Santé Canada Health Canada

Biologics and Genetic Therapies Directorate

Drug Submission Performance Annual Report

Fiscal Year

2018-2019

April 1 2018 – March 31 2019

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 work with the provinces to ensure our health care system serves the needs of Canadians.

Également disponible en français sous le titre :
Direction des produits biologiques et des thérapies génétiques – Rapport annuel du rendement des présentations de drogue – Exercice financier 2018-2019

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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 2014-2015 to 2018-2019.

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 2018 to March 31 2019.

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:

Office of Submissions and Intellectual Property, Resource Management and Operations Directorate
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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)

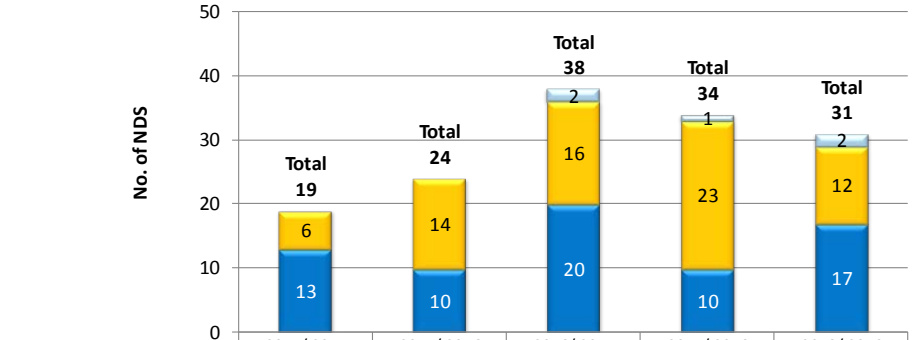
&

Supplemental New Drug Submission (SNDS)

SUBMISSIONS RECEIVED

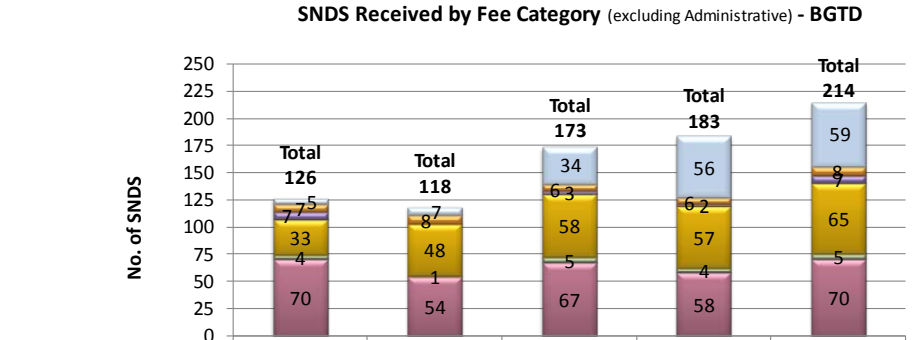
[9] [10]

New Drug Submissions (NDS) Received by Fee Category



	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Labelling Only	0	0	2	1	2
Clinical or Non-Clin and C&M	6	14	16	23	12
New Active Substance	13	10	20	10	17
Total	19	24	38	34	31
Priority (subset)	3	2	2	5	5
NOC/c Class	4	1	4	2	1
Emergency Use NDS	0	1	2	1	0
Biosimilar	2	4	7	14	8

Supplemental New Drug Submissions (SNDS) Received by Fee Category



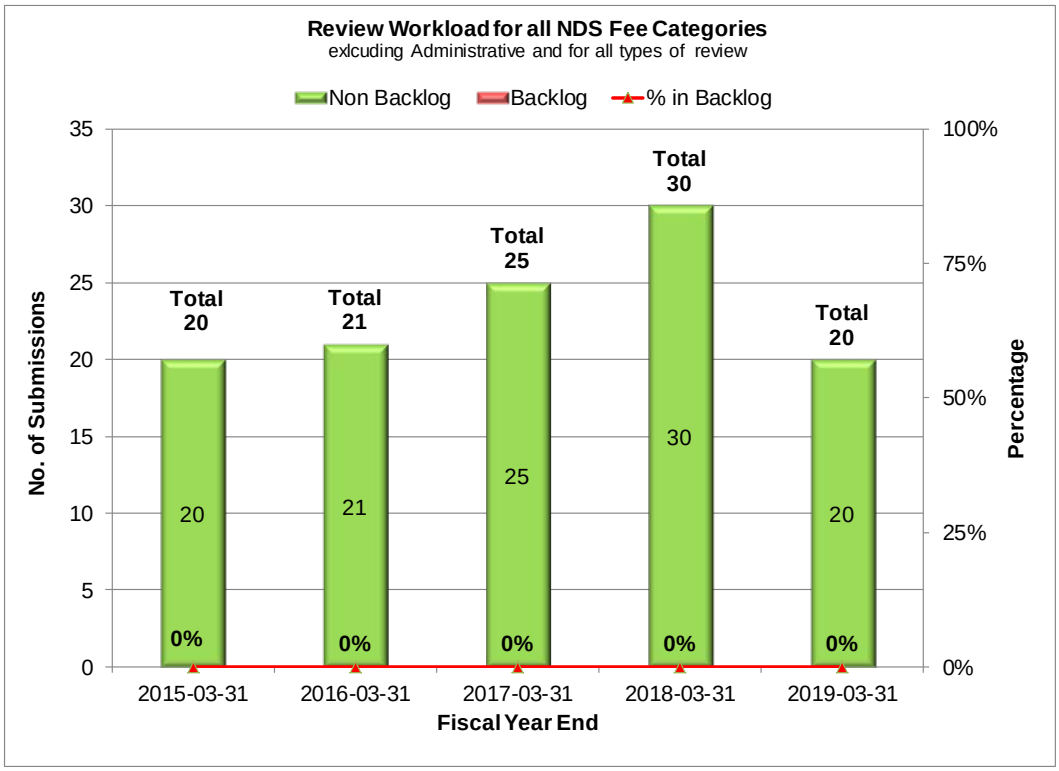
	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Labelling Only	5	7	34	56	59
Clinical or Non-Clin and C&M	7	8	6	6	8
Comparative Studies	7	0	3	2	7
Clinical or Non-Clin Only	33	48	58	57	65
Published Data Only	4	1	5	4	5
Chemistry & Manufacturing	70	54	67	58	70
Total	126	118	173	183	214
Priority (subset)	0	2	5	2	5
NOC/c Class	0	2	3	3	2
SNDS Confirmatory	2	4	5	5	5
Biosimilar	2	4	3	11	13

[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 .

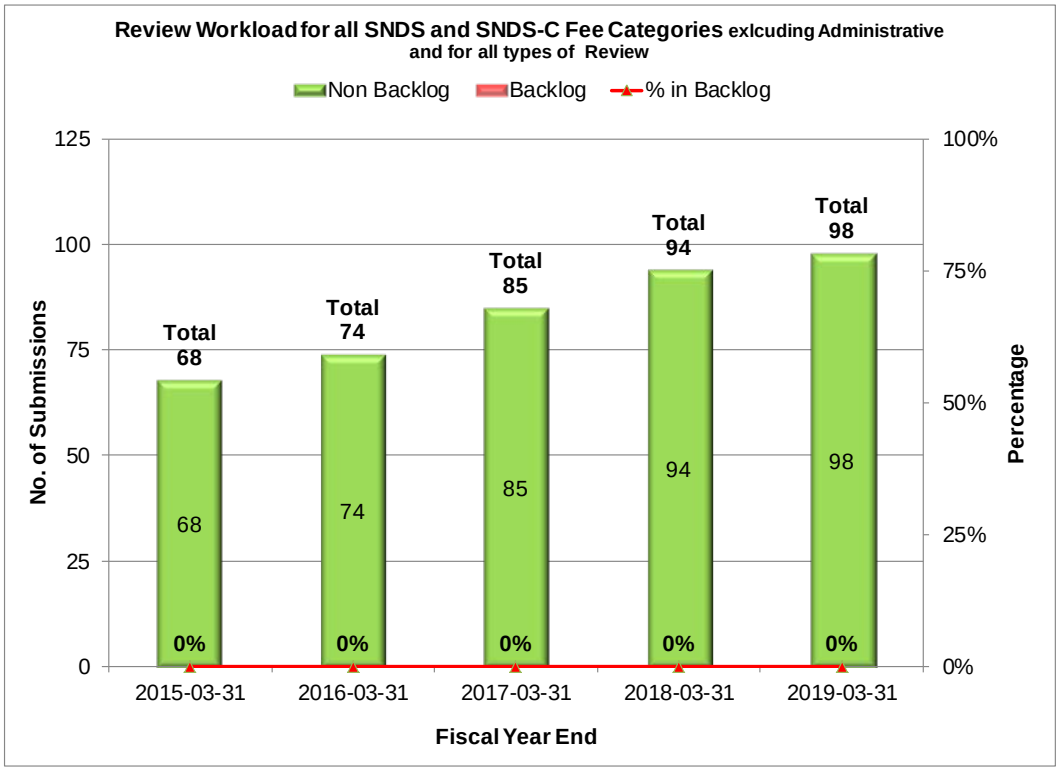
[10] **Biosimilar**: A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration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

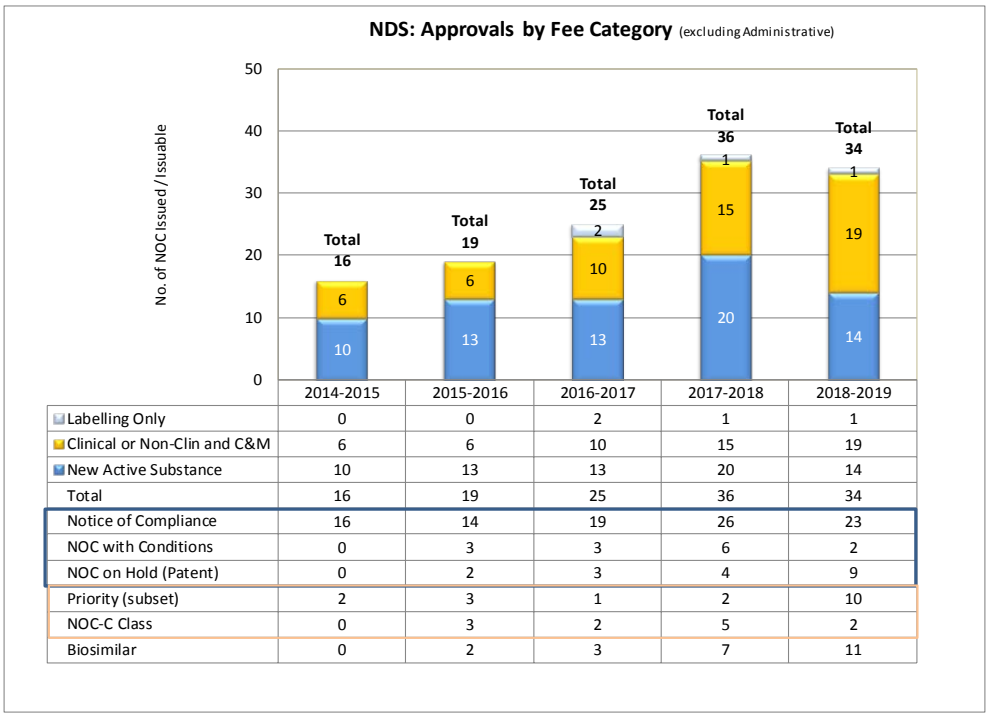
NDS All REVIEW WORKLOAD BY FEE CATEGORY - BGTD (excluding administrative) and Fiscal Year End					
	2015-03-31	2016-03-31	2017-03-31	2018-03-31	2019-03-31
Clinical or Non-Clin and C&M	**8**	**11**	**11**	**21**	**10**
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	**12**	**10**	**14**	**9**	**10**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**20**	**21**	**25**	**30**	**20**
Non Backlog	**20**	**21**	**25**	**30**	**20**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**2**	**1**	**1**	**5**	**0**
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					
	2015-03-31	2016-03-31	2017-03-31	2018-03-31	2019-03-31
Comparative Studies	**3**	**0**	**1**	**1**	**4**
Backlog	0	0	0	0	0
Chemistry & Manufacturing	**32**	**25**	**28**	**26**	**26**
Backlog	0	0	0	0	0
Clinical or Non-Clin Only	**25**	**37**	**44**	**54**	**49**
Backlog	0	0	0	0	0
Published Data	**3**	**1**	**3**	**2**	**3**
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	**5**	**10**	**4**	**4**	**6**
Backlog	0	0	0	0	0
Labelling Only	**0**	**1**	**5**	**7**	**10**
Backlog	0	0	0	0	0
Total	**68**	**74**	**85**	**94**	**98**
Non Backlog	**68**	**74**	**85**	**94**	**98**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**0**	**2**	**3**	**2**	**4**
Backlog	*0*	*0*	*0*	*0*	*0*
SNDS-C (Confirmatory)	**2**	**3**	**3**	**5**	**5**
Backlog	*0*	*0*	*0*	*0*	*0*

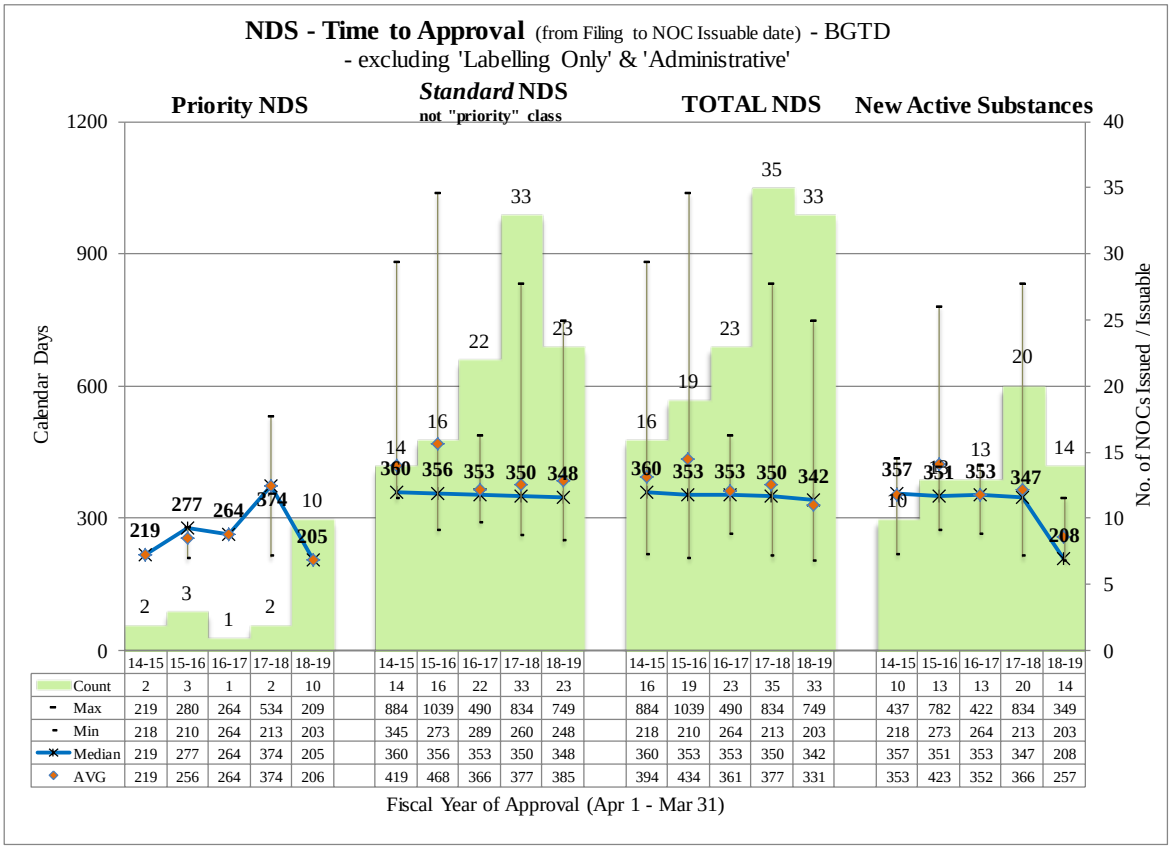
APPROVALS

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



	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
Labelling Only	0	0	2	1	1
Clinical or Non-Clin and C&M	6	6	10	15	19
New Active Substance	10	13	13	20	14
Total	16	19	25	36	34
Notice of Compliance	16	14	19	26	23
NOC with Conditions	0	3	3	6	2
NOC on Hold (Patent)	0	2	3	4	9
Priority (subset)	2	3	1	2	10
NOC-C Class	0	3	2	5	2
Biosimilar	0	2	3	7	11

NDS Approval Times

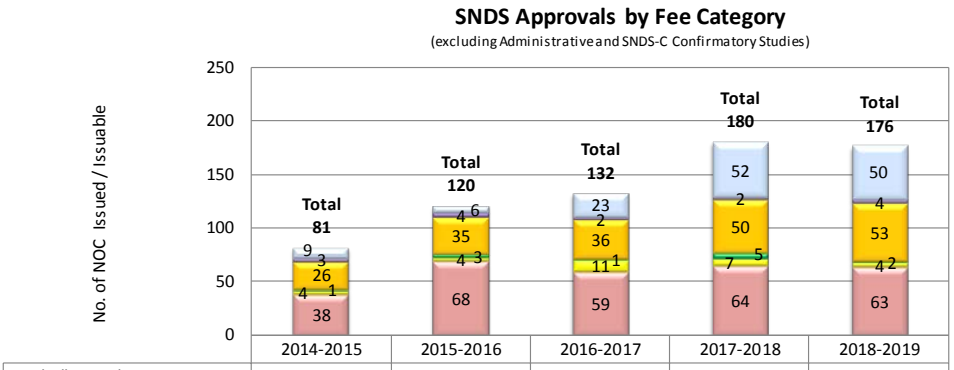


	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19
Count	2	3	1	2	10	14	16	22	33	23	16	19	23	35	33	10	13	13	20	14
Max	219	280	264	534	209	884	1039	490	834	749	884	1039	490	834	749	437	782	422	834	349
Min	218	210	264	213	203	345	273	289	260	248	218	210	264	213	203	218	273	264	213	203
Median	219	277	264	374	205	360	356	353	350	348	360	353	353	350	342	357	351	353	347	208
AVG	219	256	264	374	206	419	468	366	377	385	394	434	361	377	331	353	423	352	366	257

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.

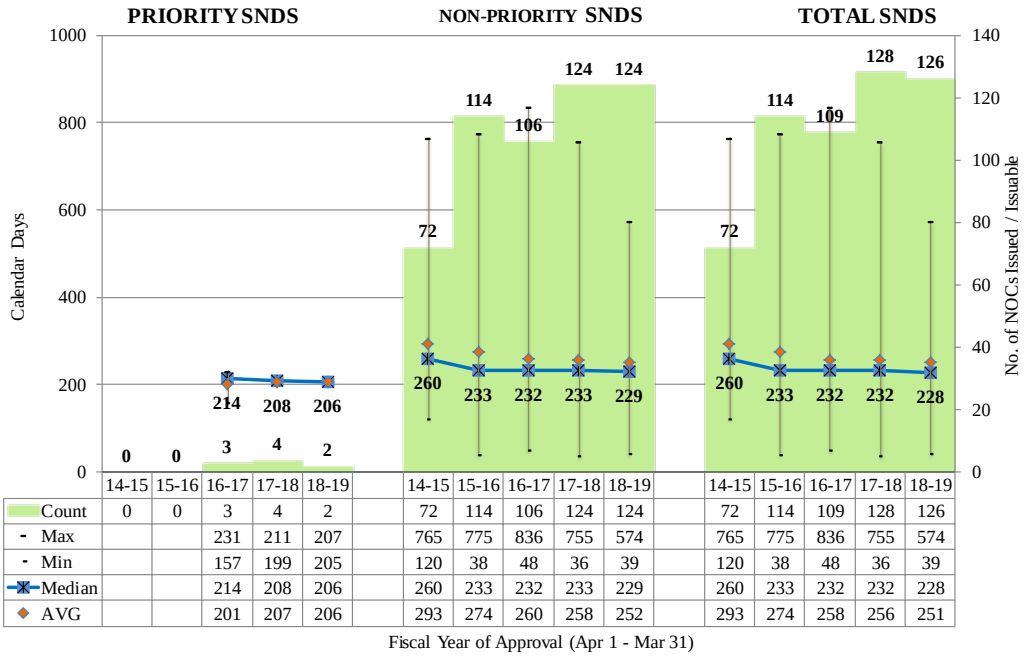
Supplemental New Drug Submission (SNDS) Approvals by Fee Category and by NOC Type



	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
Labelling Only	9	6	23	52	50
Comparative Studies	3	4	2	2	4
Clinical or Non-Clin Only	26	35	36	50	53
Published Data Only	1	3	1	5	2
Clinical or Non-Clin and C&M	4	4	11	7	4
Chemistry & Manufacturing	38	68	59	64	63
Total	81	120	132	180	176
Notice of Compliance	81	120	127	175	174
NOC with Conditions	0	0	2	4	1
Priority (subset)	0	0	3	4	2
NOC-C Class	0	0	2	4	1
Biosimilar	0	3	6 *	6 *	9

* Figures revised May 2018

SNDS Approval Times



	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19
Count	0	0	3	4	2	72	114	106	124	124	72	114	109	128	126
Max			231	211	207	765	775	836	755	574	765	775	836	755	574
Min			157	199	205	120	38	48	36	39	120	38	48	36	39
Median			214	208	206	260	233	232	233	229	260	233	232	232	228
AVG			201	207	206	293	274	260	258	252	293	274	258	256	251

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New Active Substance Approvals (NAS) – BGTD - Fiscal Year 2018-2019

New Active Substance Approvals (NAS) – BGTD Fiscal Year 2018-2019 (April 1 2018 to March 31 2019)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[11])**	**Approval Date (dd-mon-yy)**
AIMOVIG (Erenumab) - is indicated for prevention of migraine in adults who have at least 4 migraine days per month.	NAS	Novartis Pharmaceuticals Canada Inc.	18-Aug-17	1-Aug-18
BIOTHRAX (Anthrax Antigen Filtrate) - is indicated for active immunization for the prevention of disease caused by Bacillus anthracis, in individuals 18 through 65 years of age, whose occupation or other activities place them at risk of exposure, regardless of the route of exposure.	NAS	Emergent Biodefense Operations Lansing LLC	29-Dec-17	13-Dec-18
BRINEURA (Cerliponase Alfa) - is indicated for the treatment of neuronal ceroid lipofuscinosis type 2 (CLN2) disease, also known as tripeptidyl peptidase 1 (TPP1) deficiency.	PRIORITY-NAS	Biomarin International Limited	25-May-18	19-Dec-18
CRYSVITA (Burosumab) - is indicated for the treatment of X-linked hypophosphataemia (XLH) in adult and pediatric patients 1 year of age and older.	PRIORITY-NAS	Kyowa Kirin Limited	16-May-18	5-Dec-18
HEMLIBRA (Emicizumab) - is indicated for hemophilia A (congenital factor VIII deficiency) patients with factor VIII inhibitors as routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes.	PRIORITY-NAS	Hoffmann-La Roche Limited	9-Jan-18	2-Aug-18
JIVI (Antihemophilic Factor (Recombinant, B-domain deleted, PEGylated)) - is indicated in previously treated adults and adolescents (≥12 years of age) with hemophilia A (congenital Factor VIII deficiency) for: • Routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes; • Control and prevention of episodic bleeding; • Peri-operative management of bleeding (surgical prophylaxis).	NAS	Bayer Inc.	3-Nov-17	18-Oct-18
KYMRIAH (Tisagenlecleucel) - is a CD19-directed genetically modified autologous T-cell immunocellular therapy indicated for: the treatment of pediatric and young adult patients 3 to 25 years with B-cell acute lymphoblastic leukemia (ALL) who are refractory, have relapsed after allogeneic stem cell transplant (SCT) or are otherwise ineligible for SCT, or have experienced second or later relapse.	PRIORITY-NAS	Novartis Pharmaceuticals Canada Inc.	9-Feb-18	5-Sep-18

[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 2018-2019
(April 1 2018 to March 31 2019)

Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date[11])	Approval Date (dd-mon-yy)
LUTATHERA (Lutetium (177Lu) Oxodotreotide) - is indicated for the treatment of unresectable or metastatic, well-differentiated, somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adults with progressive disease.	PRIORITY-NAS	Advanced Accelerator Applications USA, Inc.	18-Jun-18	9-Jan-19
OXERVATE (Cenegermin) - is indicated for the treatment of moderate (persistent epithelial defect) or severe (corneal ulcer) neurotrophic keratitis in adults.	PRIORITY-NAS	Dompé Farmaceutici S.P.A.	16-Jul-18	8-Feb-19
PANHEMATIN (Hemin) is indicated for the amelioration of recurrent attacks of acute intermittent porphyria temporally related to the menstrual cycle in susceptible women, after initial carbohydrate therapy is known or suspected to be inadequate.	PRIORITY-NAS	Recordati Rare Diseases Canada Inc.	20-Dec-17	13-Jul-18
TAKHZYRO (Lanadelumab) - is indicated for routine prevention of attacks of hereditary angioedema (HAE) in adolescents and adults.	PRIORITY-NAS	Shire Pharma Canada ULC	22-Feb-18	19-Sep-18
UNITUXIN (Dinutuximab) - in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13 cis-retinoic acid (RA), for the treatment of high-risk neuroblastoma in pediatric patients who achieve at least a partial response to prior first-line multiagent, multimodality therapy.	NAS	United Therapeutics Corporation	14-Dec-17	28-Nov-18
VONVENDI (von Willebrand factor (Recombinant)) - is indicated for: • treatment and control of bleeding episodes in adults (age ≥18) diagnosed with von Willebrand Disease (VWD). • Perioperative management of bleeding in adults (age ≥18) diagnosed with VWD.	NAS	Shire Pharma Canada ULC	26-Jan-18	10-Jan-19
YESCARTA (Axicabtagene Ciloleucel) - is a CD19-directed genetically modified autologous T cell immunotherapy indicated for: the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.	PRIORITY-NAS	Gilead Sciences Canada Inc.	23-Jul-18	13-Feb-19

Priority Submission Approvals – BGTD - Fiscal Year 2018-2019

Priority Submission Approvals – BGTD Fiscal Year 2018-2019 (April 1 2018 to March 31 2019)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[12])**	**Approval Date (dd-mon-yy)**
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CRYSVITA (Burosumab) - is indicated for the treatment of X-linked hypophosphataemia (XLH) in adult and pediatric patients 1 year of age and older.	PRIORITY-NAS	Kyowa Kirin Limited	16-May-18	5-Dec-18
HEMLIBRA (Emicizumab) - is indicated for hemophilia A (congenital factor VIII deficiency) patients with factor VIII inhibitors as routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes.	PRIORITY-NAS	Hoffmann-La Roche Limited	9-Jan-18	2-Aug-18
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KYMRIAH (Tisagenlecleucel) - is a CD19-directed genetically modified autologous T-cell immunocellular therapy indicated for: the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.	PRIORITY-CLIN/C&M	Novartis Pharmaceuticals Canada Inc.	14-Feb-18	5-Sep-18

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

Priority Submission Approvals – BGTD Fiscal Year 2018-2019 (April 1 2018 to March 31 2019)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[12])**	**Approval Date (dd-mon-yy)**
LUTATHERA (Lutetium (177Lu) Oxodotreotide) - is indicated for the treatment of unresectable or metastatic, well-differentiated, somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adults with progressive disease.	PRIORITY-NAS	Advanced Accelerator Applications USA, Inc.	18-Jun-18	9-Jan-19
OPDIVO (Nivolumab) - new indication: Metastatic Renal Cell Carcinoma (RCC): OPDIVO, in combination with ipilimumab, is indicated for the treatment of adult patients with intermediate/poor-risk advanced or metastatic RCC.	PRIORITY-CLIN ONLY	Bristol-Myers Squibb Canada	13-Dec-17	6-Jul-18
OXERVATE (Cenegermin) - is indicated for the treatment of moderate (persistent epithelial defect) or severe (corneal ulcer) neurotrophic keratitis in adults.	PRIORITY-NAS	Dompé Farmaceutici S.P.A.	16-Jul-18	8-Feb-19
PANHEMATIN (Hemin) is indicated for the amelioration of recurrent attacks of acute intermittent porphyria temporally related to the menstrual cycle in susceptible women, after initial carbohydrate therapy is known or suspected to be inadequate.	PRIORITY-NAS	Recordati Rare Diseases Canada Inc.	20-Dec-17	13-Jul-18
SOLIRIS (Eculizumab) - new indication: is indicated in adult patients with generalized Myasthenia Gravis (gMG).	PRIORITY-CLIN ONLY	Alexion Pharma GMBH	25-Jan-18	20-Aug-18
TAKHZYRO (Lanadelumab) - is indicated for routine prevention of attacks of hereditary angioedema (HAE) in adolescents and adults.	PRIORITY-NAS	Shire Pharma Canada ULC	22-Feb-18	19-Sep-18
YESCARTA (Axicabtagene Ciloleucel) - is a CD19-directed genetically modified autologous T cell immunotherapy indicated for: the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.	PRIORITY-NAS	Gilead Sciences Canada Inc.	23-Jul-18	13-Feb-19

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**	**2014-15**	**2015-16**	**2016-17**	**2017-18**	**2018-19**
NDS	CLIN/C&M	0	2	1	3	5
NDS Total		**0**	**2**	**1**	**3**	**5**
SNDS	C&M ONLY	0	1	2	1	3
	C&M/LABELLING	0	0	1	0	0
	CLIN ONLY	0	0	0	0	2
	CLIN/C&M	0	0	2	0	0
	COMP/C&M	0	0	1	0	1
	LABELLING ONLY	0	1	0	4	2
	PUBLISHED DATA ONLY	0	1	0	0	0
SNDS Total		**0**	**3**	**6**	**5**	**8**

Biosimilars: List of NDS & SNDS issued an NOC - Fiscal Year 2018-19

Subm Type	Brand Name	Class	Company	Active Ingredient(s)	Quarter FY 2018-19	Notice of Compliance (NOC) Date
NDS	FULPHILA	CLIN/C&M	BGP PHARMA ULC	PEGFILGRASTIM	Q3	2018-Dec-24
	HADLIMA, HADLIMA PUSHTOUCH	CLIN/C&M	SAMSUNG BIOEPIS CO., LTD	ADALIMUMAB	Q1	2018-May-08
	HADLIMA, HADLIMA PUSHTOUCH	CLIN/C&M	SAMSUNG BIOEPIS CO., LTD	ADALIMUMAB	Q1	2018-May-08
	LAPELGA	CLIN/C&M	APOTEX INC.	PEGFILGRASTIM	Q1	2018-Apr-05
	MVASI	CLIN/C&M	AMGEN CANADA INC	BEVACIZUMAB	Q1	2018-Apr-30
New Drug Submission Total						**5**
SNDS	ADMELOG	LABELLING ONLY	SANOFI-AVENTIS CANADA INC	INSULIN LISPRO	Q1	2018-Apr-30
	BASAGLAR	C&M ONLY	ELI LILLY CANADA INC	INSULIN GLARGINE	Q1	2018-May-10
	BRENZYS	LABELLING ONLY	SAMSUNG BIOEPIS CO., LTD	ETANERCEPT	Q1	2018-Jun-18
	BRENZYS (PFP), BRENZYS (PFS)	CLIN ONLY	SAMSUNG BIOEPIS CO., LTD	ETANERCEPT	Q1	2018-Jun-14
	ERELZI	CLIN ONLY	SANDOZ CANADA INCORPORATED	ETANERCEPT	Q4	2019-Jan-17
	ERELZI (SENSOREADY PEN), ERELZI (PREFILLED SYRINGE)	C&M ONLY	SANDOZ CANADA INCORPORATED	ETANERCEPT	Q4	2019-Feb-11
	ERELZI (SYRINGE), ERELZI (PEN)	C&M ONLY	SANDOZ CANADA INCORPORATED	ETANERCEPT	Q4	2019-Feb-27
	RENFLEXIS	COMP/C&M	SAMSUNG BIOEPIS CO., LTD	INFLIXIMAB	Q3	2018-Nov-06
Supplemental New Drug Submission Total						**8**

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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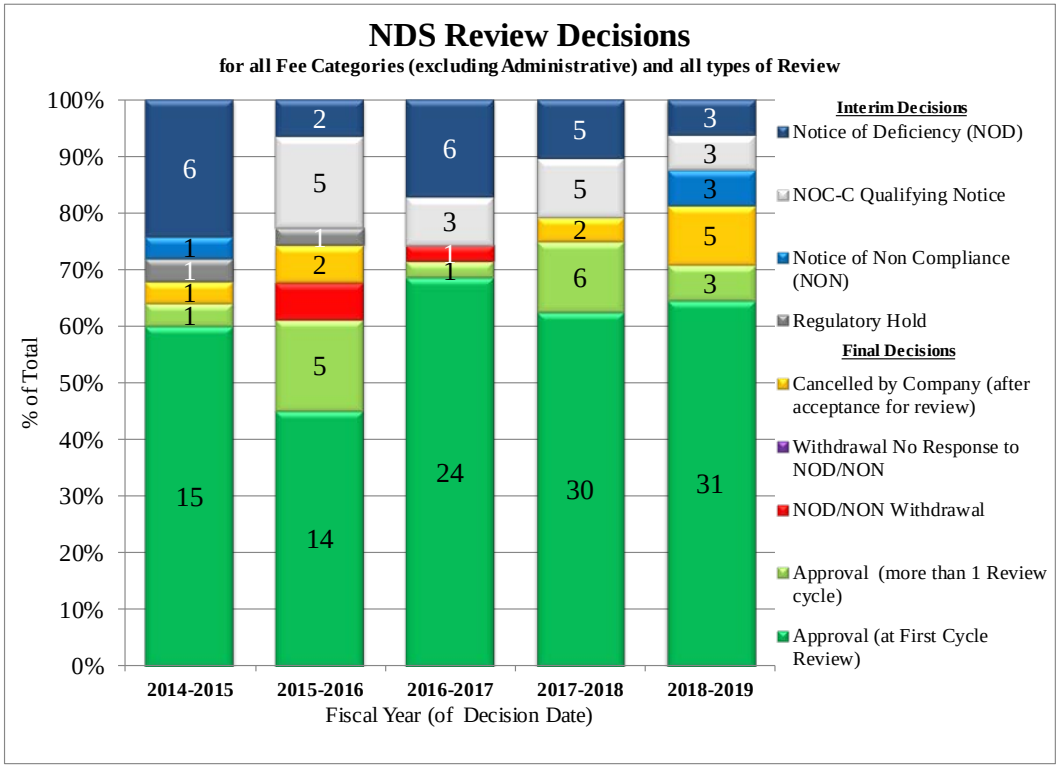
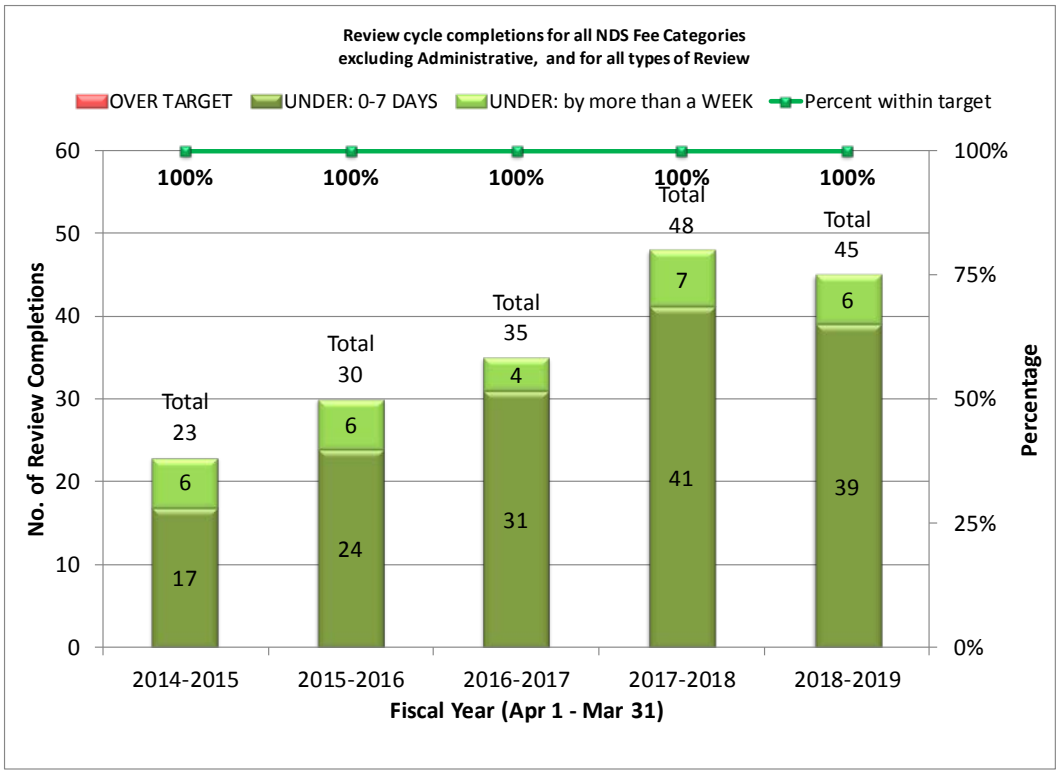
REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

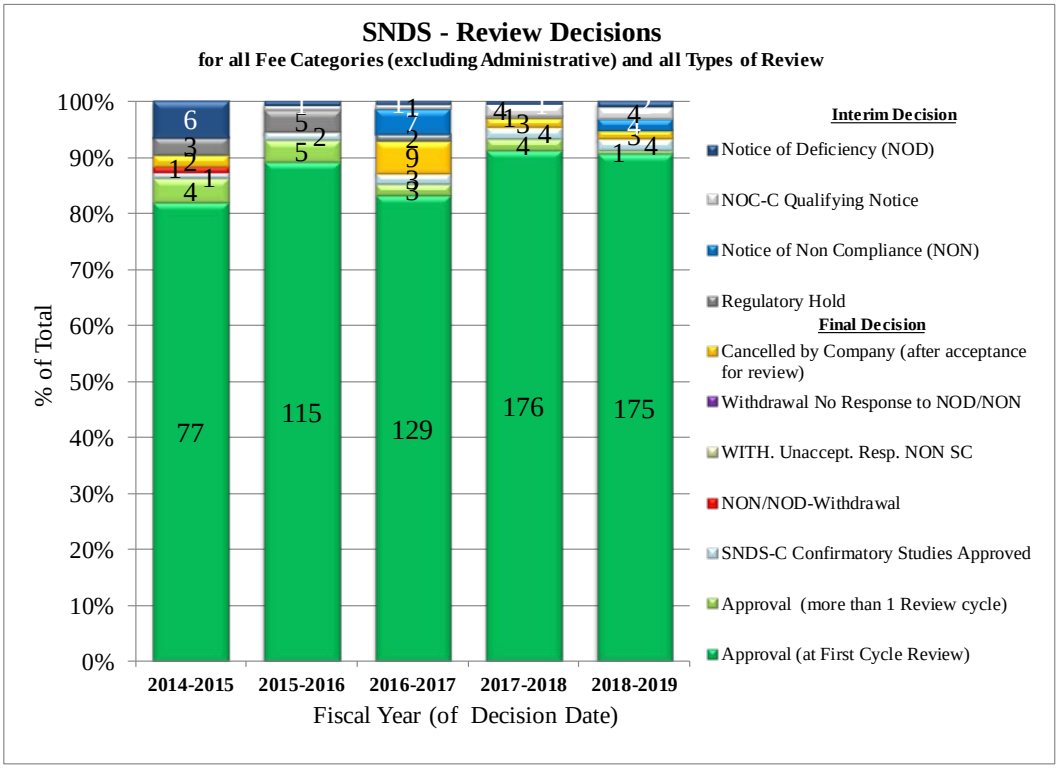


NDS: Review Cycle Completions Showing Percentage Within Target

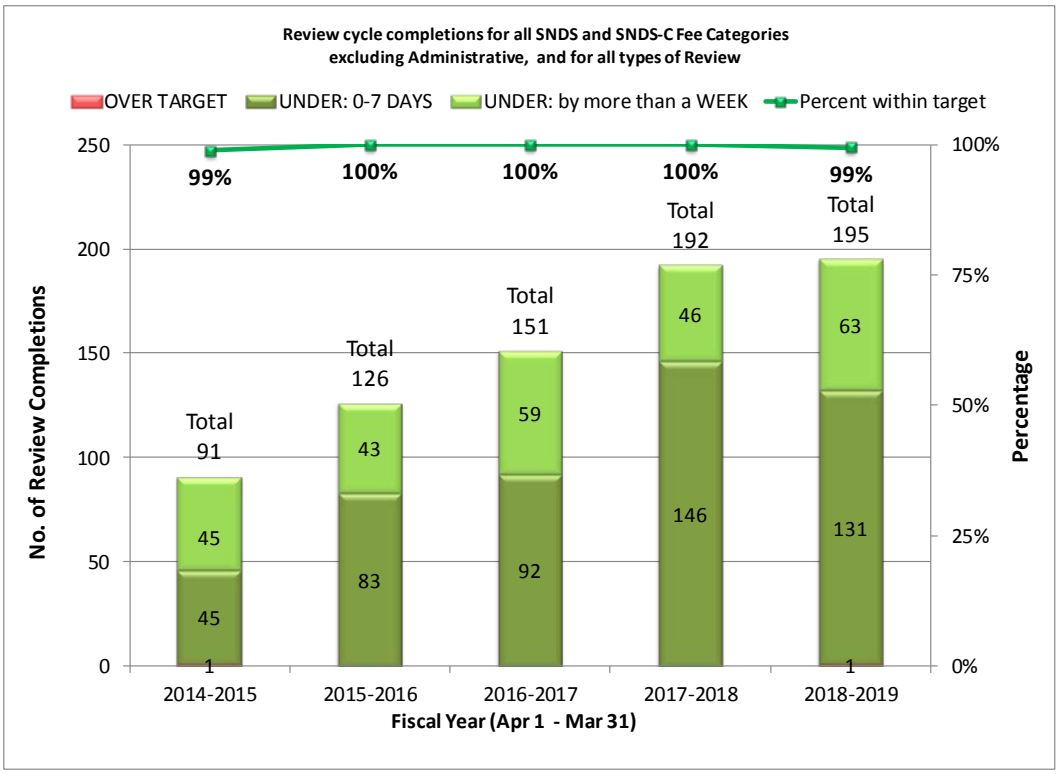


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

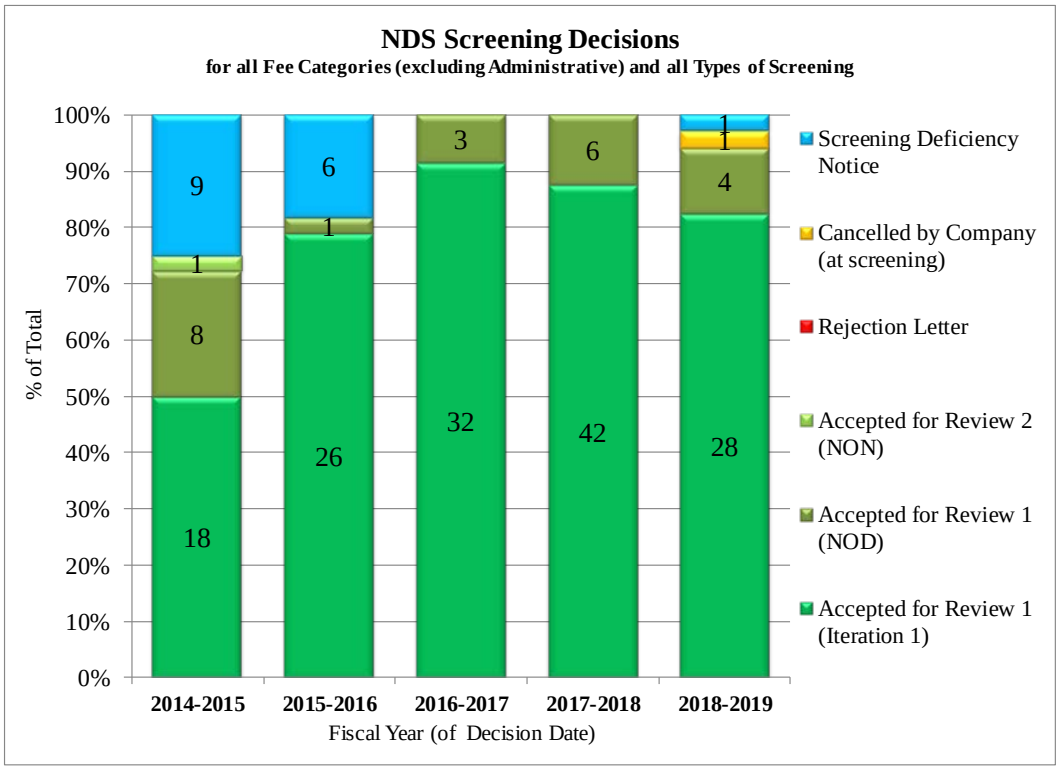


SNDS: Review Cycle Completions Showing Percentage Within Target

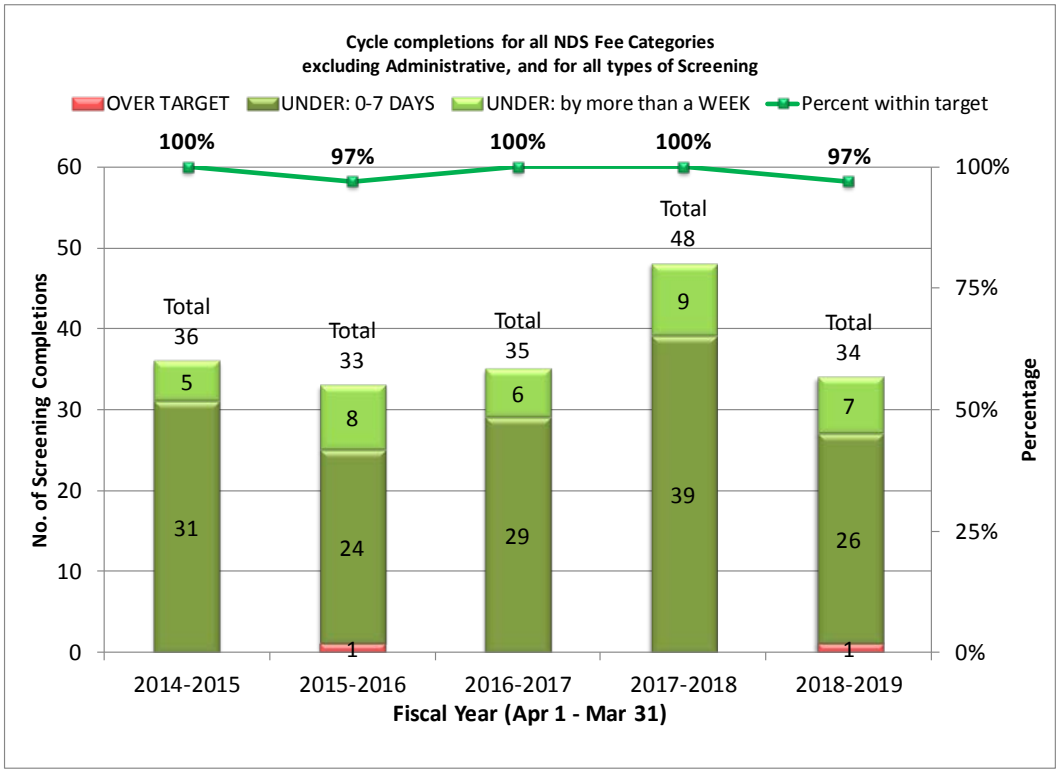


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

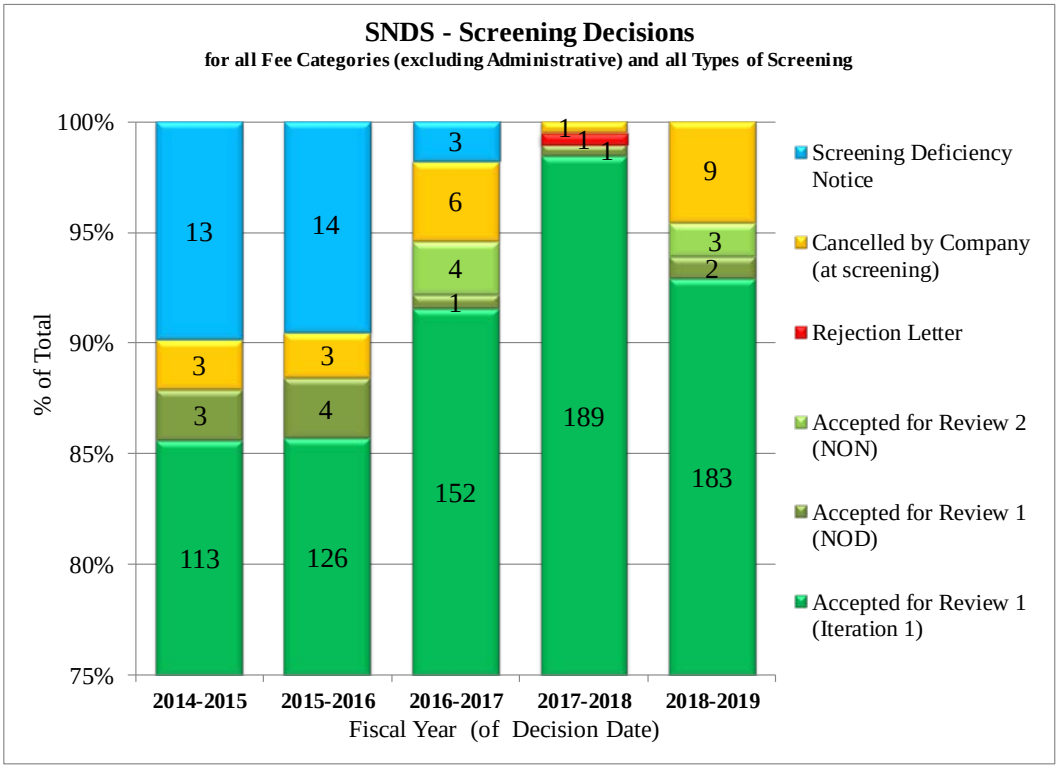


NDS: Screening Cycle Completions Showing Percentage Within Target

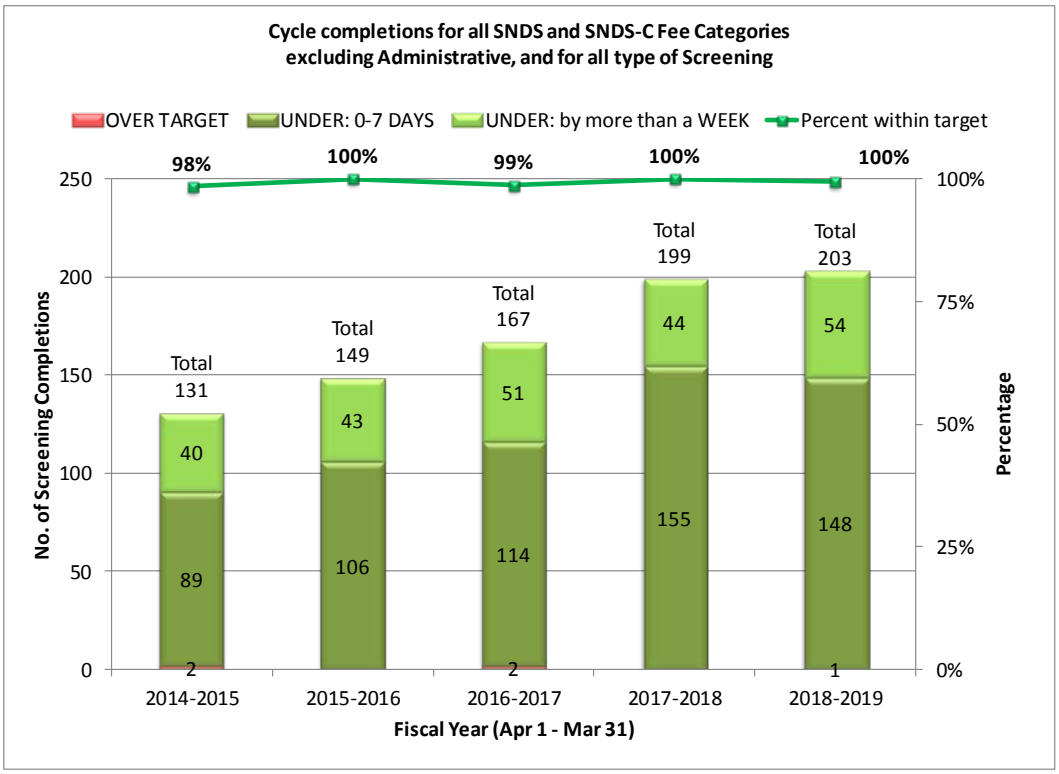


SCREENING CYCLE DECISIONS

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	**14-15**	**15-16**	**16-17**	**17-18**	**18-19**	**Final Decision in Dispute**	**Submission Status (as of May 2019)**
Total Received	**0**	**0**	**0**	**0**	**0**		

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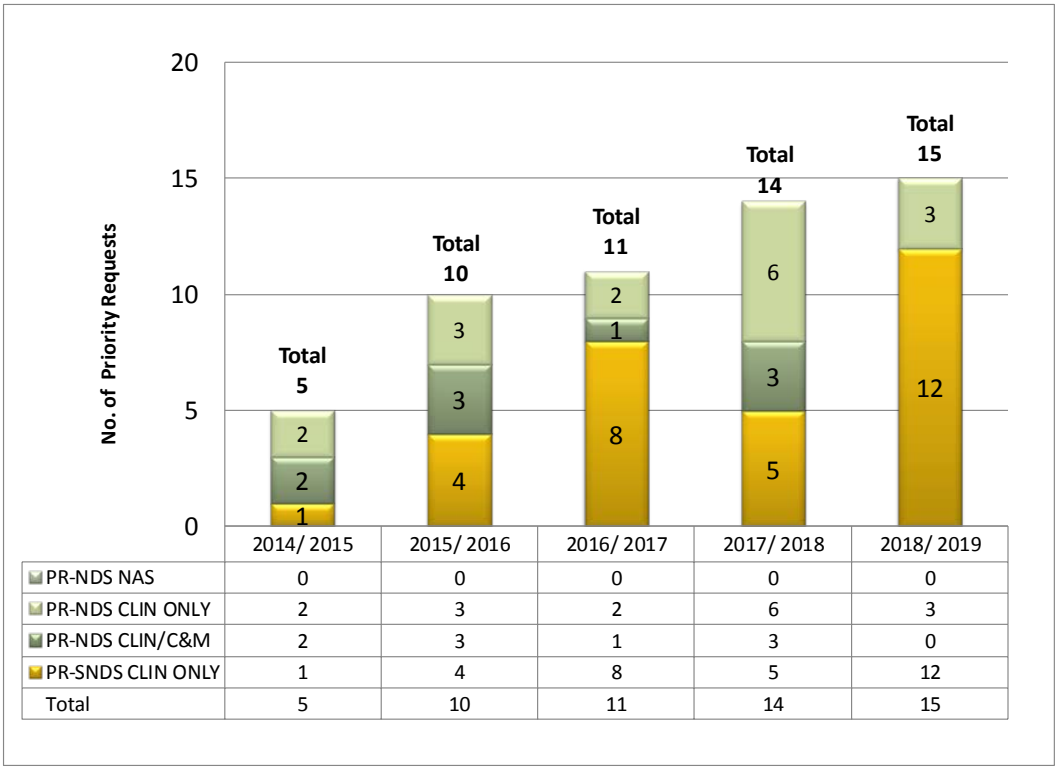
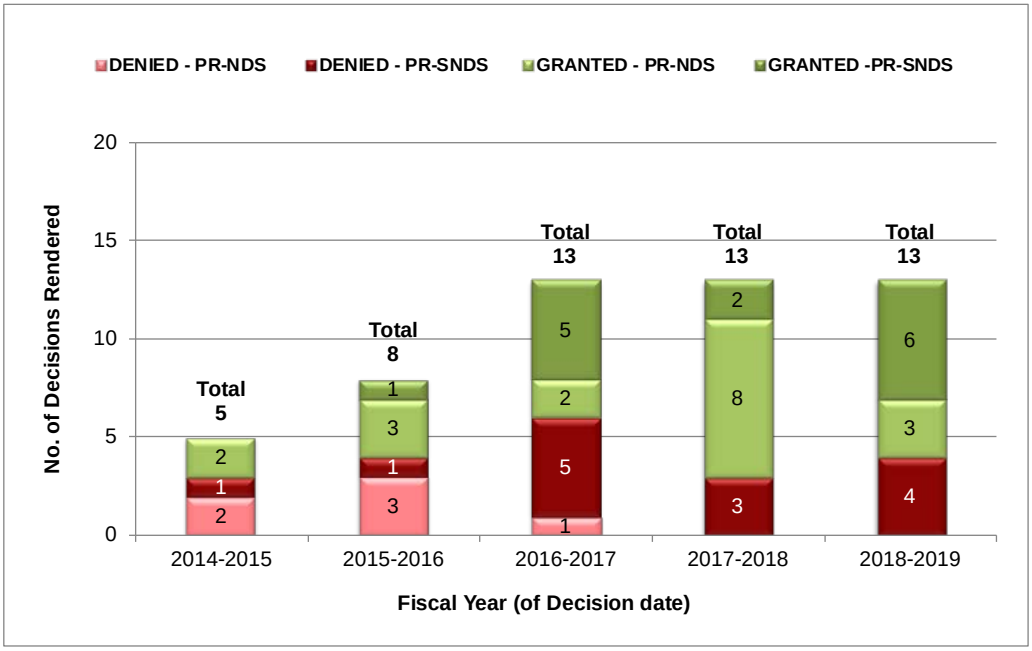
PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests Received



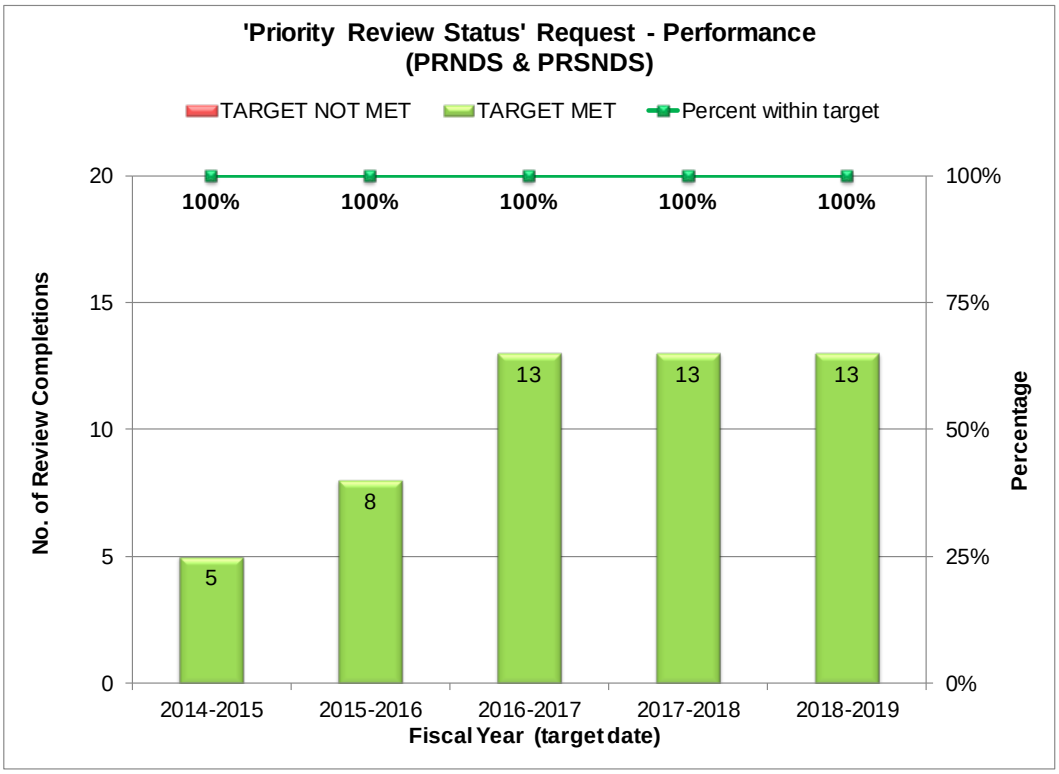
	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
PR-NDS NAS	0	0	0	0	0
PR-NDS CLIN ONLY	2	3	2	6	3
PR-NDS CLIN/C&M	2	3	1	3	0
PR-SNDS CLIN ONLY	1	4	8	5	12
Total	5	10	11	14	15

Priority Review Status Requests: Decisions Rendered



PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests: Performance



REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

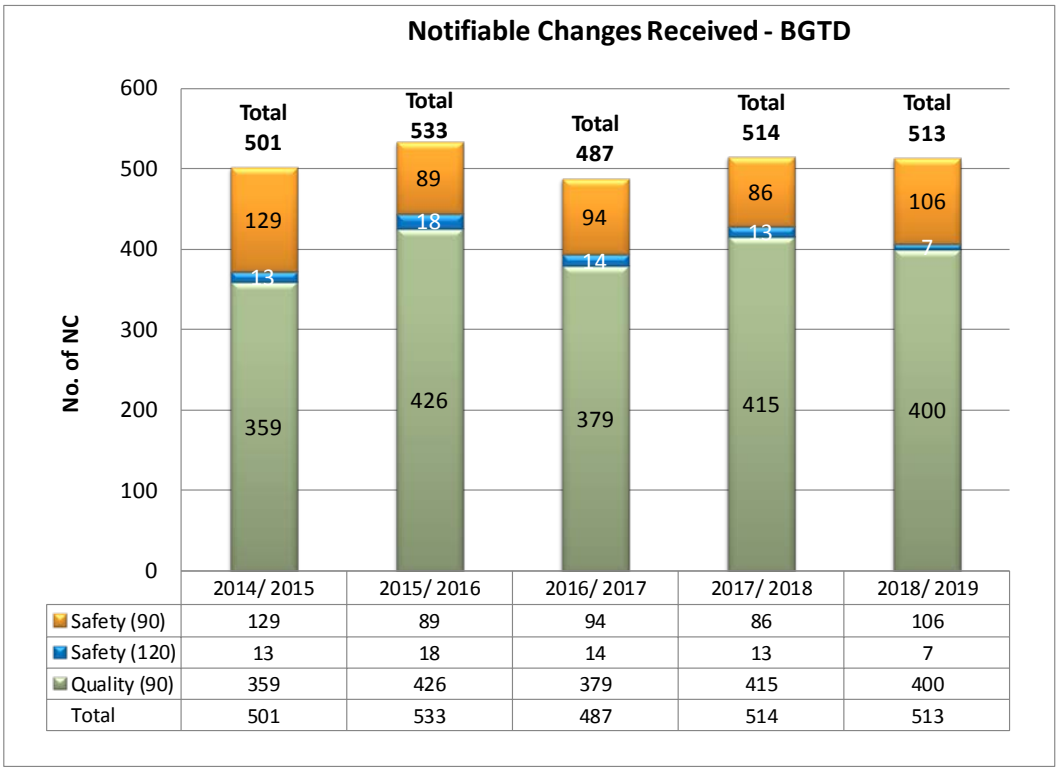
Requests for Reconsideration of Final Decisions – Priority Review Requests (for NDS and SNDS)

"Priority Review Request" - Requests for Reconsideration of Final Decisions Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	**14-15**	**15-16**	**16-17**	**17-18**	**18-19**	**Final Decision in Dispute**	**Submission Status (as of May 2019)**
Total Received	**0**	**0**	**1**	**0**	**1**		
Total Granted	***0***	***0***	***0***	***0***	***0***		
Total Pending	***0***	***0***	***0***	***0***	***1***	PR-SNDS: Priority Review Request Denied	Rejected
Total Denied	***0***	***0***	***1***	***0***		PR-SNDS: Priority Review Request Denied	Rejected

NOTIFIABLE CHANGES (NC)

NOTIFIABLE CHANGES

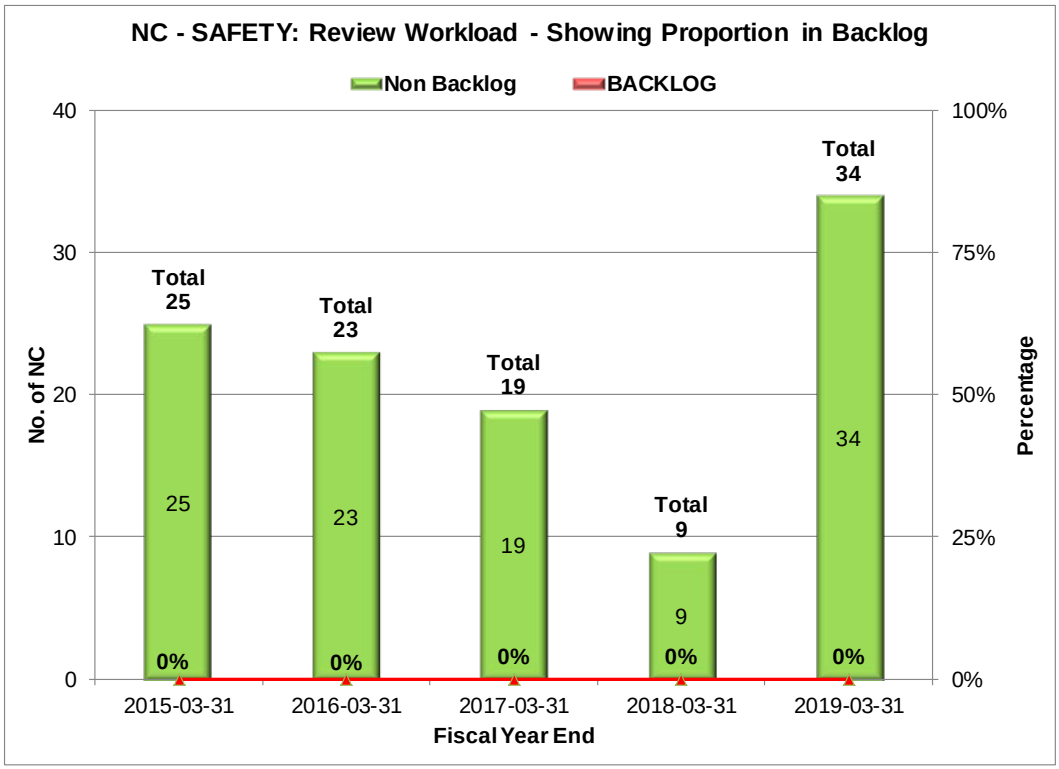
Number Received - Notifiable Changes (NC)



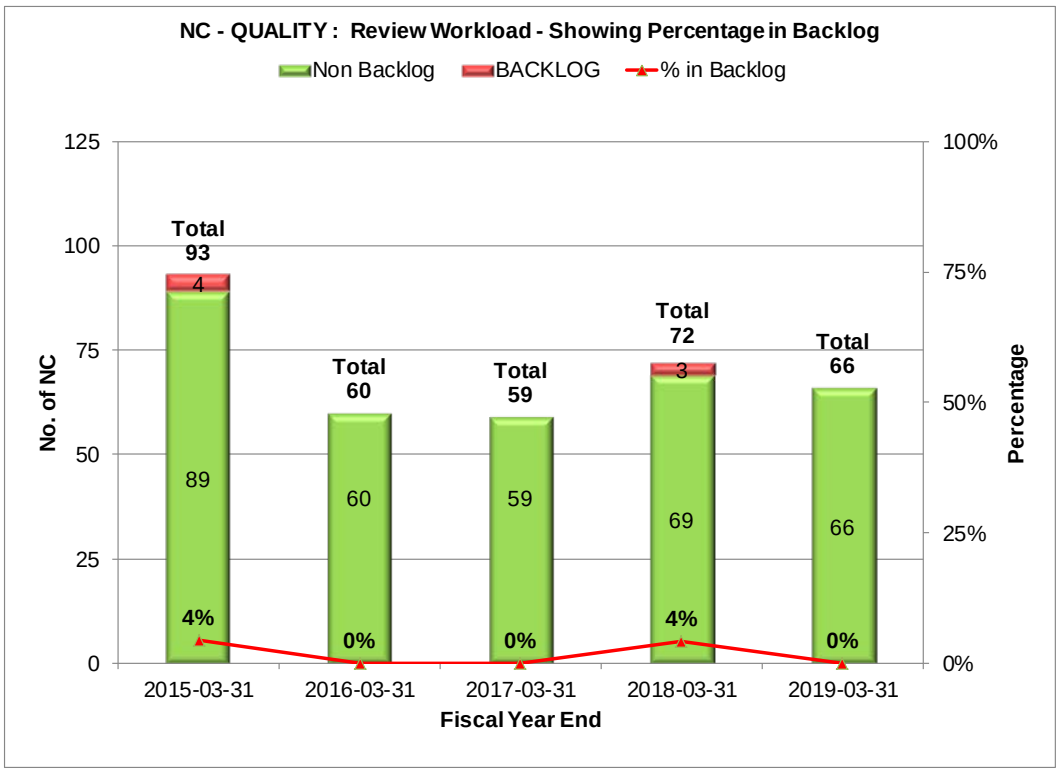
	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Safety (90)	129	89	94	86	106
Safety (120)	13	18	14	13	7
Quality (90)	359	426	379	415	400
Total	501	533	487	514	513

WORKLOAD

Notifiable Change (NC) SAFETY: Review Workload / Backlog



Notifiable Change (NC) QUALITY: Review Workload / Backlog



WORKLOAD

Notifiable Change (NC) SAFETY: Review Workload by Class

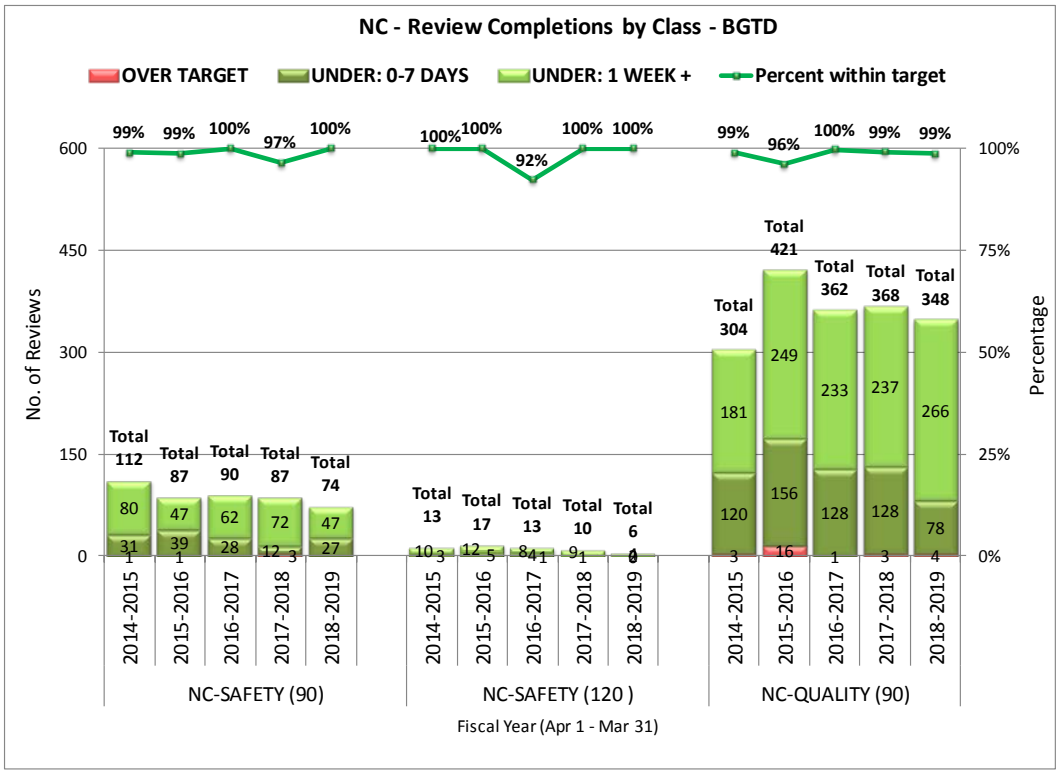
BGTD NC- SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2015-03-31	2016-03-31	2017-03-31	2018-03-31	2019-03-31
SAFETY - 90 day	22	20	15	8	34
Backlog	*0*	*0*	*0*	*0*	*0*
SAFETY - 120 day	3	3	4	1	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	25	23	19	9	34
Non Backlog	25	23	19	9	34
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

Notifiable Change (NC) QUALITY: Review Workload by Class

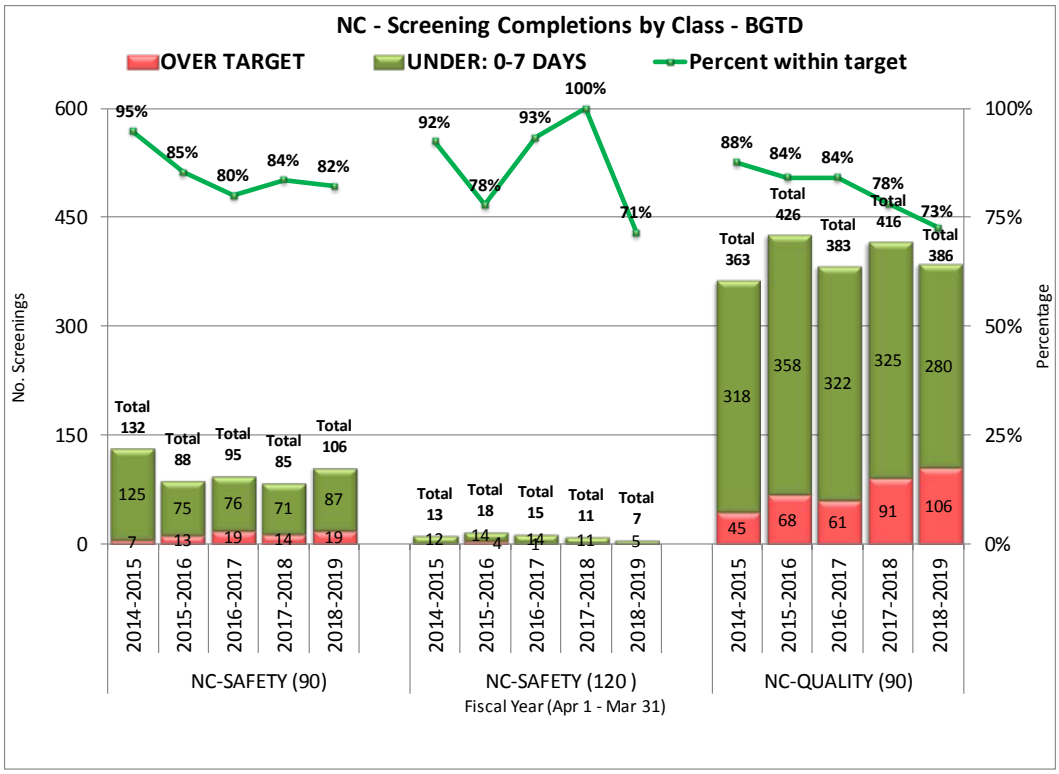
BGTD NC- QUALITY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2015-03-31	2016-03-31	2017-03-31	2018-03-31	2019-03-31
QUALITY - 90 day	93	60	59	72	66
Backlog	*4*	*0*	*0*	*3*	*0*
Total	93	60	59	72	66
Non Backlog	89	60	59	69	66
BACKLOG	4	0	0	3	0
% in Backlog	4%	0%	0%	4%	0%

PERFORMANCE

REVIEW Completions by Class - Notifiable Changes (NC)



SCREENING Completions by Class - Notifiable Changes (NC)



Decision Documents by Class - Notifiable Change (NC)

NC - QUALITY (90)					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NO OBJECTION LETTER	302	410	363	381	358
NOT SATISFACTORY NOTICE	0	3	1	0	0
REJECTION LETTER (SCR)	8	33	7	12	16
CANCELLED BY COMPANY	3	6	13	8	16
SCREENING DEFICIENCY NOTICE	12	7	5	2	0
NC - HOLD (PATENT)	0	0	0	0	3

NC - SAFETY (90)					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NO OBJECTION LETTER	112	81	97	88	78
NOT SATISFACTORY NOTICE	0	2	0	0	0
REJECTION LETTER (SCR)	5	1	0	0	0
CANCELLED BY COMPANY	4	4	3	6	5
SCREENING DEFICIENCY NOTICE	1	1	1	1	0
NC - HOLD (PATENT)	0	1	0	0	0

NC - SAFETY (120)					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NO OBJECTION LETTER	12	15	12	12	6
NOT SATISFACTORY NOTICE	0	2	1	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	1	0
CANCELLED BY COMPANY	1	1	1	2	2

NC - ADMINISTRATIVE					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NO OBJECTION LETTER	43	30	22	9	5

REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

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

NC					
	Year of Reconsideration Request				
	14-15	**15-16**	**16-17**	**17-18**	**18-19**
Total	**0**	**0**	**0**	**0**	**0**

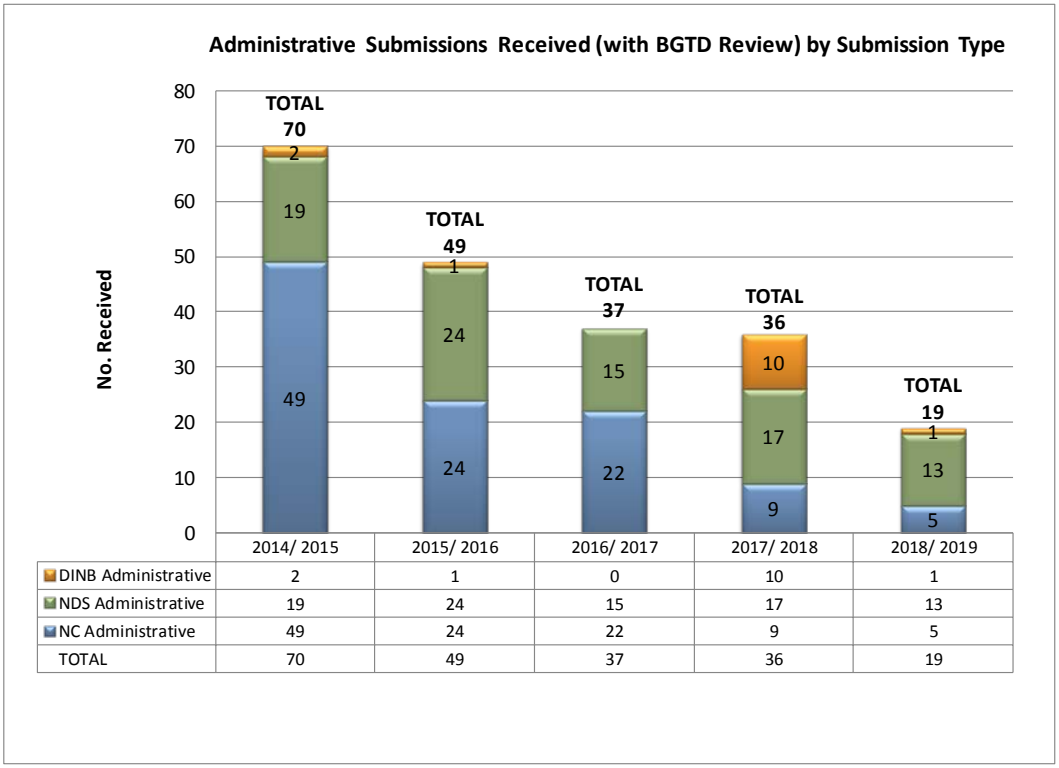
Administrative Submissions

Submissions in support of a manufacturer or product name change.

ADMINISTRATIVE SUBMISSIONS (BGTD)

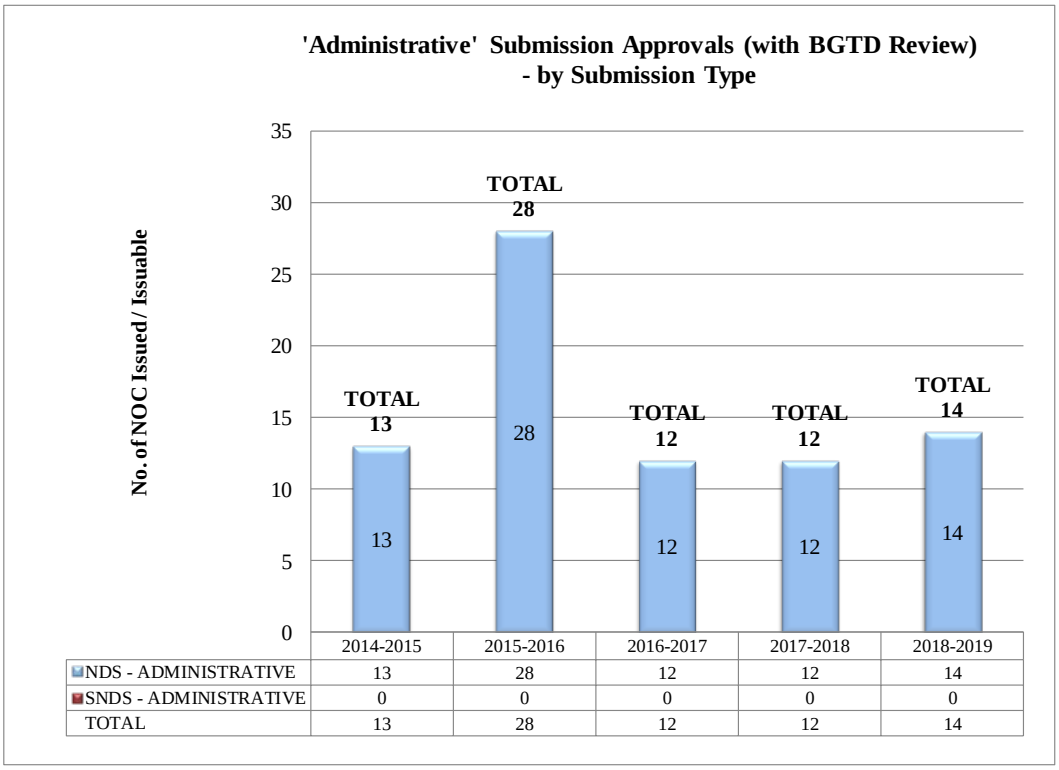
(e.g. product name changes that require a drug name review)

Administrative Submissions Received (with BGTD review)



	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
DINB Administrative	2	1	0	10	1
NDS Administrative	19	24	15	17	13
NC Administrative	49	24	22	9	5
TOTAL	70	49	37	36	19

Administrative Submission Approvals (with BGTD Review)

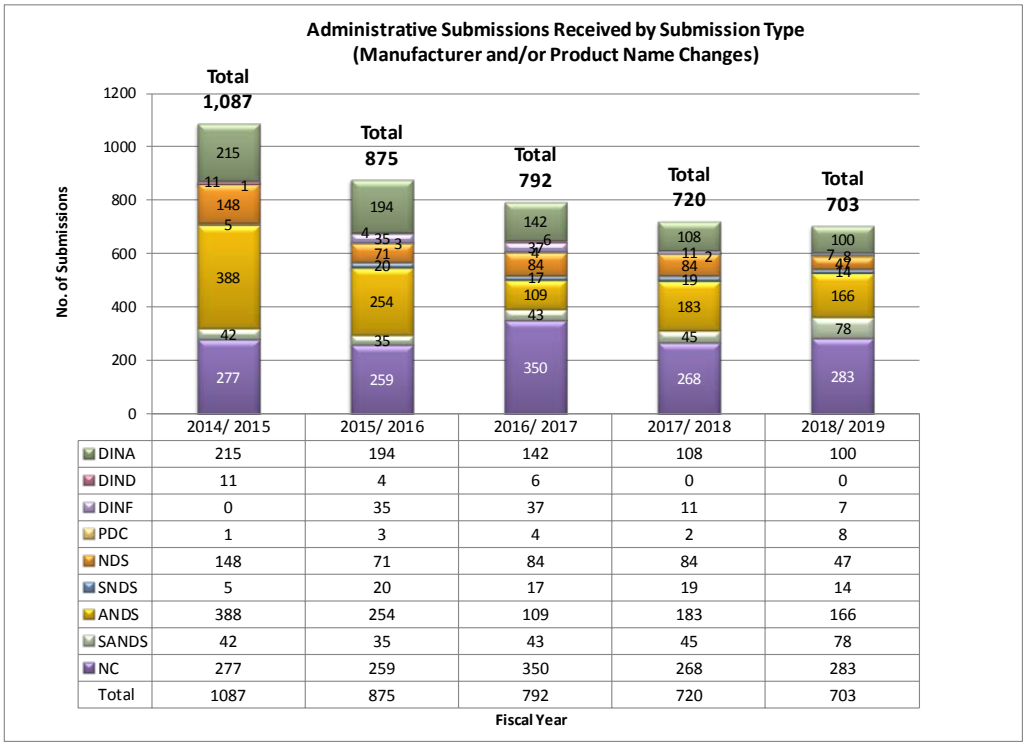


	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
NDS - ADMINISTRATIVE	13	28	12	12	14
SNDS - ADMINISTRATIVE	0	0	0	0	0
TOTAL	13	28	12	12	14

ADMINISTRATIVE SUBMISSIONS

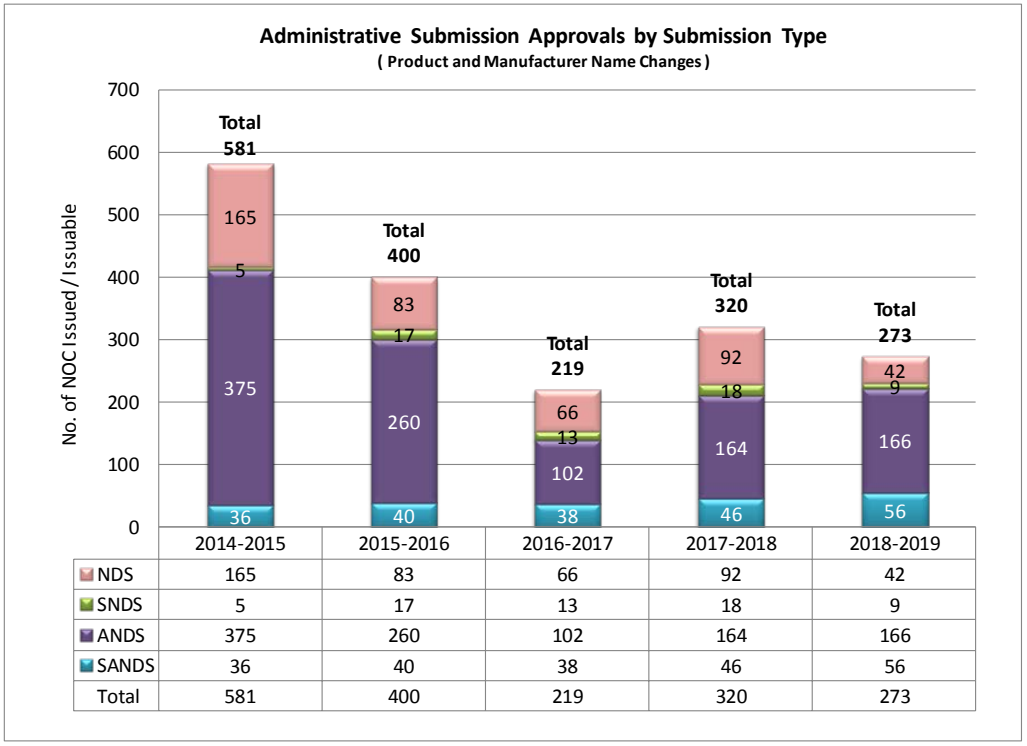
(Manufacturer and/or Product Name Changes) [13]

Administrative Submissions Received by Submission Type



	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
DINA	215	194	142	108	100
DIND	11	4	6	0	0
DINF	0	35	37	11	7
PDC	1	3	4	2	8
NDS	148	71	84	84	47
SNDS	5	20	17	19	14
ANDS	388	254	109	183	166
SANDS	42	35	43	45	78
NC	277	259	350	268	283
Total	1087	875	792	720	703

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



	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
NDS	165	83	66	92	42
SNDS	5	17	13	18	9
ANDS	375	260	102	164	166
SANDS	36	40	38	46	56
Total	581	400	219	320	273

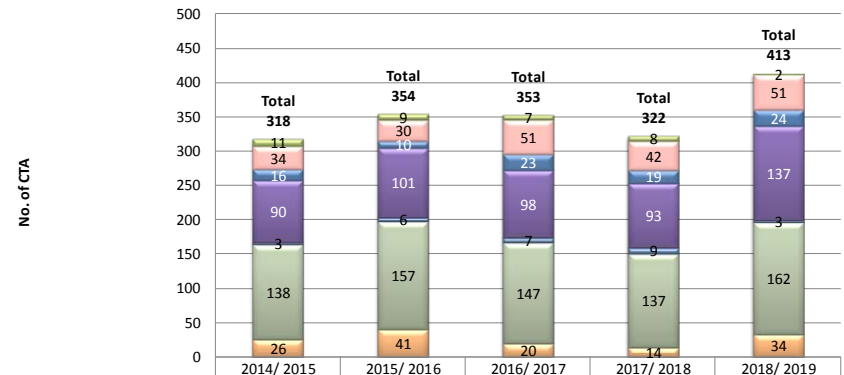
[13] The screening functions for Administrative submissions and the review functions for Labelling Only submissions with an Administrative component were moved from the Office of Submissions and Intellectual Property (OSIP) to the labelling area of the Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD) at TPD in December 2018.

Clinical Trial Applications and Amendments

(CTA & CTA-A)

CLINICAL TRIAL APPLICATIONS

Number Received - Clinical Trial Application (CTA)

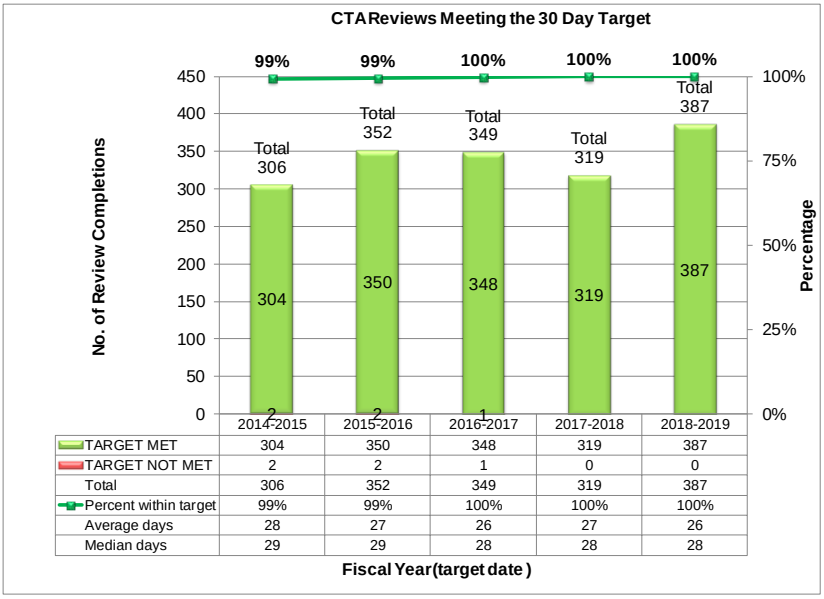


	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Phase 1 HEALTHY HUMAN-30	11	9	7	8	2
Phase 1 OTHER - 30 DAYS	34	30	51	42	51
Phase 1/2 - 30 DAYS	16	10	23	19	24
Phase 2 - 30 DAYS	90	101	98	93	137
PHASE 2/3 - 30 DAYS	3	6	7	9	3
Phase 3 - 30 DAYS	138	157	147	137	162
Phase Other	26	41	20	14	34
Total	318	354	353	322	413

Decision Documents - Clinical Trial Application (CTA)

CTA (30 day target)					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NO OBJECTION LETTER	283	336	328	307	380
CANCELLED BY COMPANY DURING REVIEW	18	10	21	12	7
CANCELLED BY COMPANY AT PROCESSING	5	2	10	6	6
NOT SATISFACTORY NOTICE	4	3	0	0	1
REJECTION LETTER (SCR)	1	1	1	0	2
SCREENING DEFICIENCY NOTICE	0	3	0	0	0

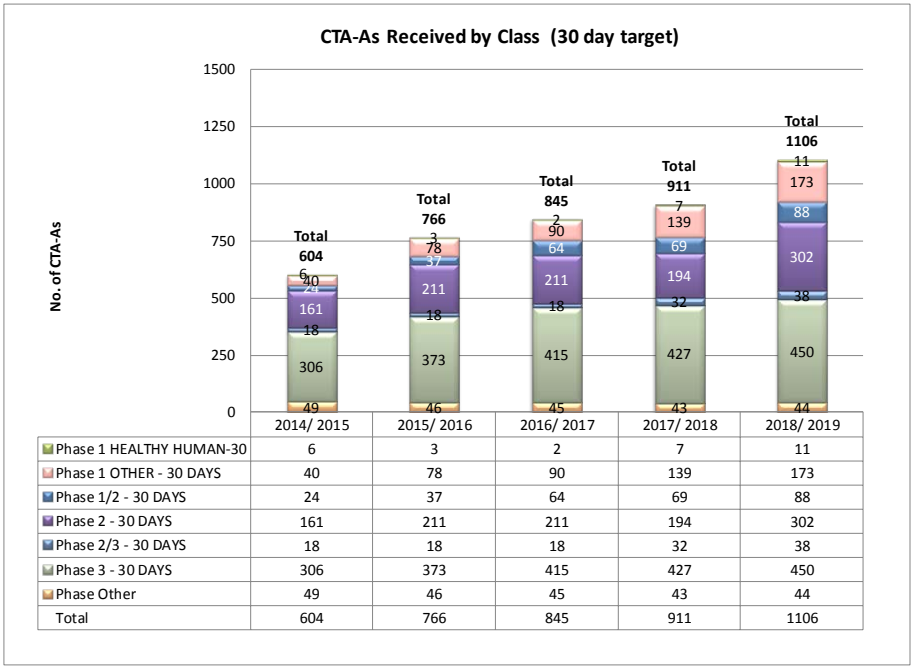
Performance - Clinical Trials Applications (CTA) Reviews Meeting the 30 Day Target



	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
TARGET MET	304	350	348	319	387
TARGET NOT MET	2	2	1	0	0
Total	306	352	349	319	387
Percent within target	99%	99%	100%	100%	100%
Average days	28	27	26	27	26
Median days	29	29	28	28	28

CLINICAL TRIAL APPLICATION-AMENDMENTS

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

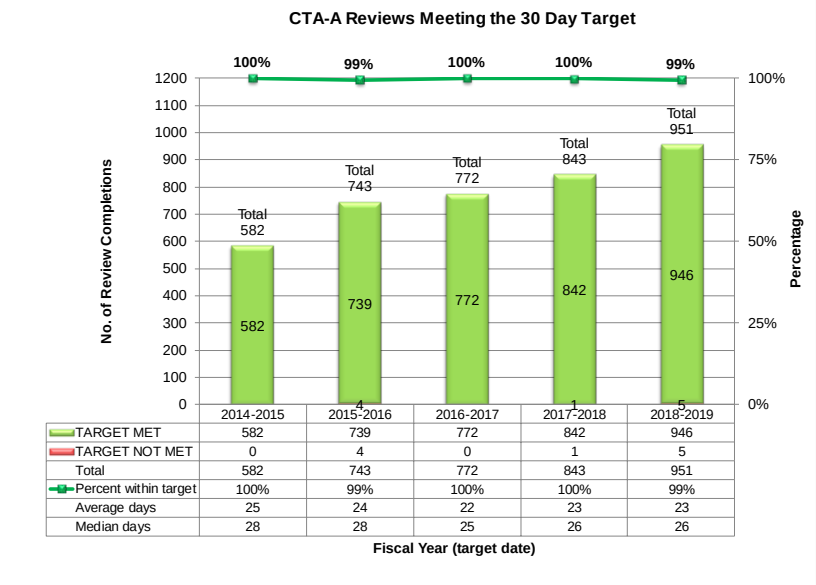


	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Phase 1 HEALTHY HUMAN-30	6	3	2	7	11
Phase 1 OTHER - 30 DAYS	40	78	90	139	173
Phase 1/2 - 30 DAYS	24	37	64	69	88
Phase 2 - 30 DAYS	161	211	211	194	302
Phase 2/3 - 30 DAYS	18	18	18	32	38
Phase 3 - 30 DAYS	306	373	415	427	450
Phase Other	49	46	45	43	44
Total	604	766	845	911	1106

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

CTA-A (30 day target)					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NO OBJECTION LETTER	574	747	794	869	1048
CANCELLED BY COMPANY DURING REVIEW	8	5	7	15	4
CANCELLED BY COMPANY AT PROCESSING	6	2	10	9	9
NOT SATISFACTORY NOTICE	0	2	0	0	0
REJECTION LETTER (SCR)	5	10	15	15	20

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



	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
TARGET MET	582	739	772	842	946
TARGET NOT MET	0	4	0	1	5
Total	582	743	772	843	951
Percent within target	100%	99%	100%	100%	99%
Average days	25	24	22	23	23
Median days	28	28	25	26	26

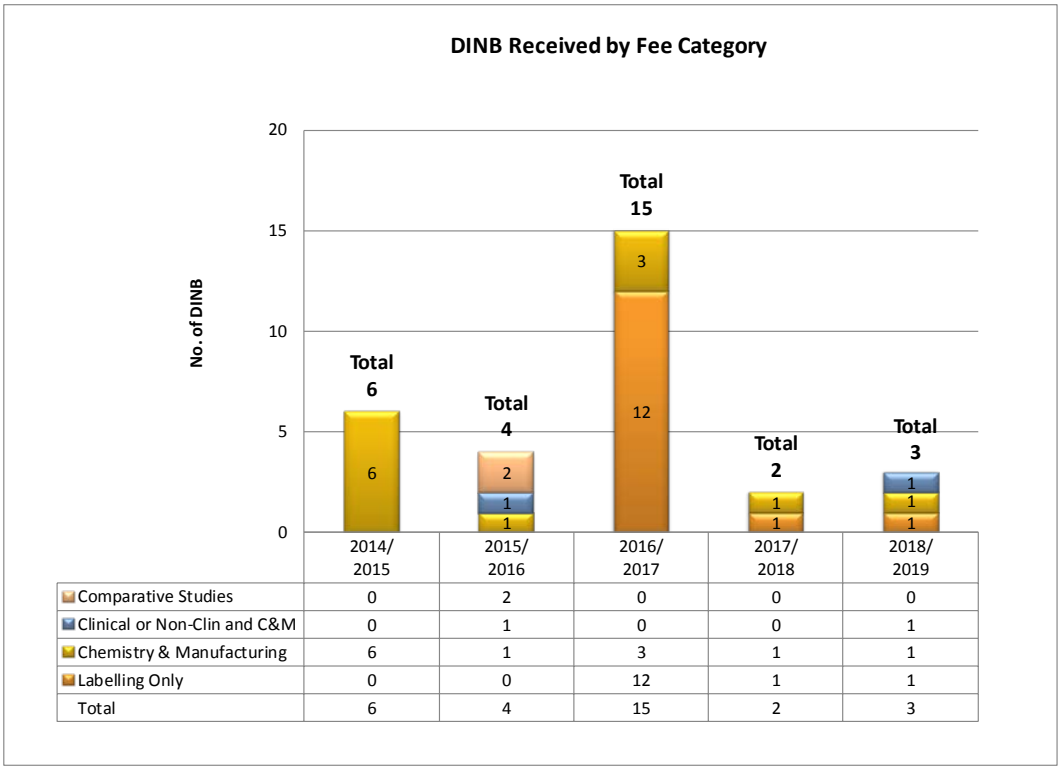
Application for a Drug Identification Number

DINB

Biological Products

DINB: Application for a Drug Identification Number – BIOLOGICAL Products

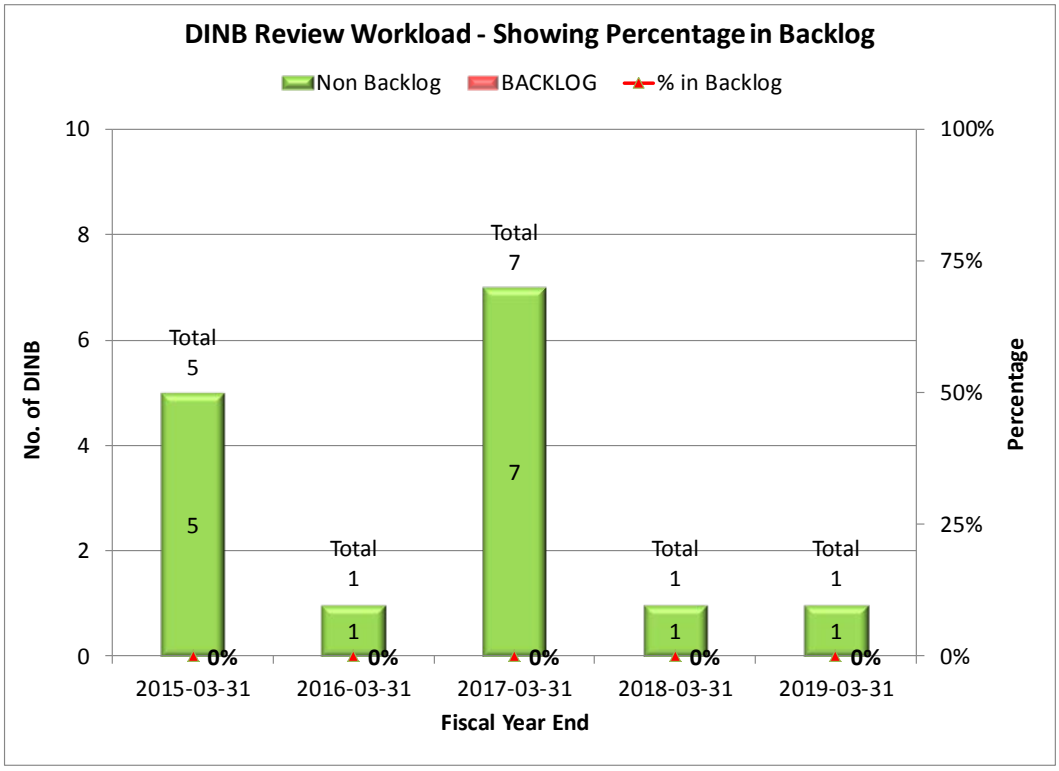
DINB: Number Received



	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Comparative Studies	0	2	0	0	0
Clinical or Non-Clin and C&M	0	1	0	0	1
Chemistry & Manufacturing	6	1	3	1	1
Labelling Only	0	0	12	1	1
Total	6	4	15	2	3

REVIEW WORKLOAD

DINB: Review Workload Showing Percentage in Backlog

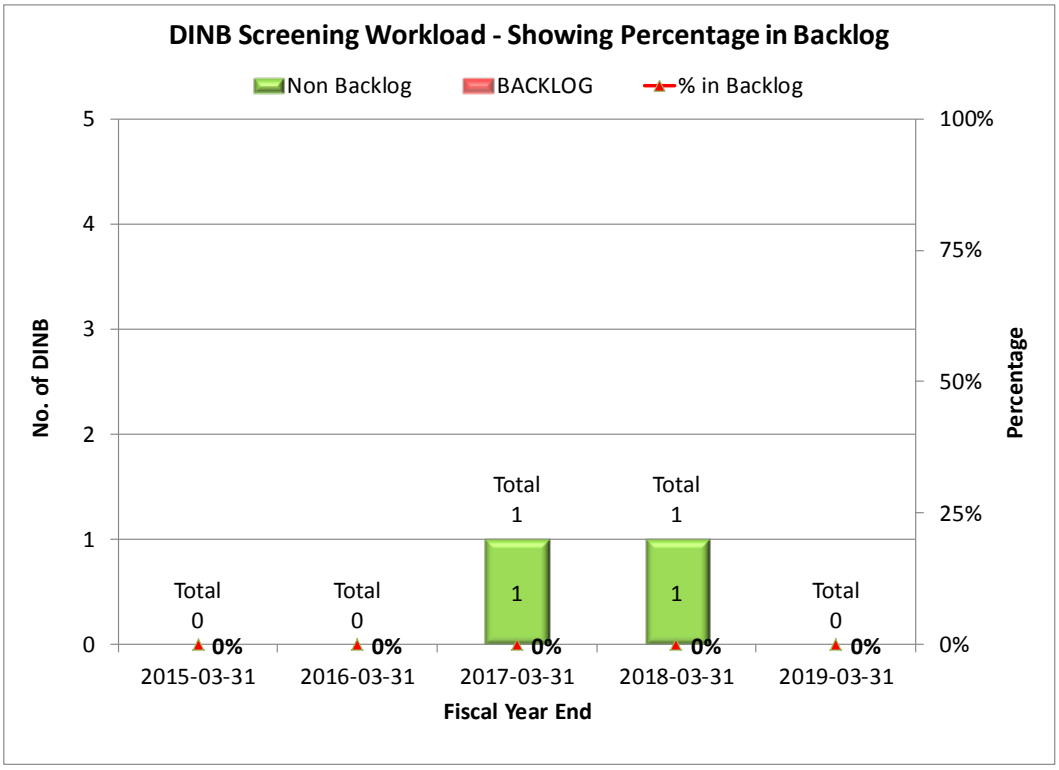


DINB: Review Workload by Class

DINB All REVIEW WORKLOAD BY FEE CATEGORY - BGTD (excluding administrative) and Fiscal Year End					
	2015-03-31	2016-03-31	2017-03-31	2018-03-31	2019-03-31
Labelling Only	**0**	**0**	**6**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**5**	**1**	**1**	**0**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**5**	**1**	**7**	**1**	**1**
Non Backlog	**5**	**1**	**7**	**1**	**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					
	2015-03-31	2016-03-31	2017-03-31	2018-03-31	2019-03-31
Labelling Only	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**0**	**0**	**1**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**0**	**0**	**1**	**1**	**0**
Non Backlog	0	0	1	1	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DECISION DOCUMENTS

DINB: Decision Documents by Class

DINB - LABELLING ONLY					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NO OBJECTION LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	0	0	6	6	0

DINB - CHEMISTRY & MANUFACTURING					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NO OBJECTION LETTER	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTIFICATION FORM DIN SUB	1	0	0	1	0
SCREENING DEFICIENCY NOTICE	6	0	0	1	0
CANCELLED BY COMPANY	0	0	0	0	0

DINB - CLIN/C&M					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NO OBJECTION LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	2	0	0	0	0
CANCELLED BY COMPANY	0	1	0	0	0

DINB - ADMINISTRATIVE					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NOTIFICATION FORM/DIN ISSUED	2	0	0	0	0
CANCELLED BY COMPANY	0	0	0	1	0

DINB - COMPARATIVE STUDIES					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
REJECTION LETTER (SCREENING)	0	1	0	0	0
SCREENING DEFICIENCY NOTICE	0	1	0	0	0

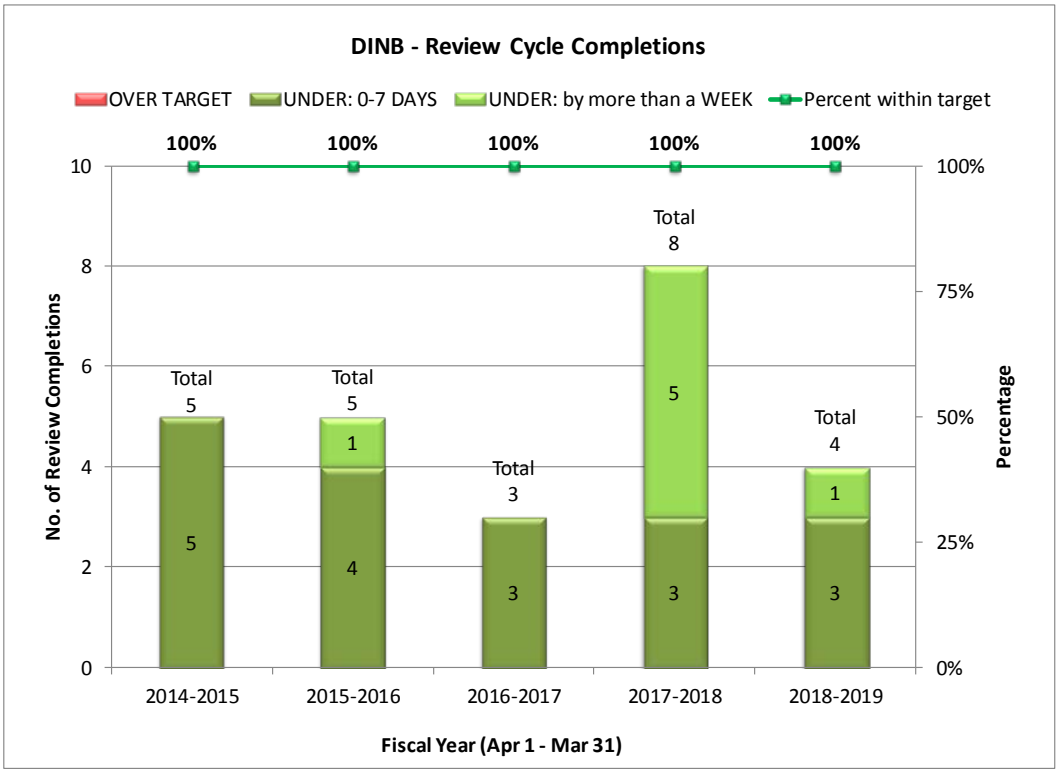
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

DINB: Requests for Reconsideration of Final Decisions

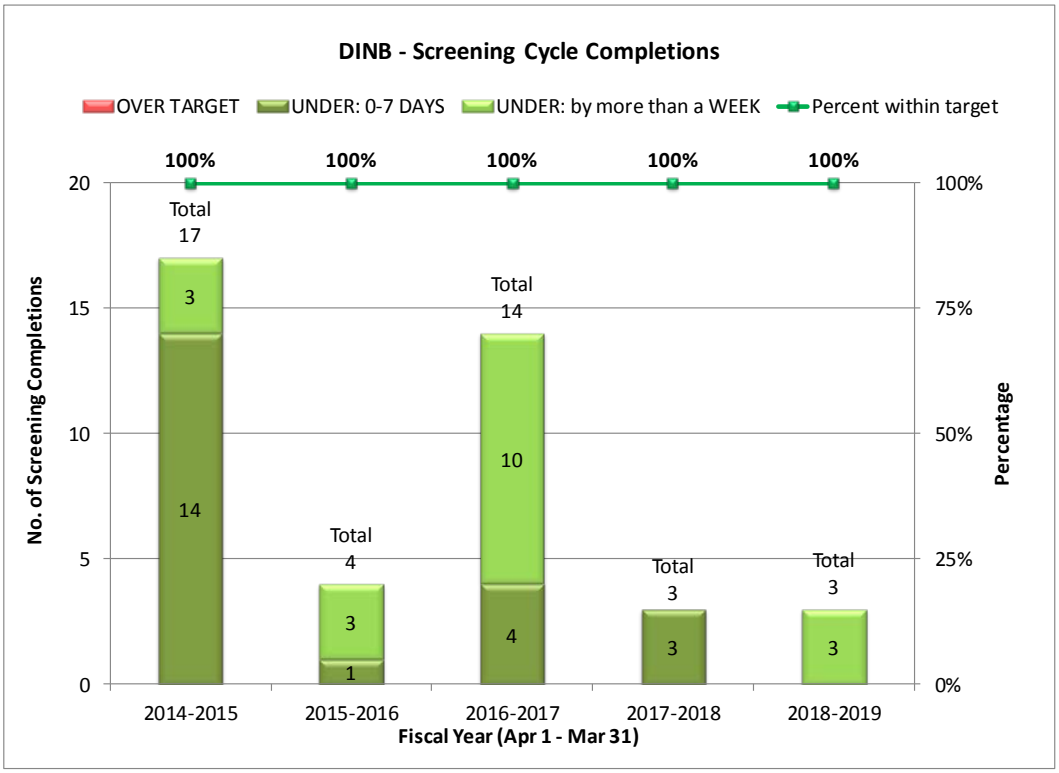
DINB					
	Year of Reconsideration Request				
	14-15	**15-16**	**16-17**	**17-18**	**18-19**
Total	**0**	**0**	**0**	**0**	**0**

PERFORMANCE

DINB: Review Cycle Completions

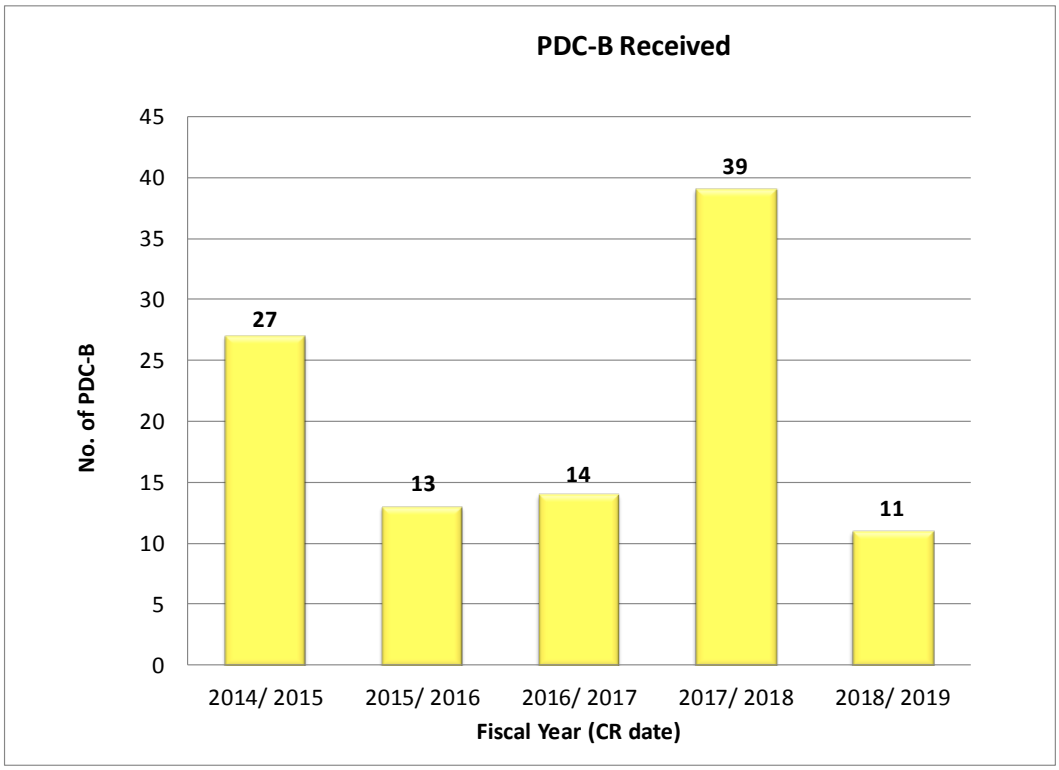


DINB: Screening Cycle Completions



PDC-B: Post Authorization Division 1 Changes - Biologics

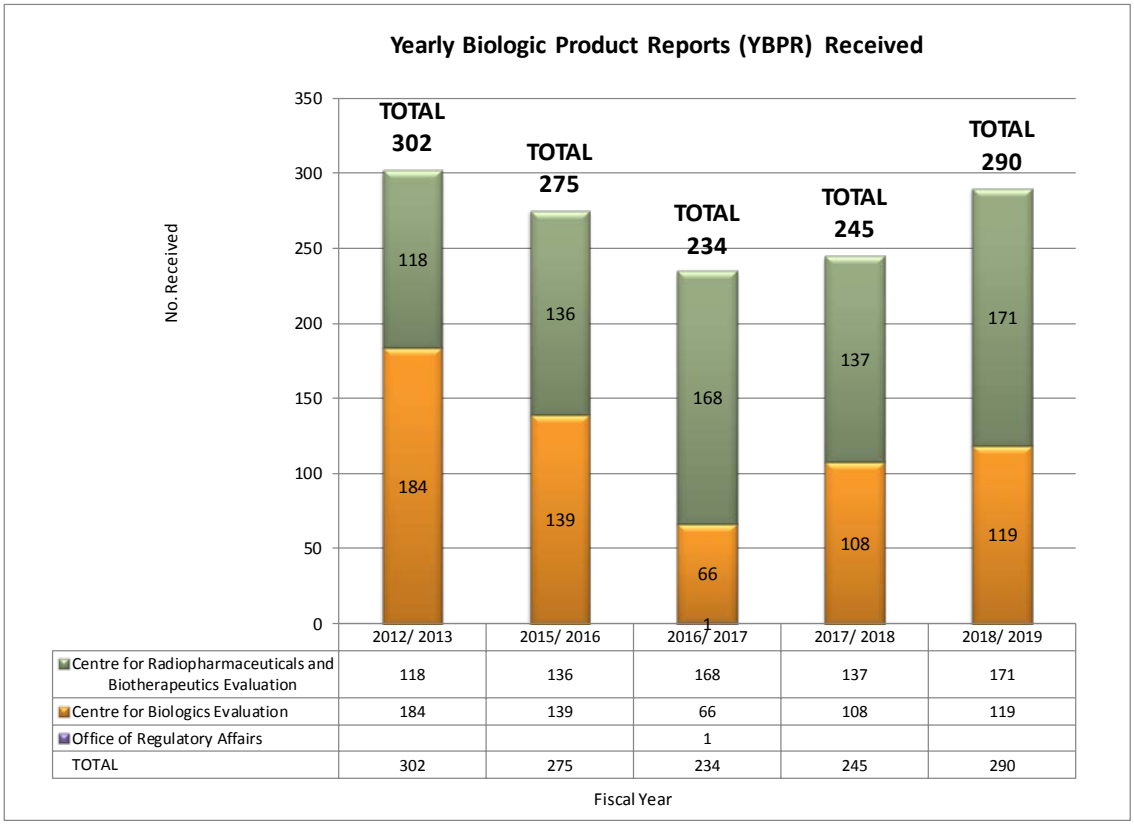
PDC-B: Post Authorization Division 1 Changes- Biologics Received



YBPR: Yearly Biologic Product Reports

[14]

Yearly Biologic Product Reports (YBPR) Received



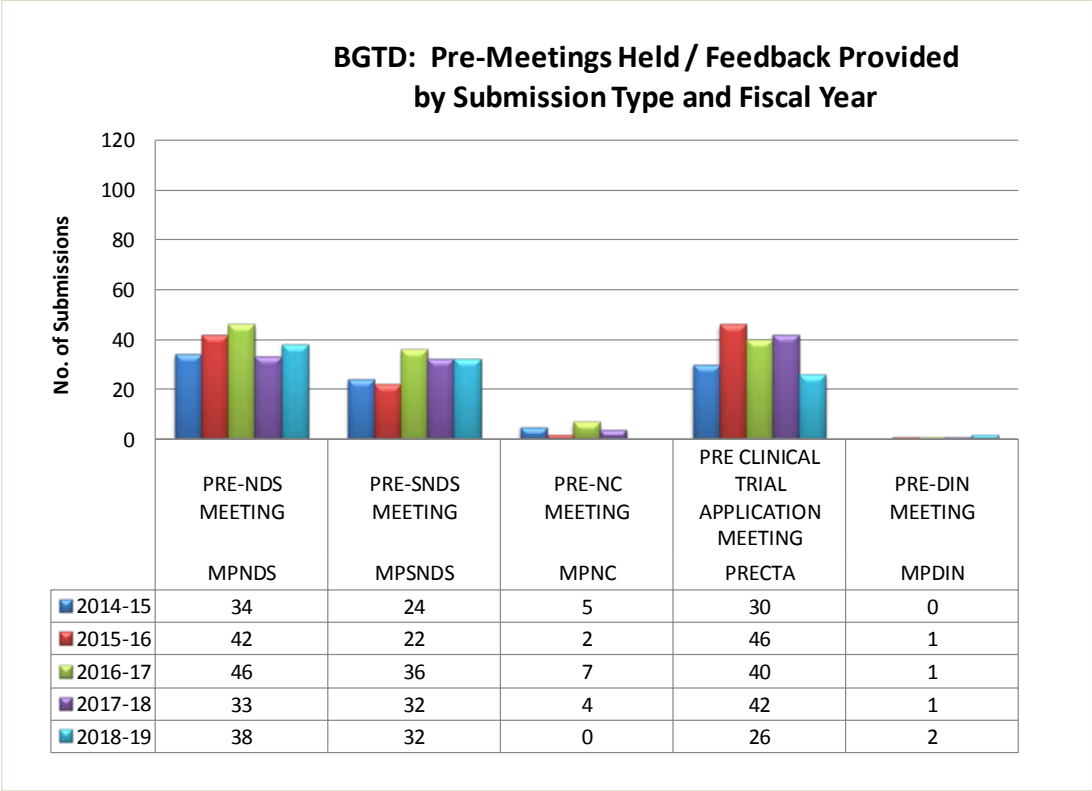
	2012/ 2013	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Centre for Radiopharmaceuticals and Biotherapeutics Evaluation	118	136	168	137	171
Centre for Biologics Evaluation	184	139	66	108	119
Office of Regulatory Affairs			1		
TOTAL	302	275	234	245	290

[14] 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

[15]

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
2014-15	34	24	5	30	0
2015-16	42	22	2	46	1
2016-17	46	36	7	40	1
2017-18	33	32	4	42	1
2018-19	38	32	0	26	2

[15] 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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