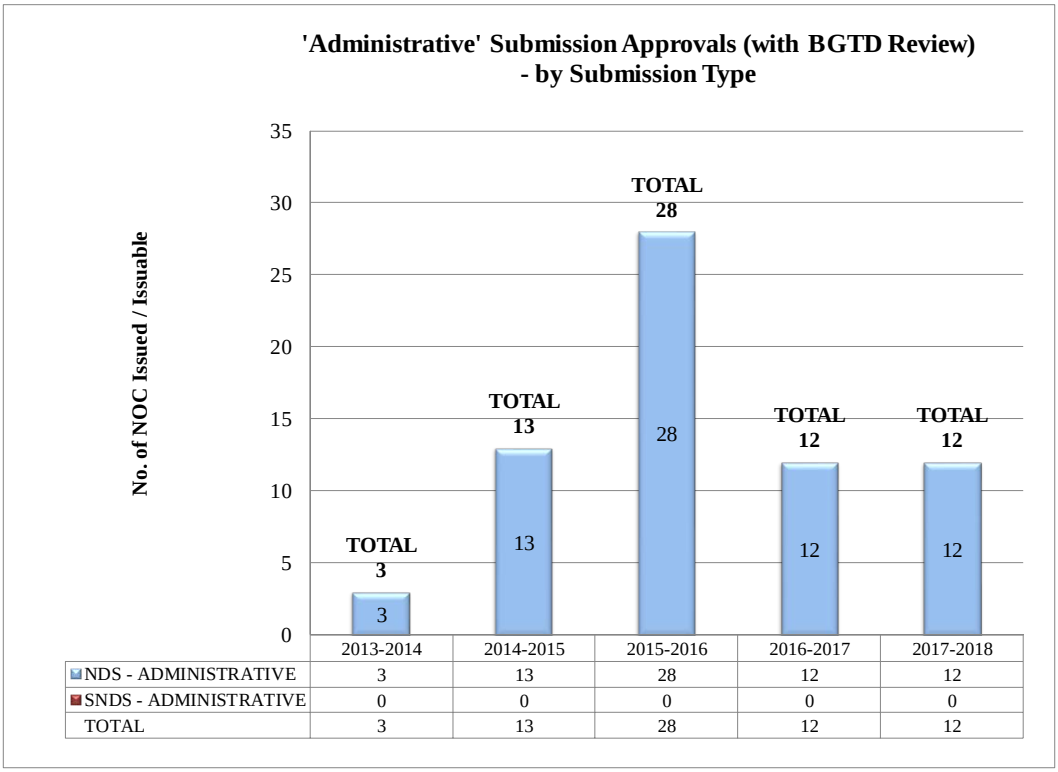
ADMINISTRATIVE SUBMISSIONS with BGTD review

Administrative Submissions Received (with BGTD review)



	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
DINB Administrative	0	2	1	0	10
NDS Administrative	5	19	24	15	17
SNDS Administrative	0	0	0	0	0
NC Administrative	23	49	24	22	9
TOTAL	28	70	49	37	36

Administrative Submission Approvals (with BGTD Review)

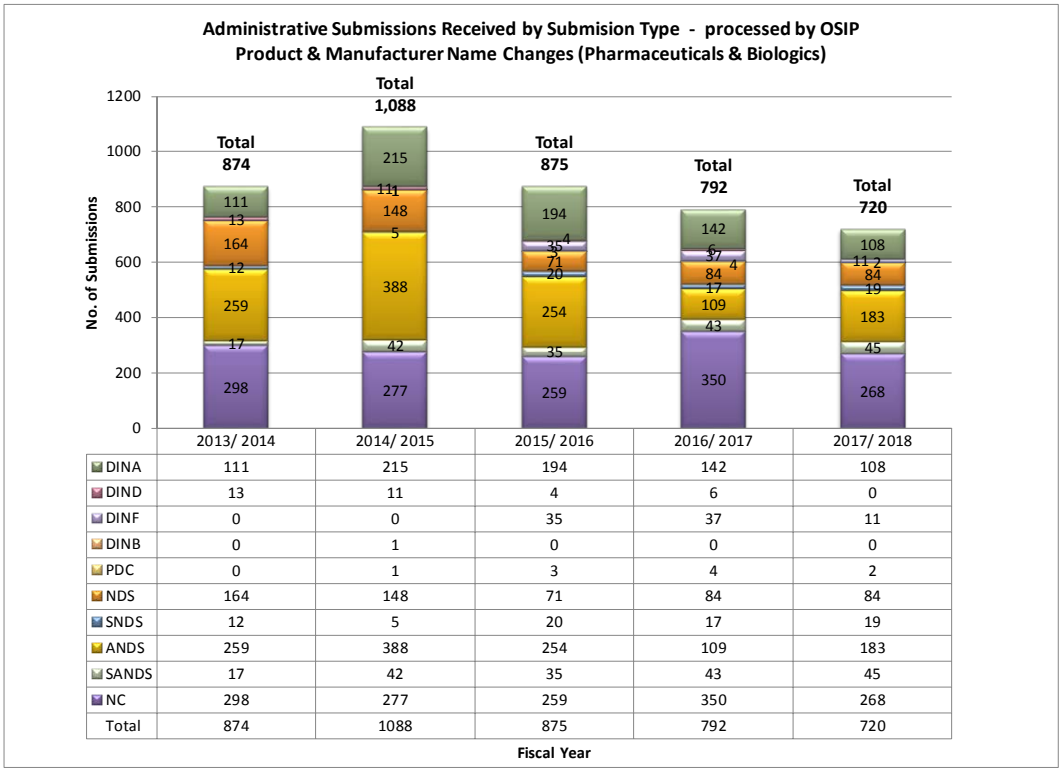


	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
NDS - ADMINISTRATIVE	3	13	28	12	12
SNDS - ADMINISTRATIVE	0	0	0	0	0
TOTAL	3	13	28	12	12

ADMINISTRATIVE SUBMISSIONS (Processed by OSIP)

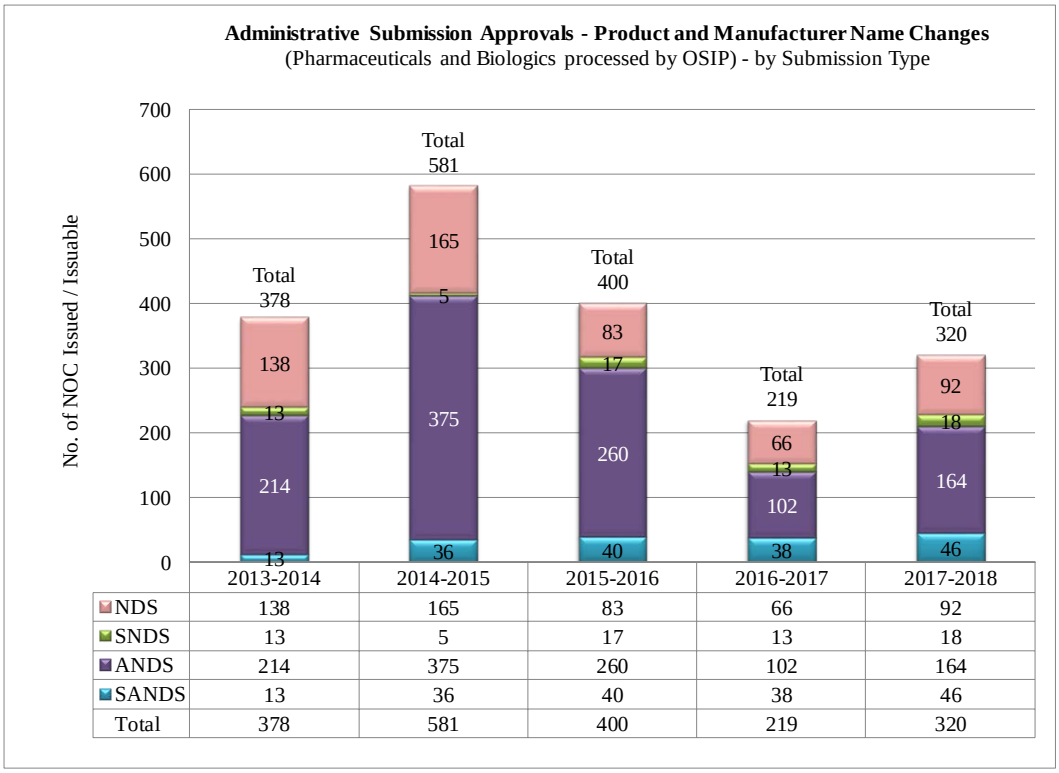
(Product & Manufacturer Name Changes)
(Admin NCs are for cross-referenced changes)

Administrative Submissions Received by Submission Type (OSIP)



	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
DINA	111	215	194	142	108
DIND	13	11	4	6	0
DINF	0	0	35	37	11
DINB	0	1	0	0	0
PDC	0	1	3	4	2
NDS	164	148	71	84	84
SNDS	12	5	20	17	19
ANDS	259	388	254	109	183
SANDS	17	42	35	43	45
NC	298	277	259	350	268
Total	874	1088	875	792	720

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



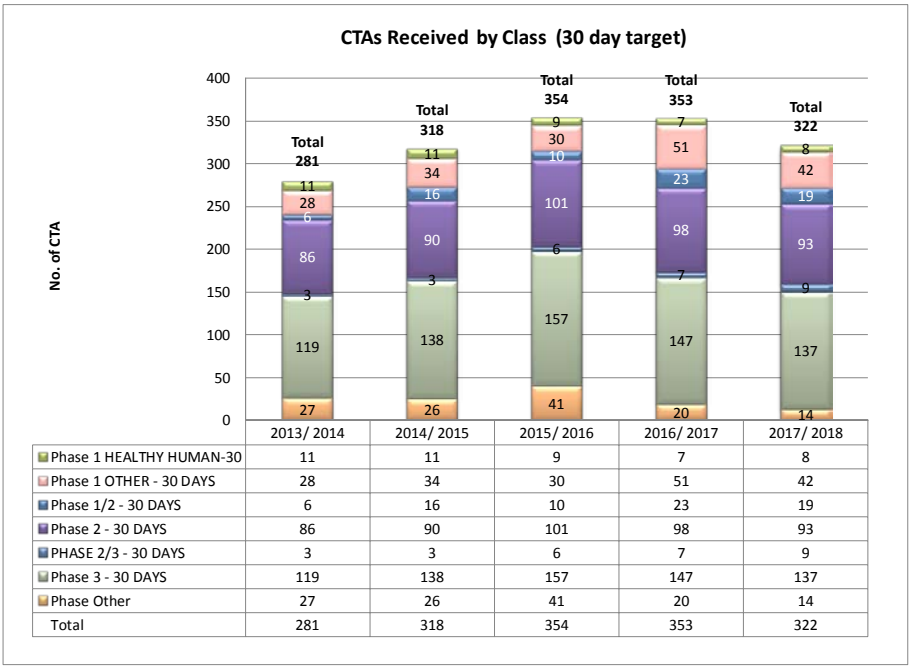
	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
NDS	138	165	83	66	92
SNDS	13	5	17	13	18
ANDS	214	375	260	102	164
SANDS	13	36	40	38	46
Total	378	581	400	219	320

Clinical Trial Applications and Amendments

(CTA & CTA-A)

CLINICAL TRIAL APPLICATIONS

Number Received - Clinical Trial Application (CTA)

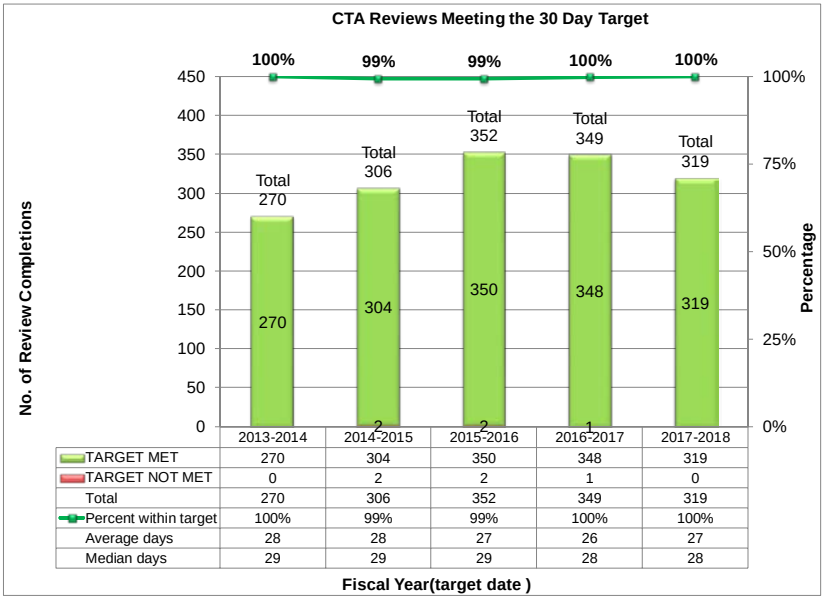


	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Phase 1 HEALTHY HUMAN-30	11	11	9	7	8
Phase 1 OTHER - 30 DAYS	28	34	30	51	42
Phase 1/2 - 30 DAYS	6	16	10	23	19
Phase 2 - 30 DAYS	86	90	101	98	93
PHASE 2/3 - 30 DAYS	3	3	6	7	9
Phase 3 - 30 DAYS	119	138	157	147	137
Phase Other	27	26	41	20	14
Total	281	318	354	353	322

Decision Documents - Clinical Trial Application (CTA)

CTA (30 day target)					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NO OBJECTION LETTER	255	283	336	328	307
CANCELLED BY COMPANY DURING REVIEW	7	18	10	21	12
CANCELLED BY COMPANY AT PROCESSING	0	5	2	10	6
NOT SATISFACTORY NOTICE	6	4	3	0	0
REJECTION LETTER (SCR)	0	1	1	1	0
SCREENING DEFICIENCY NOTICE	0	0	3	0	0

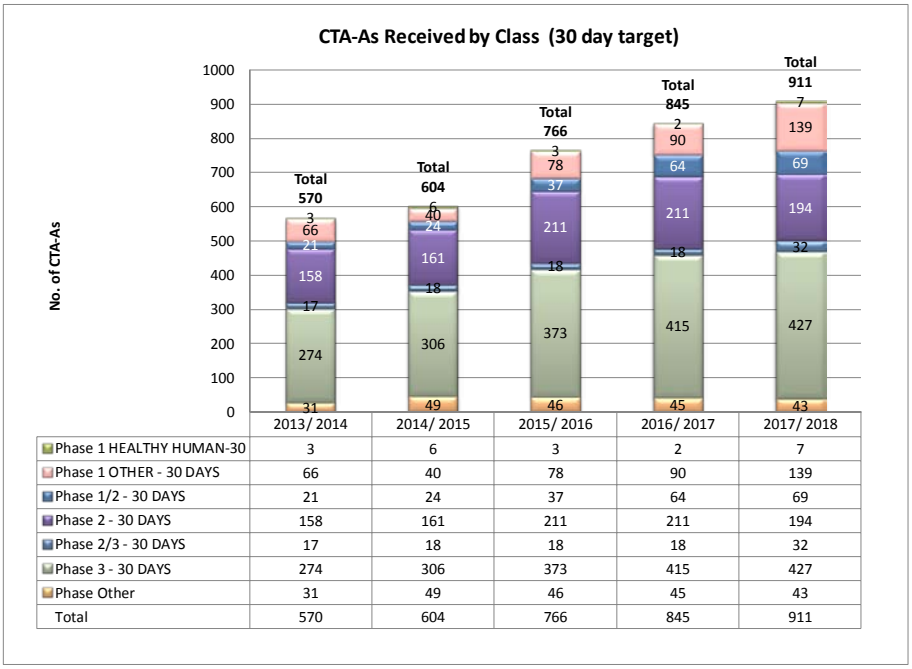
Performance - Clinical Trials Applications (CTA) Reviews Meeting the 30 Day Target



	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
TARGET MET	270	304	350	348	319
TARGET NOT MET	0	2	2	1	0
Total	270	306	352	349	319
Percent within target	100%	99%	99%	100%	100%
Average days	28	28	27	26	27
Median days	29	29	29	28	28

CLINICAL TRIAL APPLICATION-AMENDMENTS

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

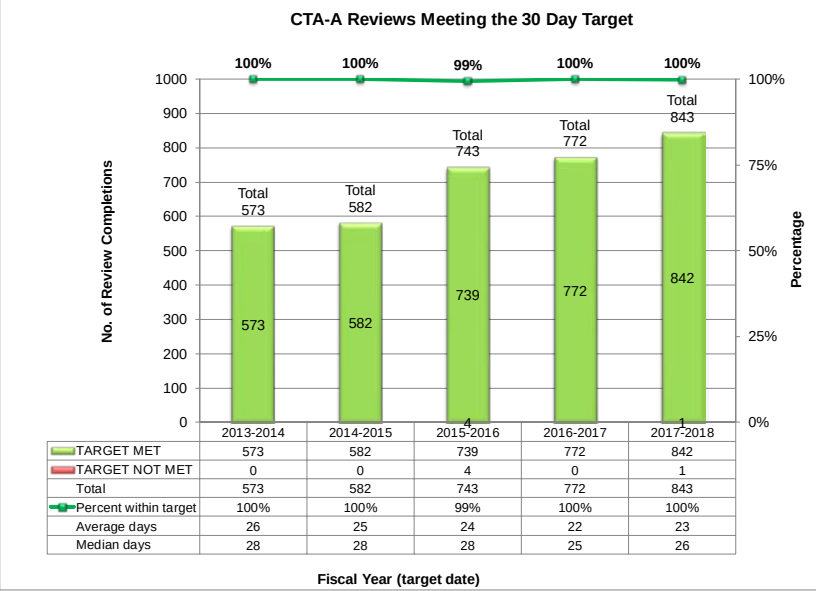


	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Phase 1 HEALTHY HUMAN-30	3	6	3	2	7
Phase 1 OTHER - 30 DAYS	66	40	78	90	139
Phase 1/2 - 30 DAYS	21	24	37	64	69
Phase 2 - 30 DAYS	158	161	211	211	194
Phase 2/3 - 30 DAYS	17	18	18	18	32
Phase 3 - 30 DAYS	274	306	373	415	427
Phase Other	31	49	46	45	43
Total	570	604	766	845	911

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

CTA-A (30 day target)					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NO OBJECTION LETTER	572	574	747	794	869
CANCELLED BY COMPANY DURING REVIEW	3	8	5	7	15
CANCELLED BY COMPANY AT PROCESSING	0	6	2	10	9
NOT SATISFACTORY NOTICE	0	0	2	0	0
REJECTION LETTER (SCR)	3	5	10	15	15

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



	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
TARGET MET	573	582	739	772	842
TARGET NOT MET	0	0	4	0	1
Total	573	582	743	772	843
Percent within target	100%	100%	99%	100%	100%
Average days	26	25	24	22	23
Median days	28	28	28	25	26

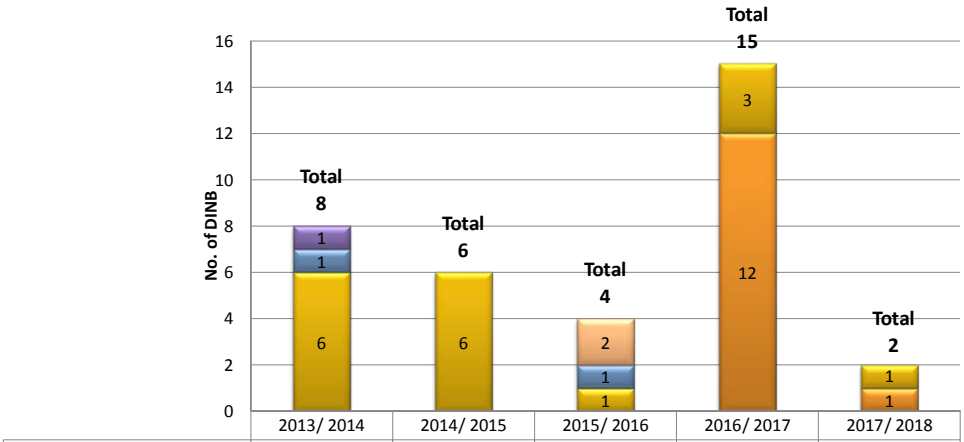
Application for a Drug Identification Number

DINB

Biological Products

DINB: Application for a Drug Identification Number – BIOLOGICAL Products

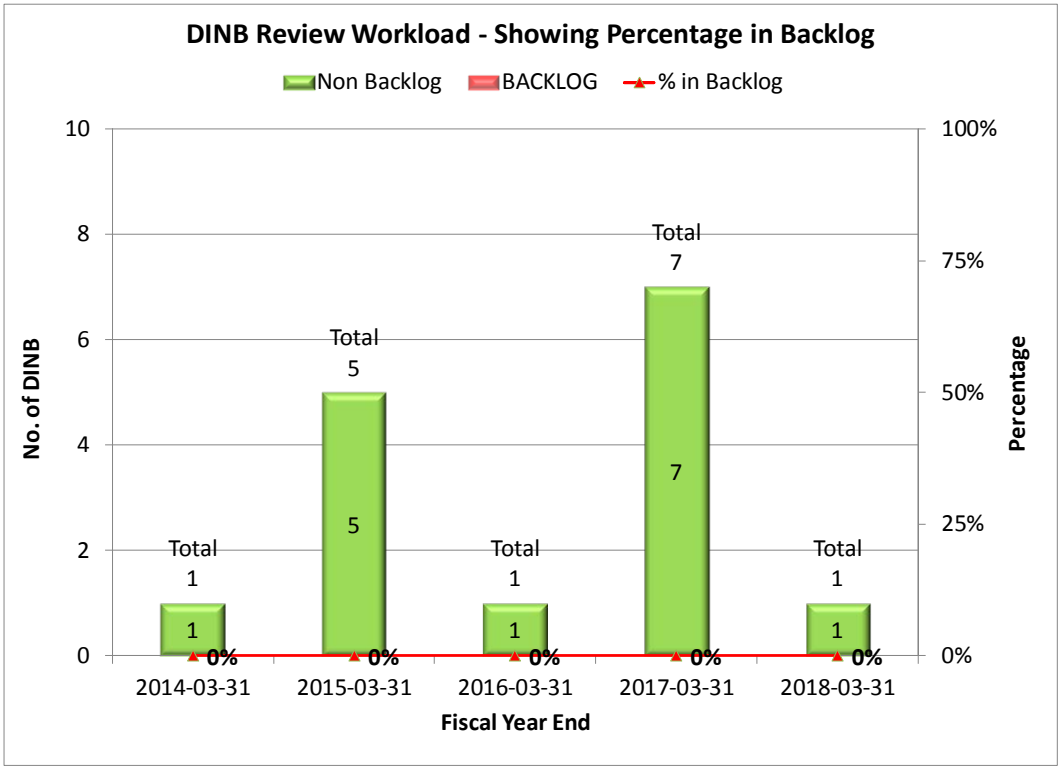
DINB: Number Received



	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Comparative Studies			2		
Clinical or Non-Clin Only	1				
Clinical or Non-Clin and C&M	1		1		
Chemistry & Manufacturing	6	6	1	3	1
Labelling Only				12	1
Unassigned					
Total	8	6	4	15	2

REVIEW WORKLOAD

DINB: Review Workload Showing Percentage in Backlog

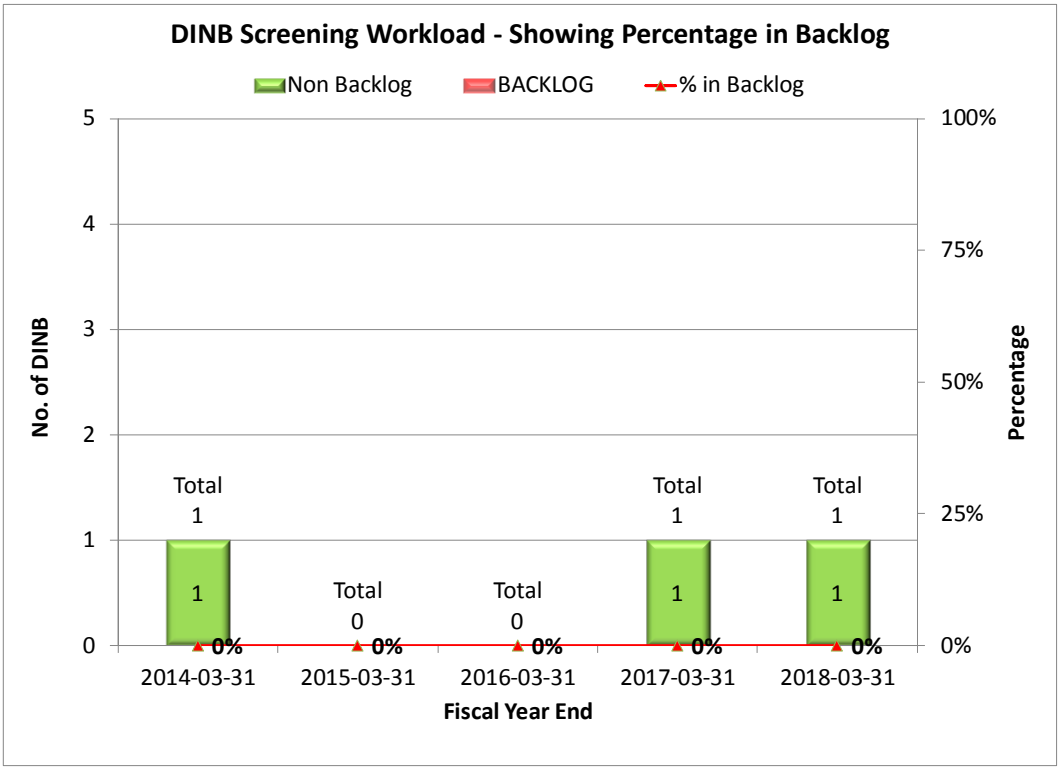


DINB: Review Workload by Class

DINB All REVIEW WORKLOAD BY FEE CATEGORY - BGTD (excluding administrative) and Fiscal Year End					
	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Labelling Only	**0**	**0**	**0**	**6**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**1**	**5**	**1**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**1**	**5**	**1**	**7**	**1**
Non Backlog	**1**	**5**	**1**	**7**	**1**
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					
	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Labelling Only	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**1**	**0**	**0**	**1**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**1**	**0**	**0**	**1**	**1**
Non Backlog	**1**	**0**	**0**	**1**	**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	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NO OBJECTION LETTER					
SCREENING DEFICIENCY NOTICE					
CANCELLED BY COMPANY				6	6

DINB - CHEMISTRY & MANUFACTURING					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NO OBJECTION LETTER	4				
NOTICE OF DEFICIENCY					
NOTIFICATION FORM DIN SUB		1			1
SCREENING DEFICIENCY NOTICE	1	6			1
CANCELLED BY COMPANY					

DINB - CLIN/C&M					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NO OBJECTION LETTER	1				
SCREENING DEFICIENCY NOTICE		2			
CANCELLED BY COMPANY			1		

DINB - ADMINISTRATIVE					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NOTIFICATION FORM/DIN ISSUED		2			
CANCELLED BY COMPANY					1

DINB - COMPARATIVE STUDIES					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
REJECTION LETTER (SCREENING)			1		
SCREENING DEFICIENCY NOTICE			1		

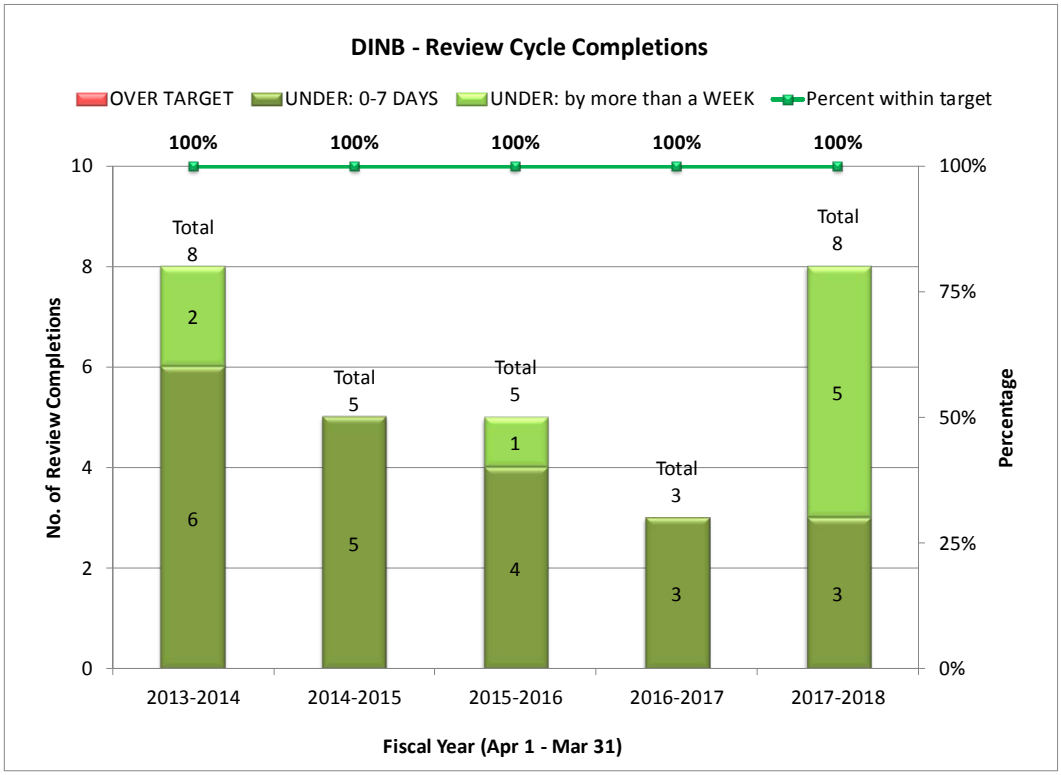
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

DINB: Requests for Reconsideration of Final Decisions

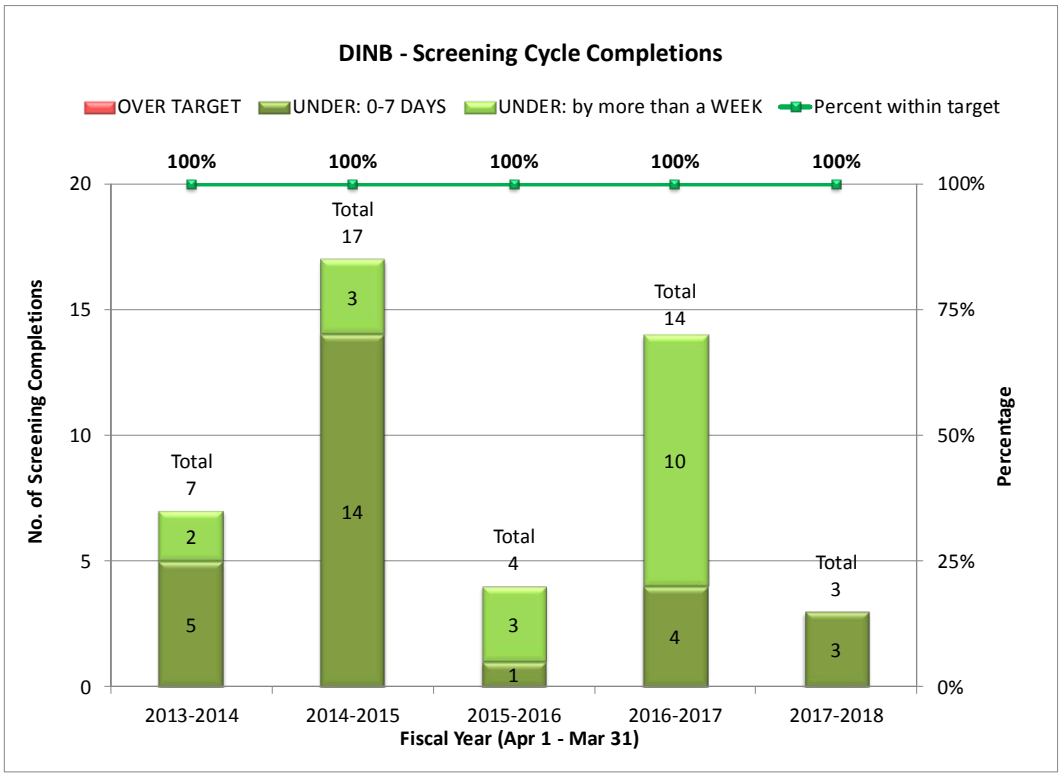
DINB					
Year of Reconsideration Request					
	13-14	**14-15**	**15-16**	**16-17**	**17-18**
Total	**0**	**0**	**0**	**0**	**0**

PERFORMANCE

DINB: Review Cycle Completions

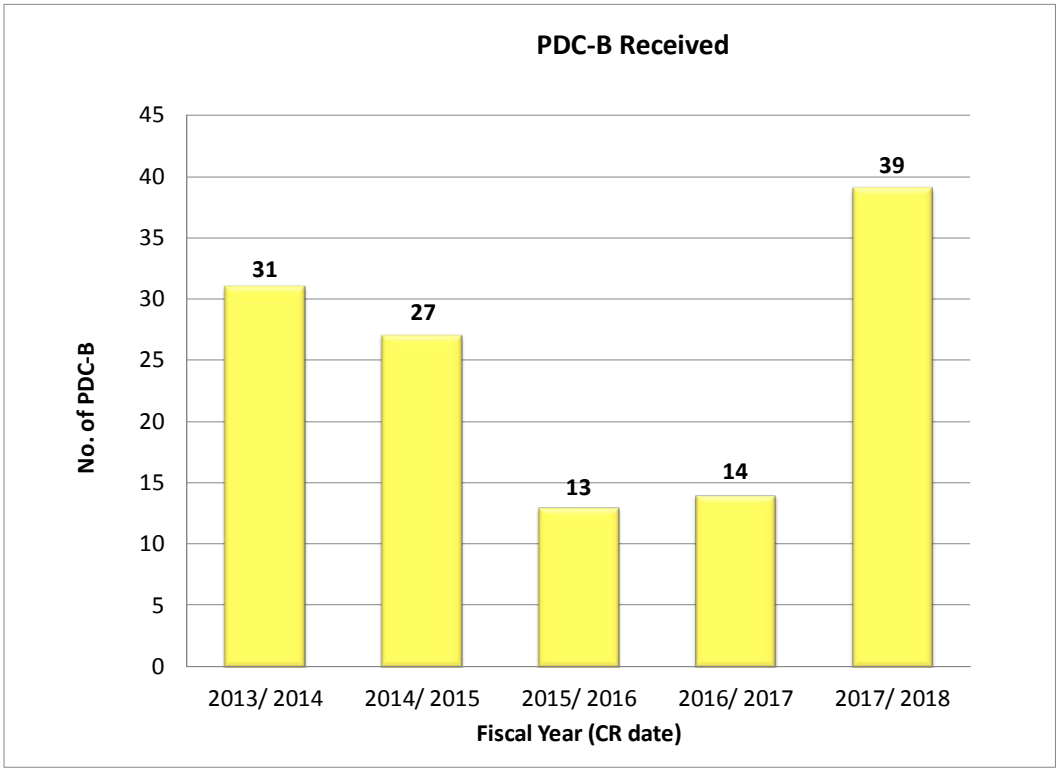


DINB: Screening Cycle Completions



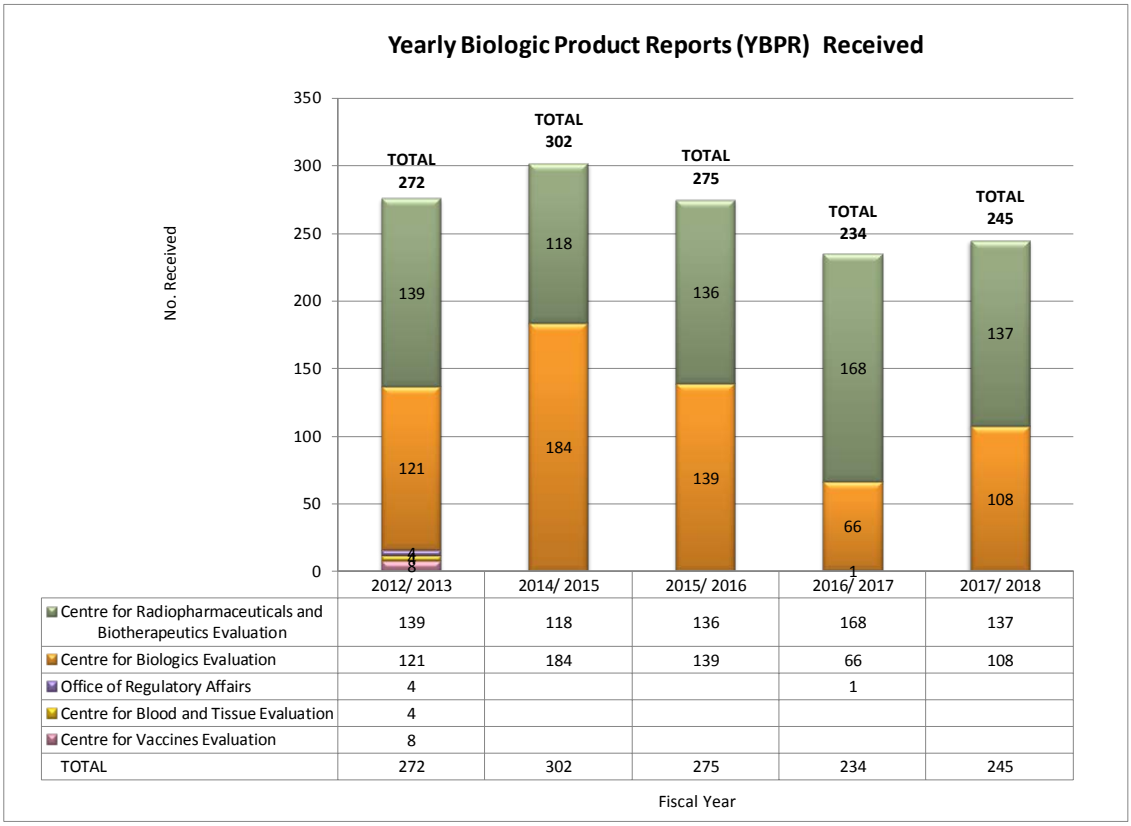
PDC-B: Post Authorization Division 1 Changes - Biologics

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



YBPR: Yearly Biologic Product Reports[13]

Yearly Biologic Product Reports (YBPR) Received



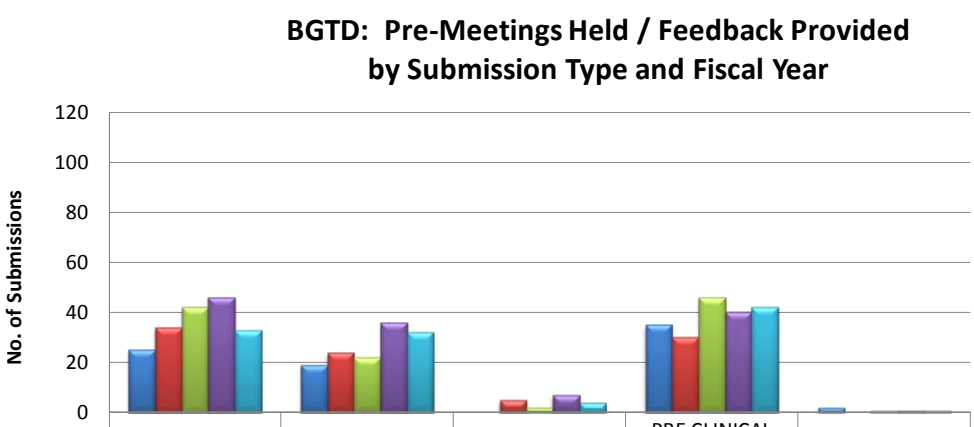
	2012/ 2013	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Centre for Radiopharmaceuticals and Biotherapeutics Evaluation	139	118	136	168	137
Centre for Biologics Evaluation	121	184	139	66	108
Office of Regulatory Affairs	4			1	
Centre for Blood and Tissue Evaluation	4				
Centre for Vaccines Evaluation	8				
TOTAL	272	302	275	234	245

[13] 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

[14]

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
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
2017-18	33	32	4	42	1

[14] 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

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