



Santé
Canada Health
Canada

Biologics and Genetic Therapies Directorate

Drug Submission Performance Annual
Report

Fiscal Year

2018-2019

April 1 2018 – March 31 2019



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 review¹ 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.

Approvals² 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
Finance Building, A.L. # 0202A1
101 Tunney’s Pasture Driveway, Tunney’s Pasture
Ottawa, Ontario, K1A 0K9

Tel: (613) 941-7281 Fax: (613) 941-0825

Email: hc.osip-bppi.sc@canada.ca

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 Only⁶	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
Administrative Submission⁷	Submissions in support of a manufacturer or product name change.
Disinfectants⁸	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)**

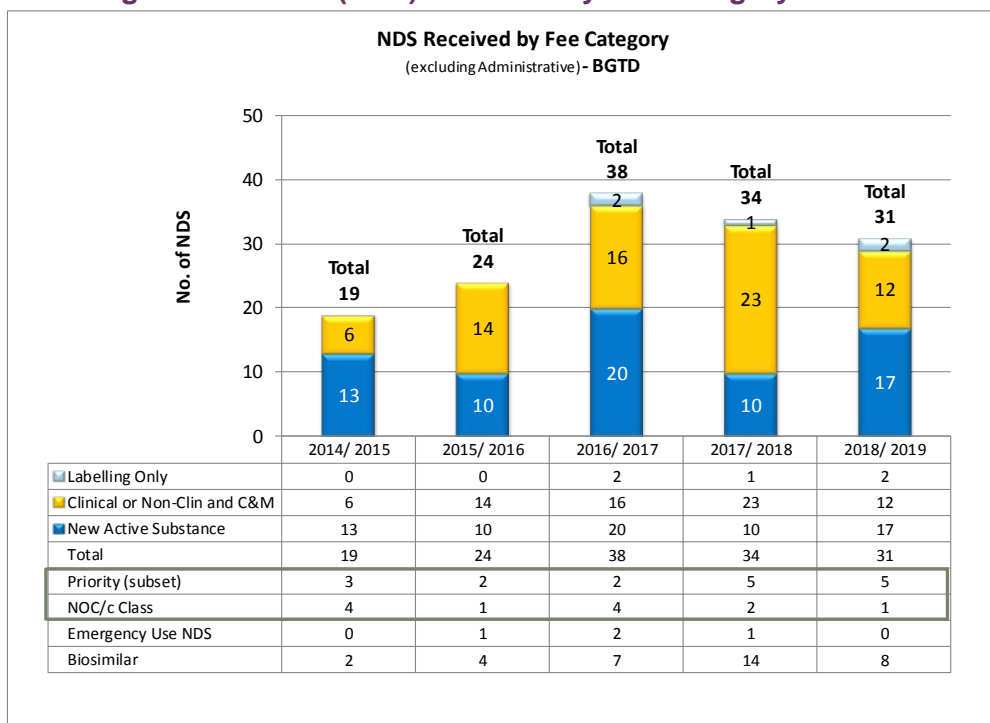
&

**Supplemental New Drug Submission
(SNDS)**

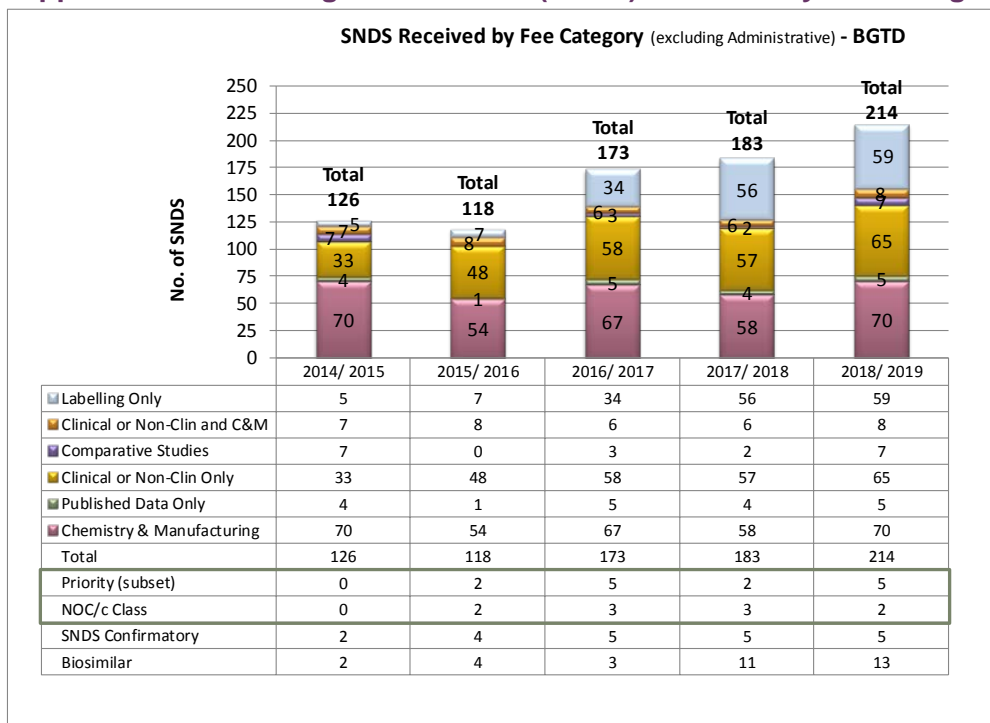
SUBMISSIONS RECEIVED

9 10

New Drug Submissions (NDS) Received by Fee Category



Supplemental New Drug Submissions (SNDS) Received by Fee Category

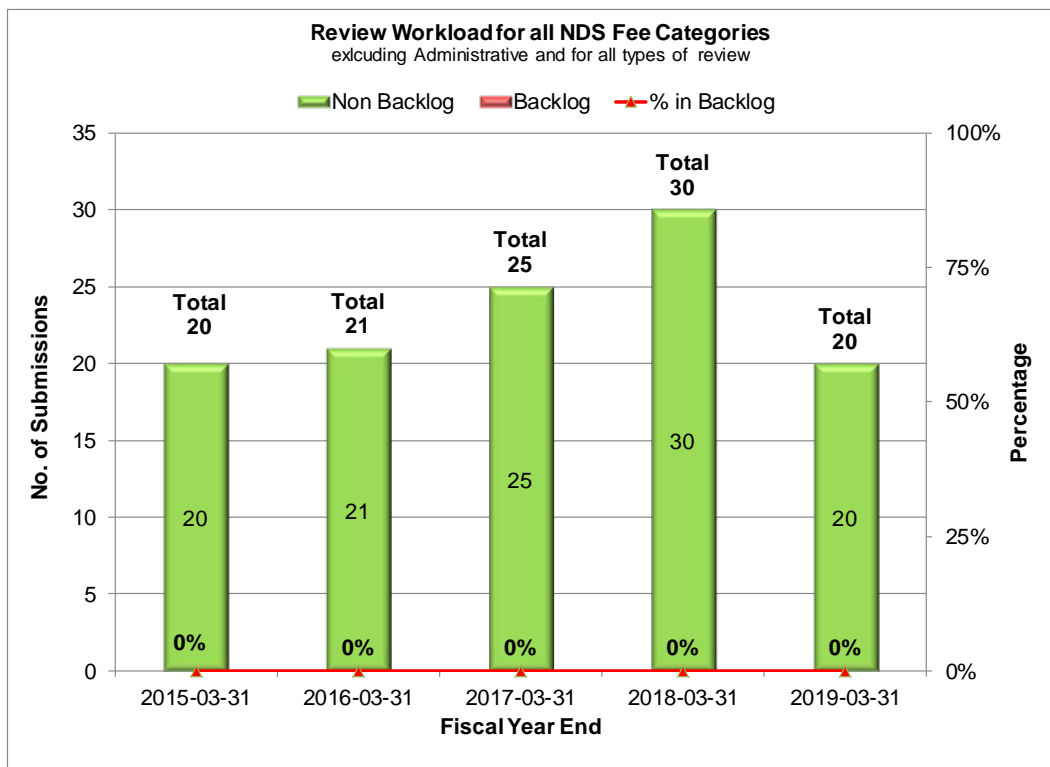


⁹ Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the [Priority Review of Drug Submissions Policy](#) , the [Notice of Compliance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

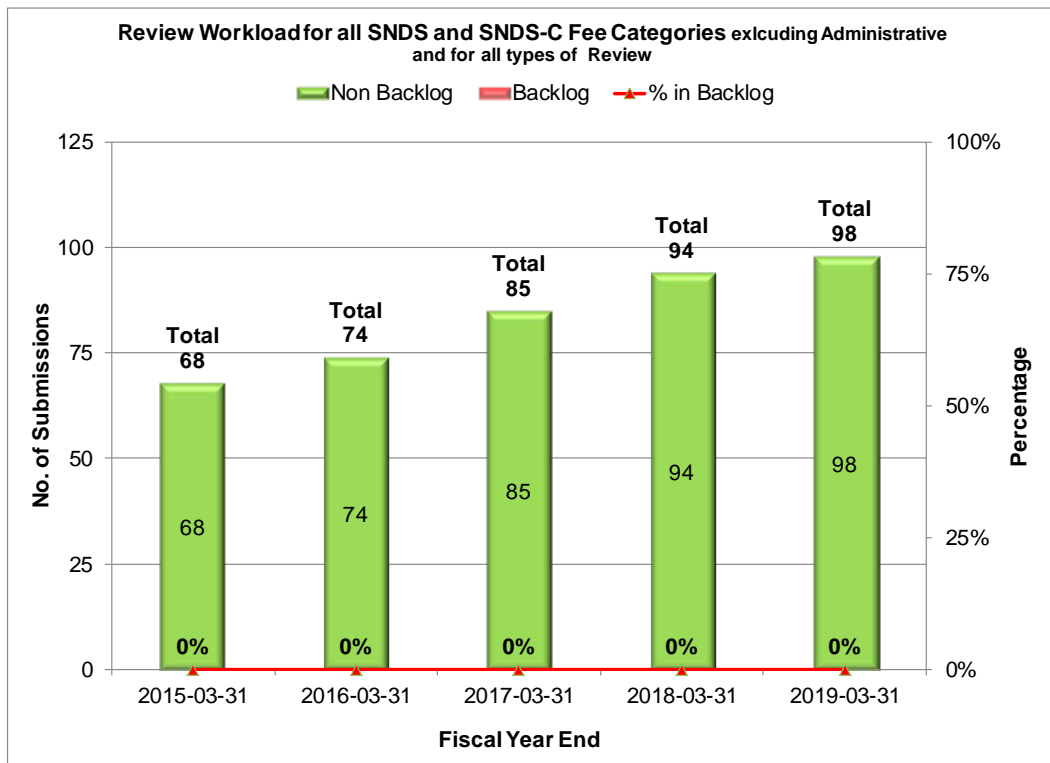
¹⁰ **Biosimilar:** A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration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

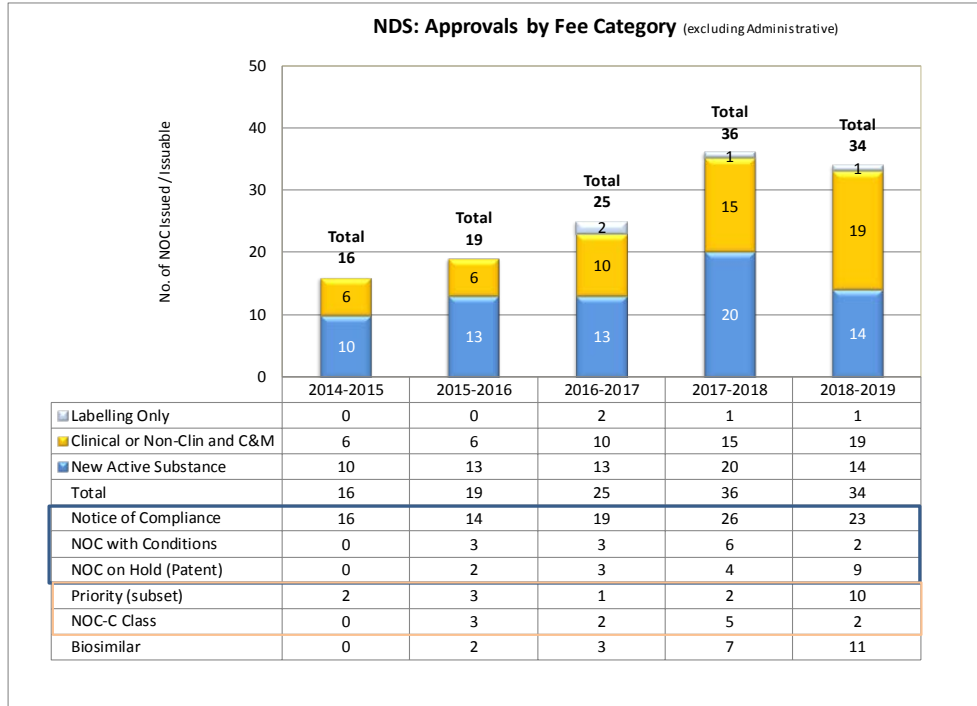
NDS All REVIEW WORKLOAD BY FEE CATEGORY - BGTD (excluding administrative) and Fiscal Year End					
	2015-03-31	2016-03-31	2017-03-31	2018-03-31	2019-03-31
Clinical or Non-Clin and C&M	8	11	11	21	10
<i>Backlog</i>	0	0	0	0	0
New Active Substance	12	10	14	9	10
<i>Backlog</i>	0	0	0	0	0
Total	20	21	25	30	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
<i>Backlog</i>	0	0	0	0	0

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

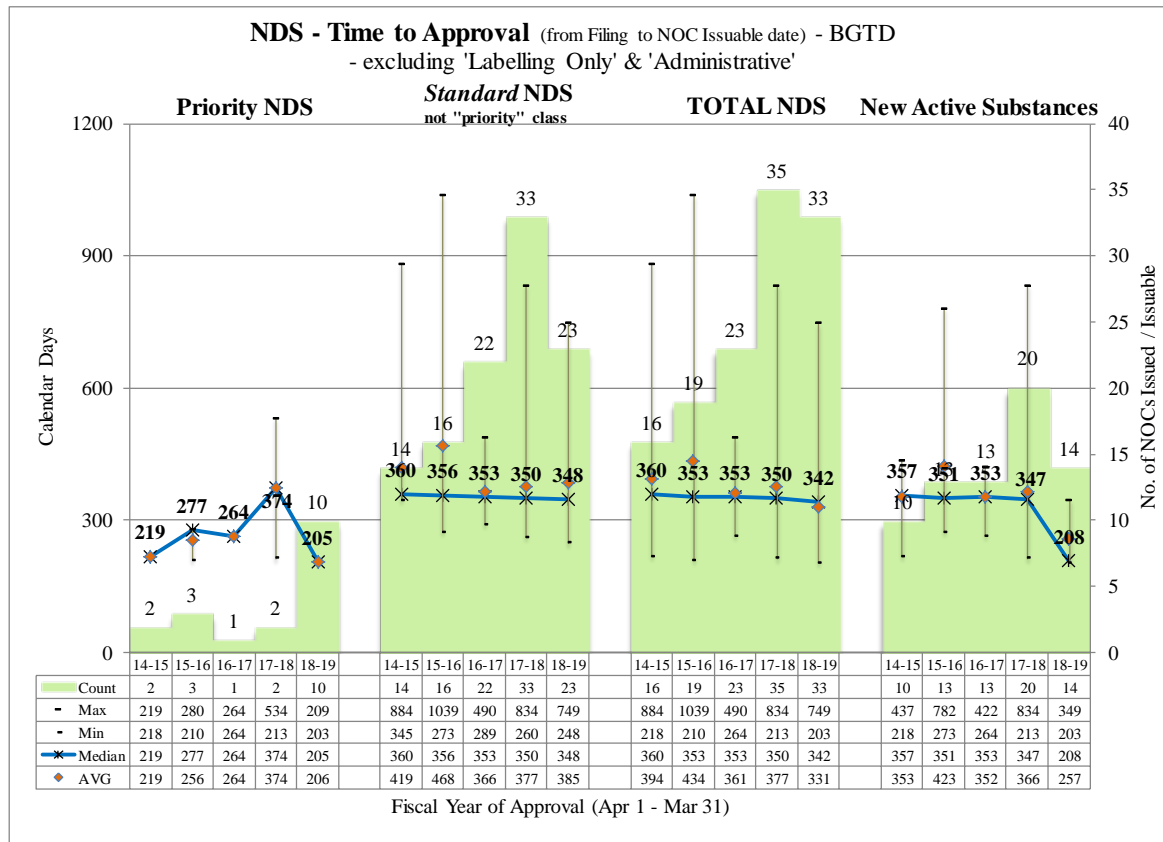
SNDS and SNDS-C All REVIEW WORKLOAD BY FEE CATEGORY - BGTD (excluding administrative) and Fiscal Year End					
	2015-03-31	2016-03-31	2017-03-31	2018-03-31	2019-03-31
Comparative Studies	3	0	1	1	4
<i>Backlog</i>	0	0	0	0	0
Chemistry & Manufacturing	32	25	28	26	26
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clin Only	25	37	44	54	49
<i>Backlog</i>	0	0	0	0	0
Published Data	3	1	3	2	3
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clin and C&M	5	10	4	4	6
<i>Backlog</i>	0	0	0	0	0
Labelling Only	0	1	5	7	10
<i>Backlog</i>	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
<i>Backlog</i>	0	0	0	0	0
SNDS-C (Confirmatory)	2	3	3	5	5
<i>Backlog</i>	0	0	0	0	0

APPROVALS

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



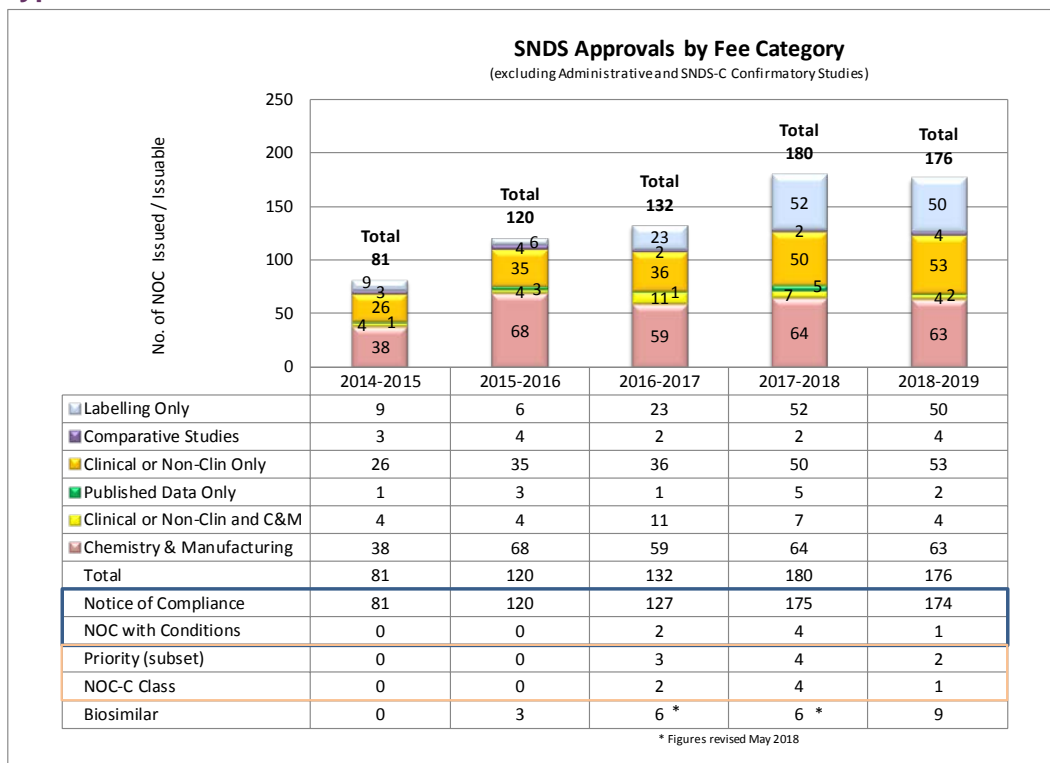
NDS Approval Times



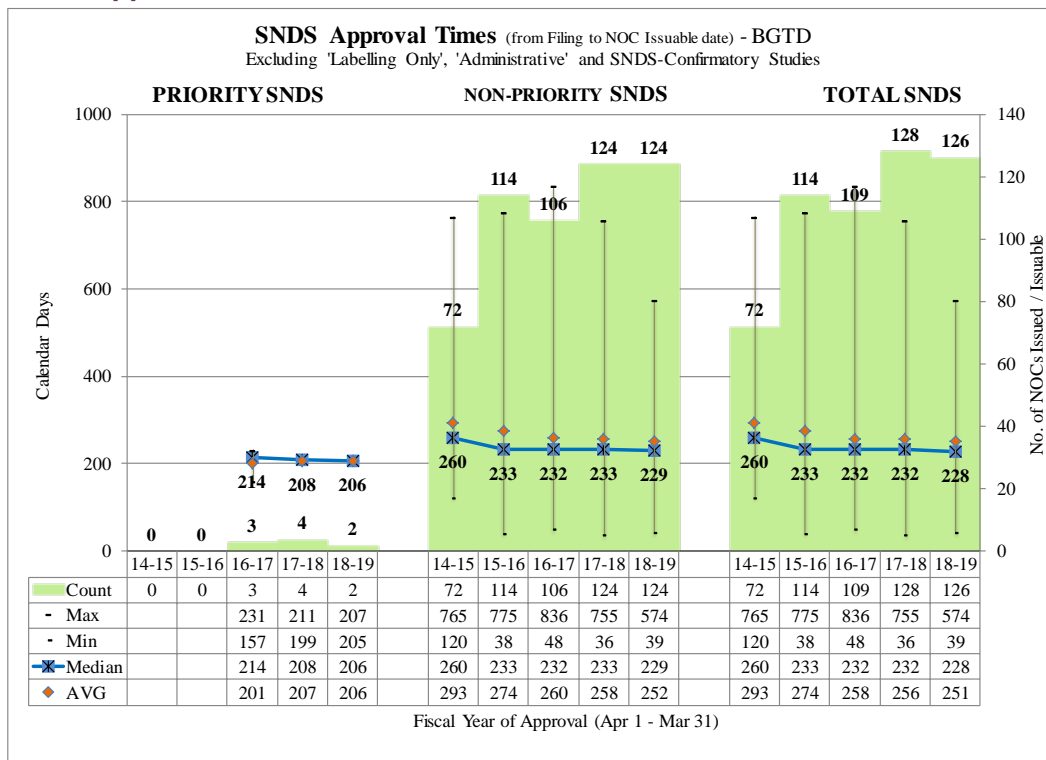
Approval Time is the total number of calendar days between the date a submission is filed (CR date) and the date it is approved (NOC Issuable). This includes time in processing, screening, review and any time taken by the company to respond to notices of deficiency or non-compliance.

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



SNDS Approval Times



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 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 Date¹¹)	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 Date¹¹)	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)
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
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
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 Date¹²)	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 (PPF), 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	

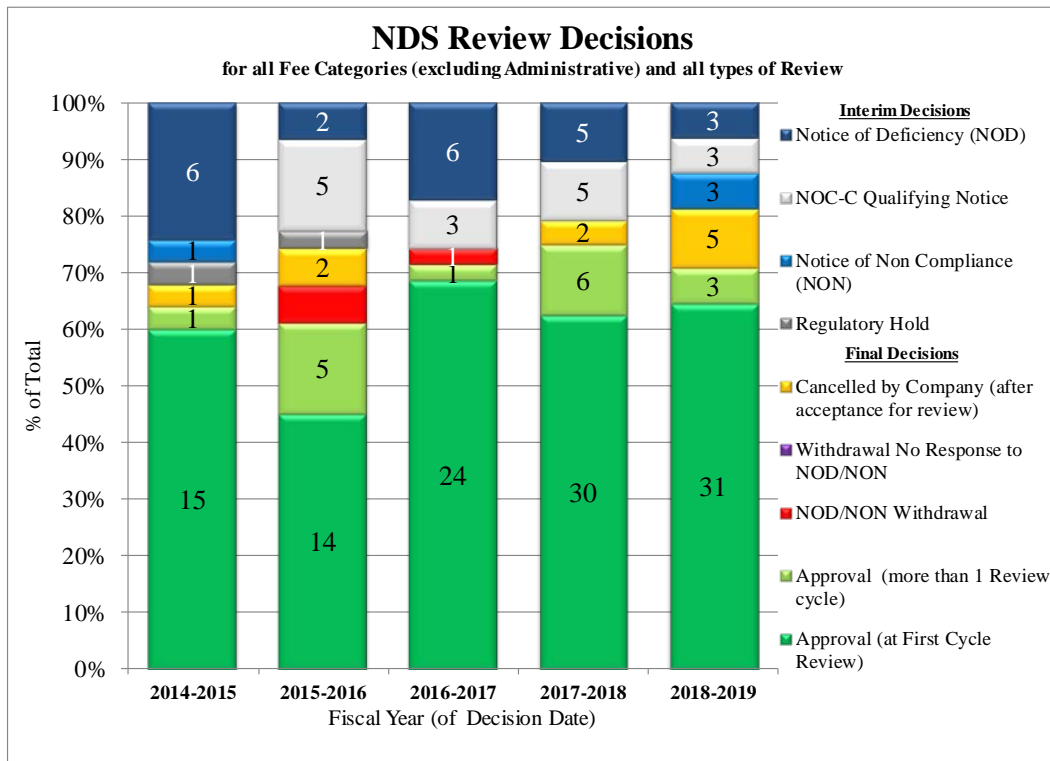
Please note: Approved Biosimilars that remain on Intellectual Property HOLD are not included.

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

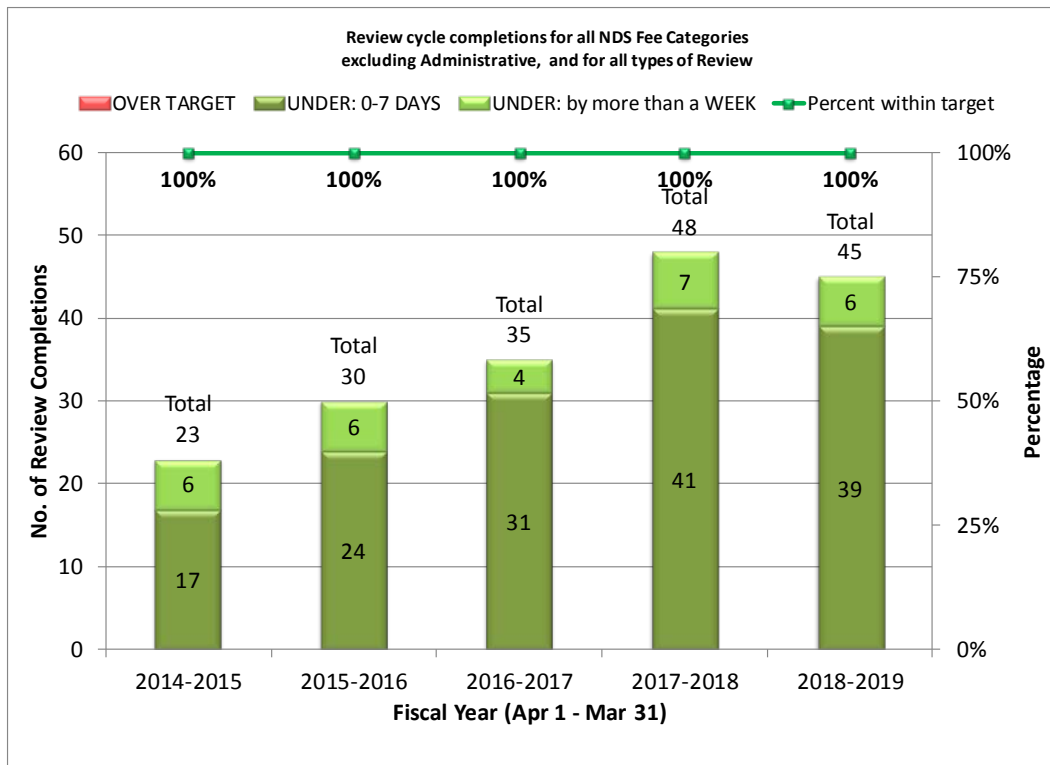
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REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

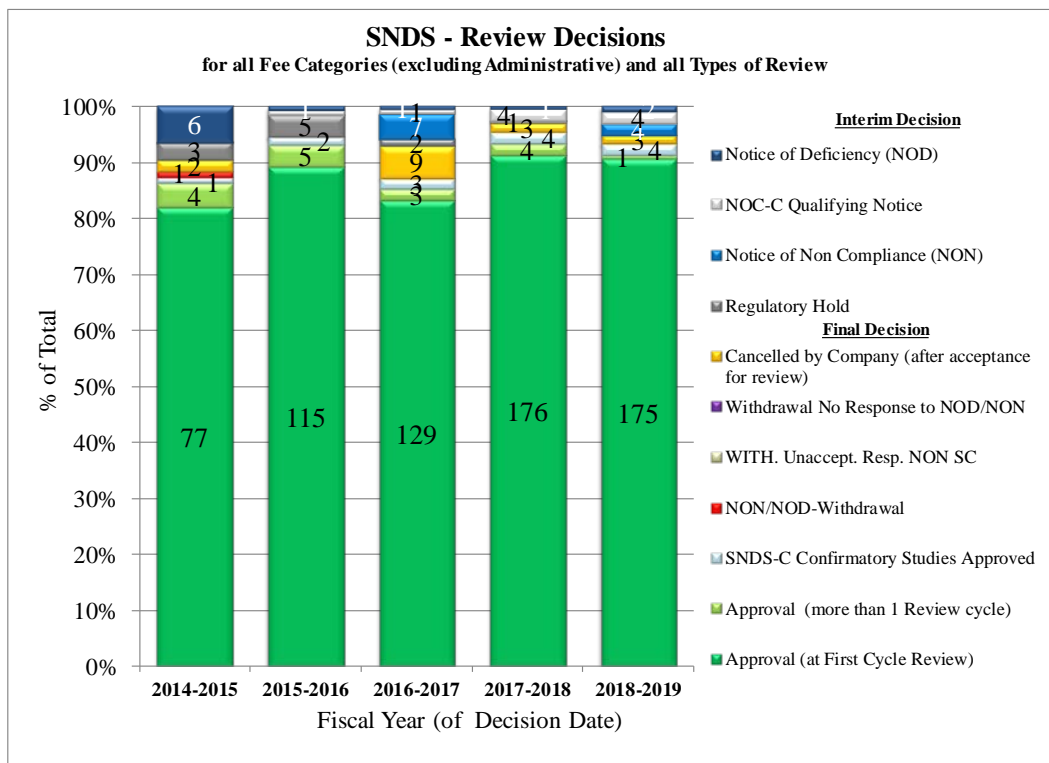


NDS: Review Cycle Completions Showing Percentage Within Target

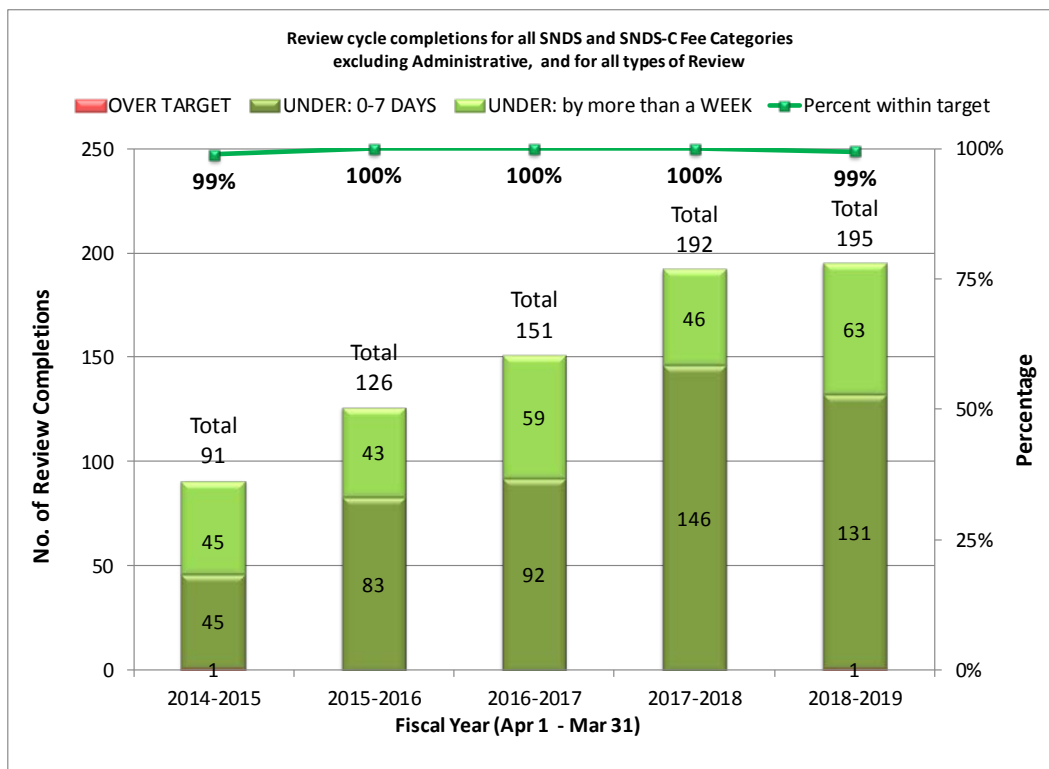


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

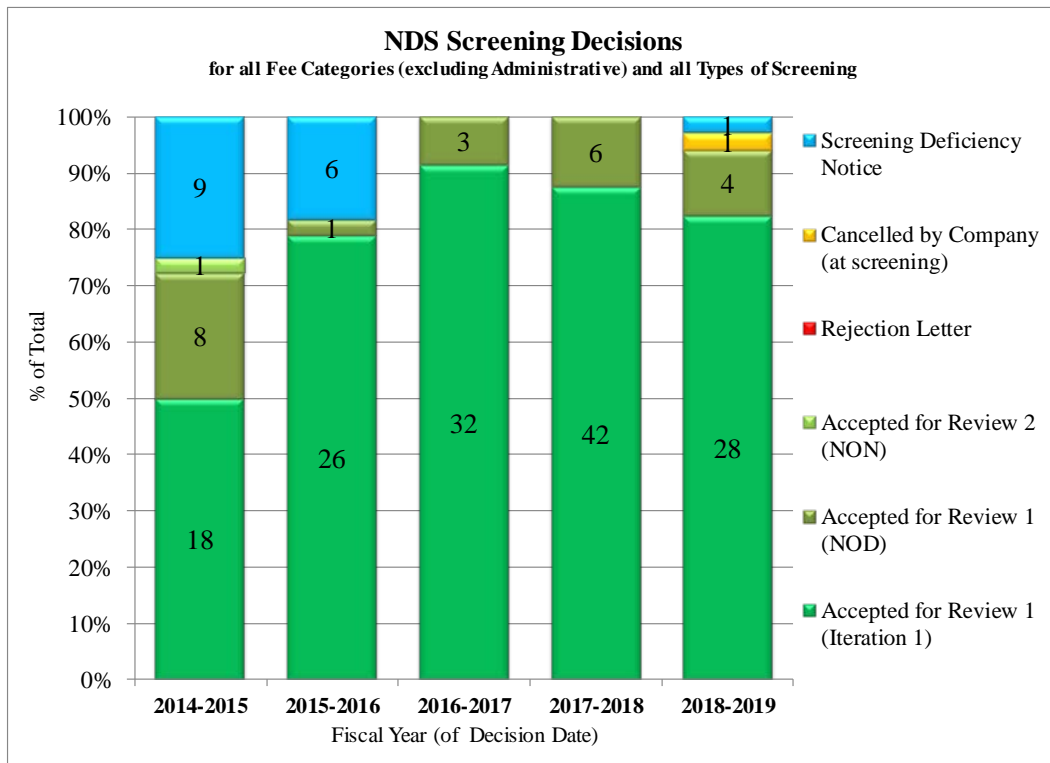


SNDS: Review Cycle Completions Showing Percentage Within Target

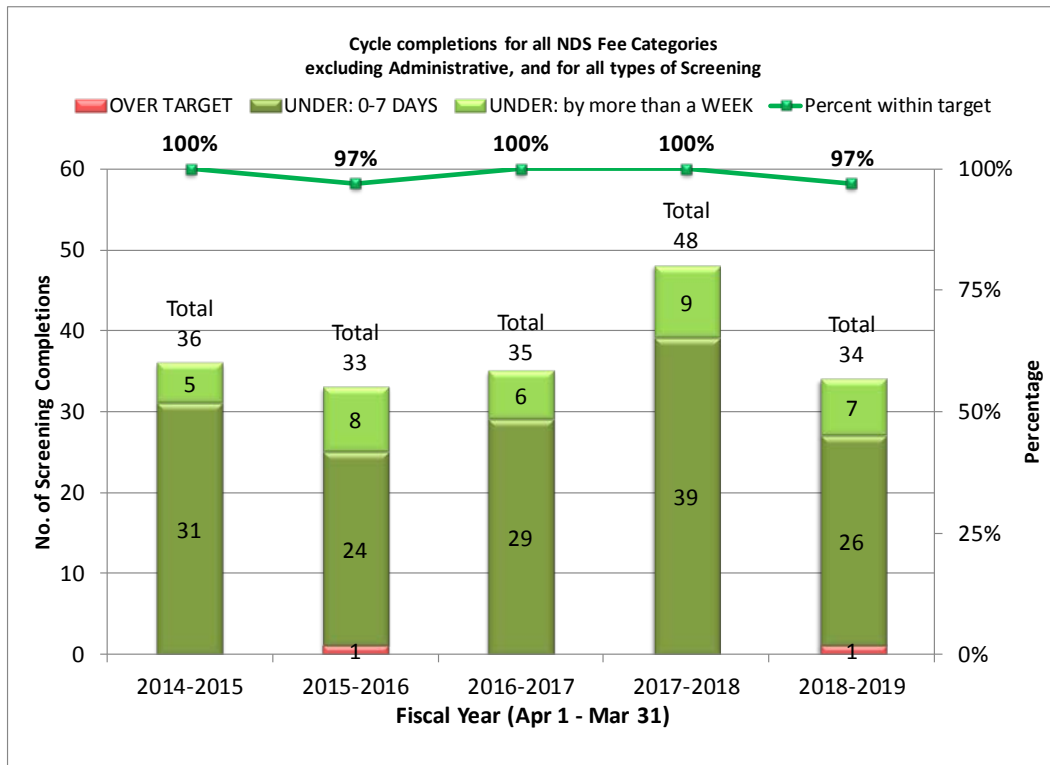


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

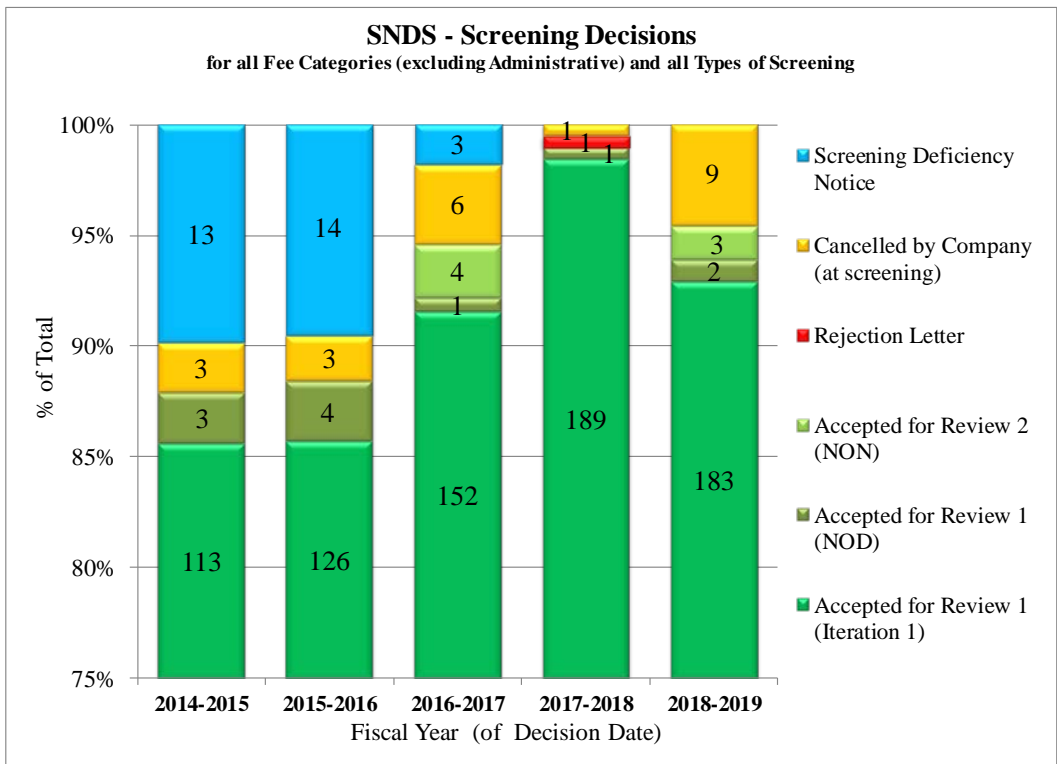


NDS: Screening Cycle Completions Showing Percentage Within Target

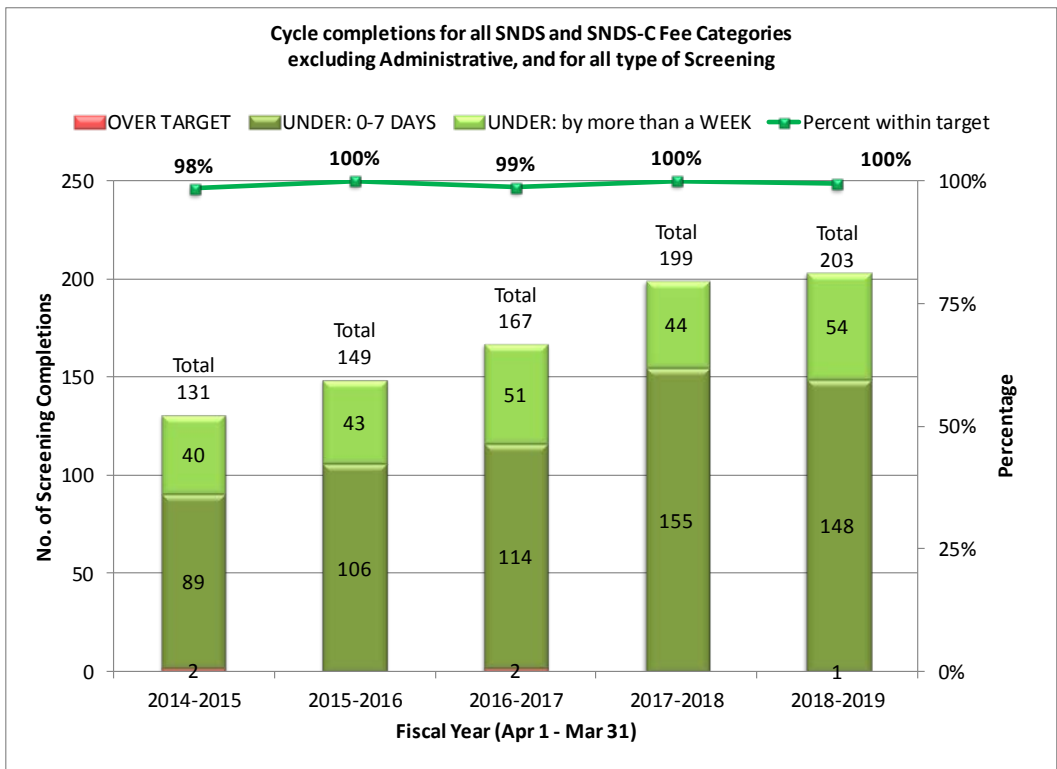


SCREENING CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Screening Decisions



SNDS: Screening Cycle Completions Showing Percentage Within Target



REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

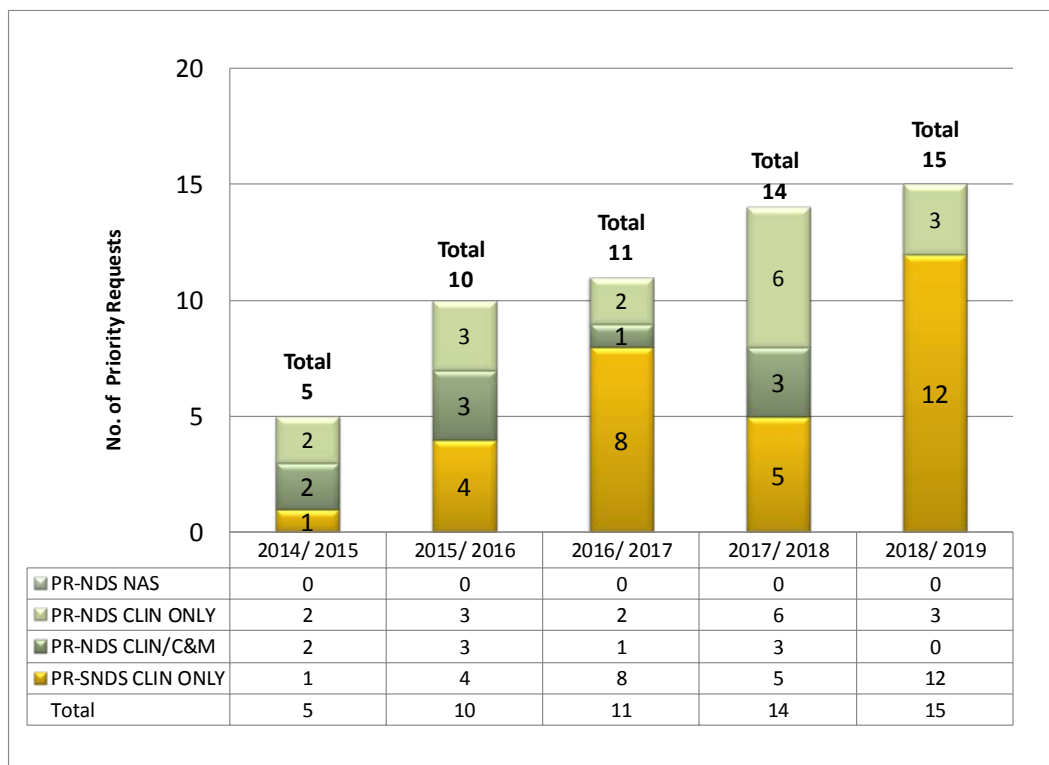
Requests for Reconsideration of Final Decisions –NDS, SNDS & ANDS

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		

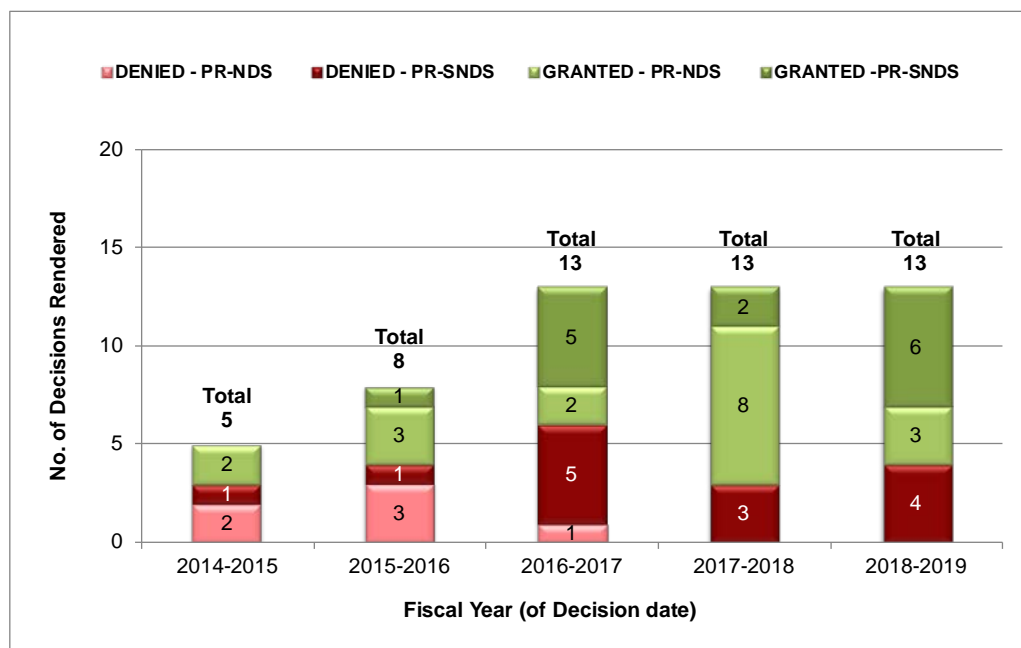
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PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests Received

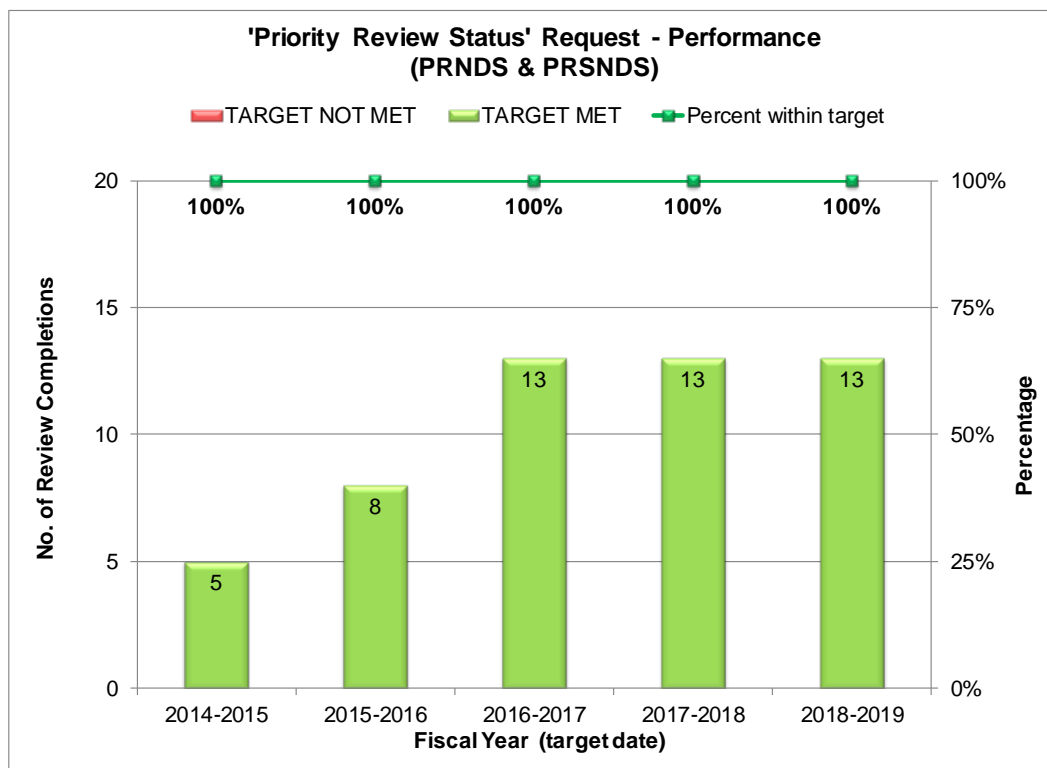


Priority Review Status Requests: Decisions Rendered



PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests: Performance



REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

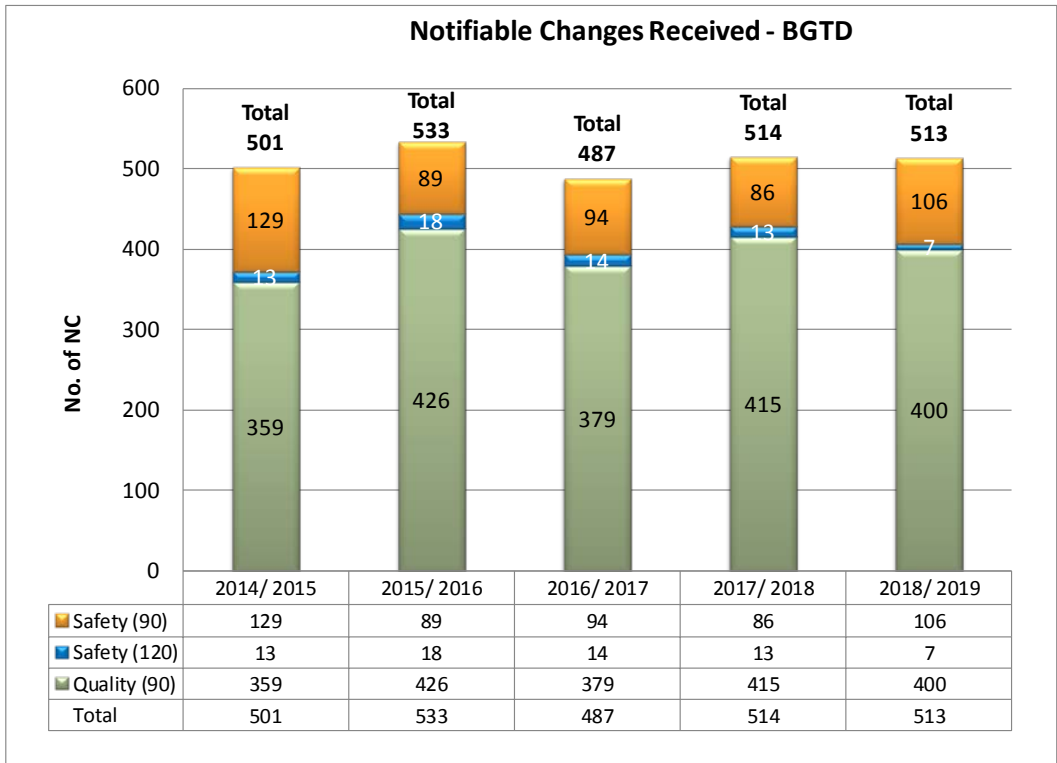
Requests for Reconsideration of Final Decisions – Priority Review Requests (for NDS and SNDS)

"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		
<i>Total Granted</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>		
<i>Total Pending</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>1</i>	PR-SNDS: Priority Review Request Denied	Rejected
<i>Total Denied</i>	<i>0</i>	<i>0</i>	<i>1</i>	<i>0</i>		PR-SNDS: Priority Review Request Denied	Rejected

NOTIFIABLE CHANGES (NC)

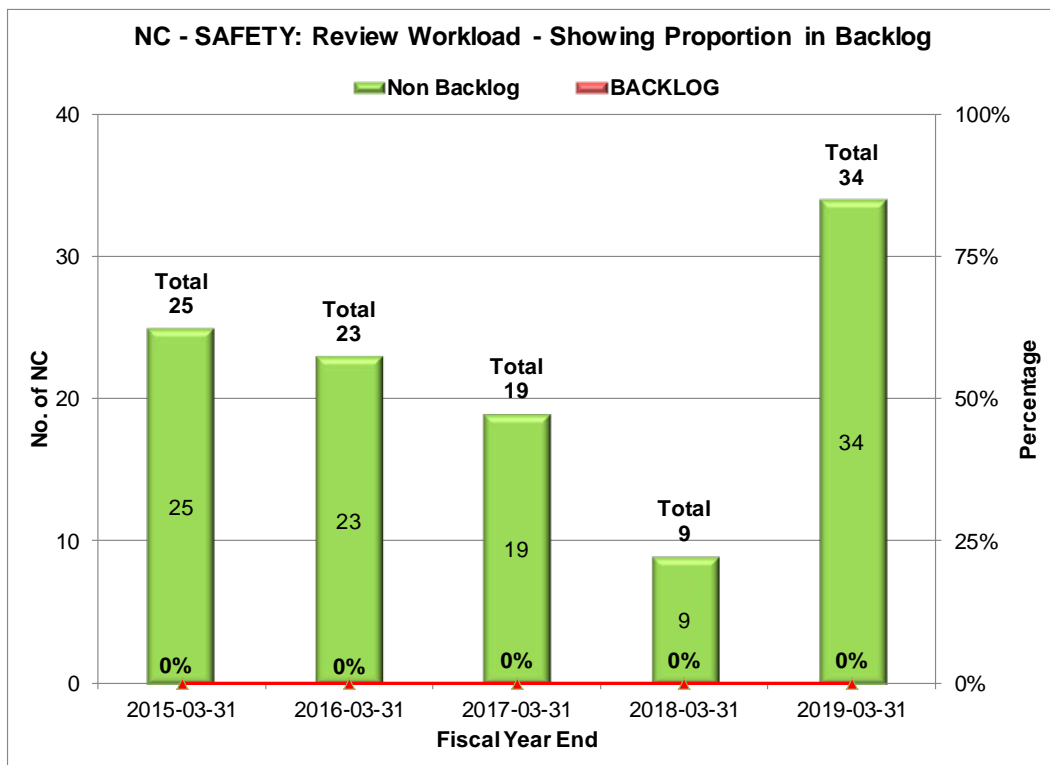
NOTIFIABLE CHANGES

Number Received - Notifiable Changes (NC)

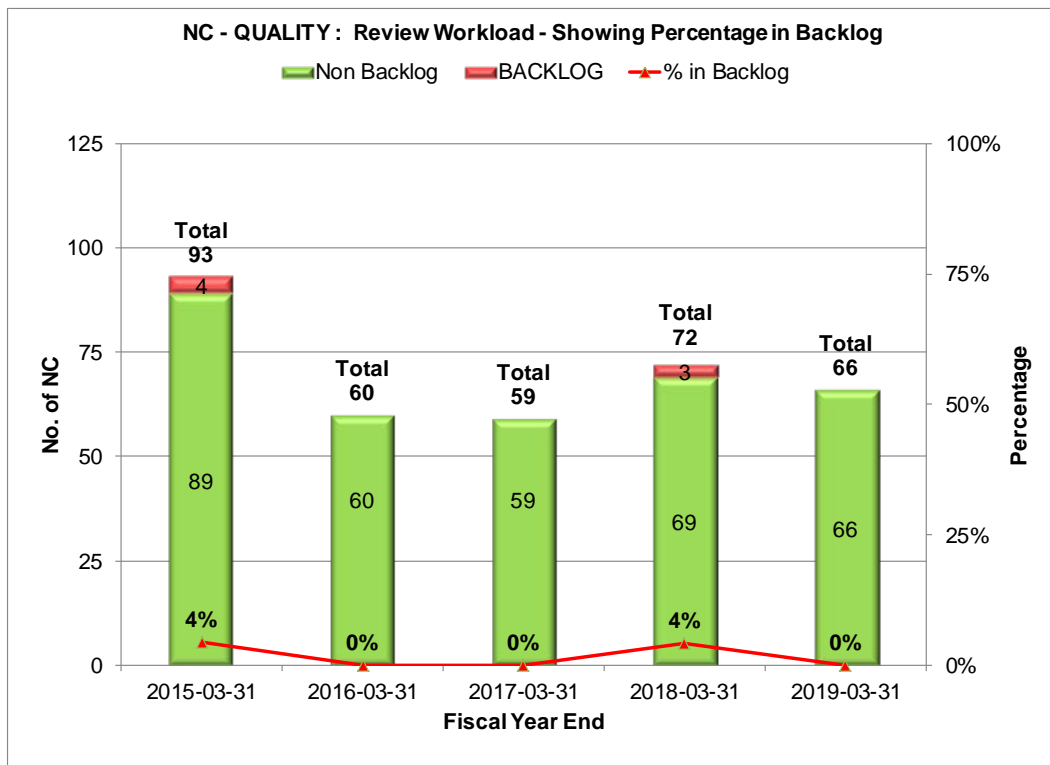


WORKLOAD

Notifiable Change (NC) SAFETY: Review Workload / Backlog



Notifiable Change (NC) QUALITY: Review Workload / Backlog



WORKLOAD**Notifiable Change (NC) SAFETY: Review Workload by Class**

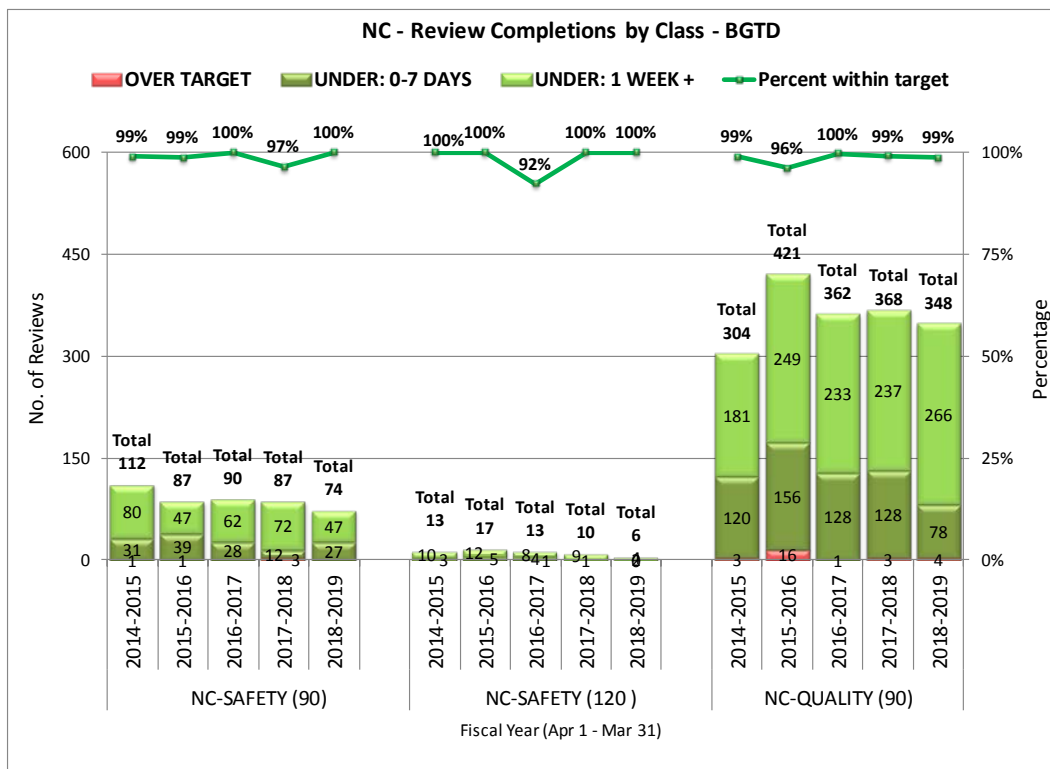
BGTD NC- SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2015-03-31	2016-03-31	2017-03-31	2018-03-31	2019-03-31
SAFETY - 90 day	22	20	15	8	34
Backlog	0	0	0	0	0
SAFETY - 120 day	3	3	4	1	0
Backlog	0	0	0	0	0
Total	25	23	19	9	34
Non Backlog	25	23	19	9	34
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

Notifiable Change (NC) QUALITY: Review Workload by Class

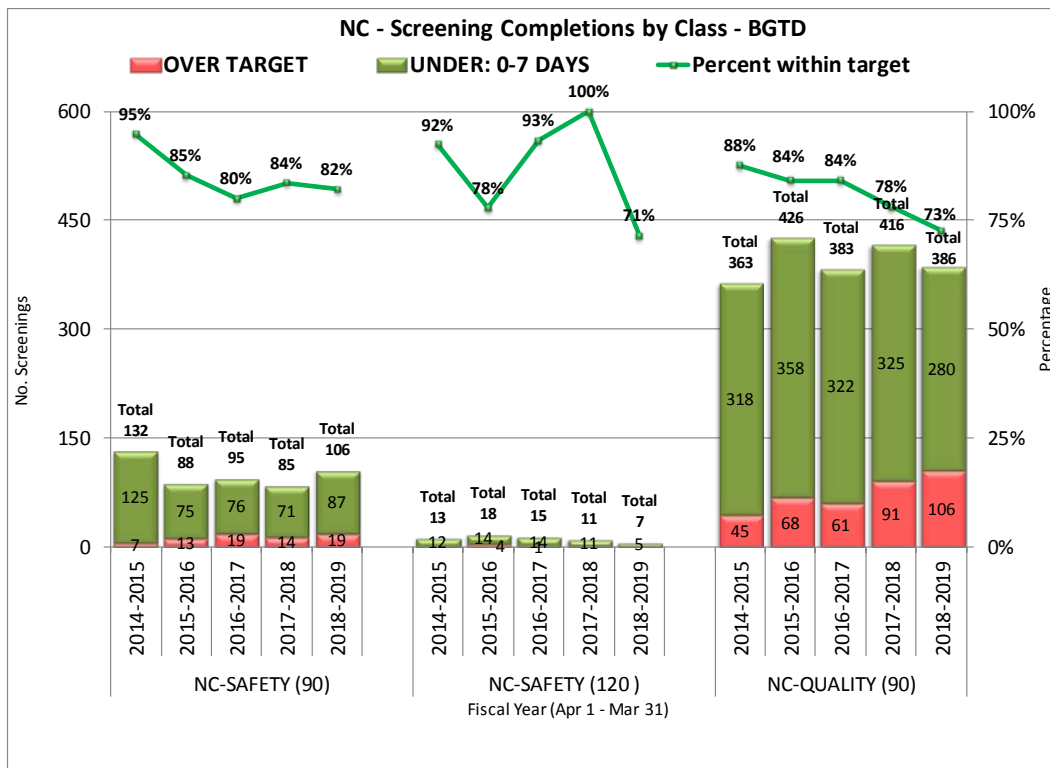
BGTD NC- QUALITY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2015-03-31	2016-03-31	2017-03-31	2018-03-31	2019-03-31
QUALITY - 90 day	93	60	59	72	66
Backlog	4	0	0	3	0
Total	93	60	59	72	66
Non Backlog	89	60	59	69	66
BACKLOG	4	0	0	3	0
% in Backlog	4%	0%	0%	4%	0%

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

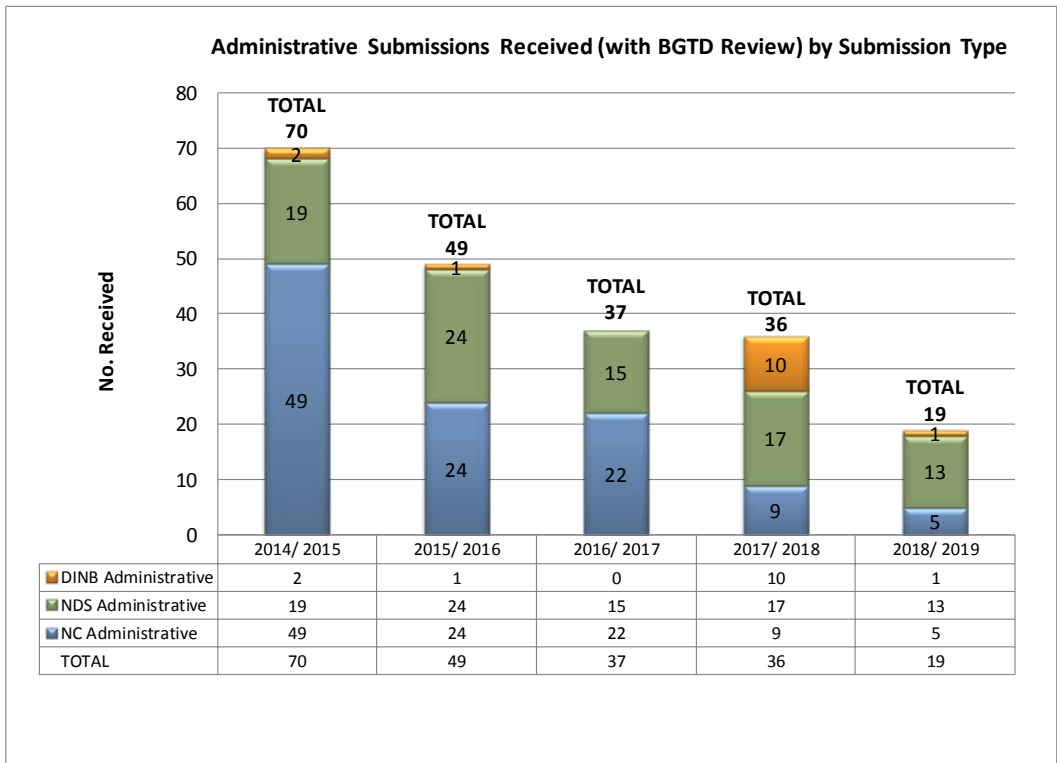
Administrative Submissions

Submissions in support of a manufacturer or product name change.

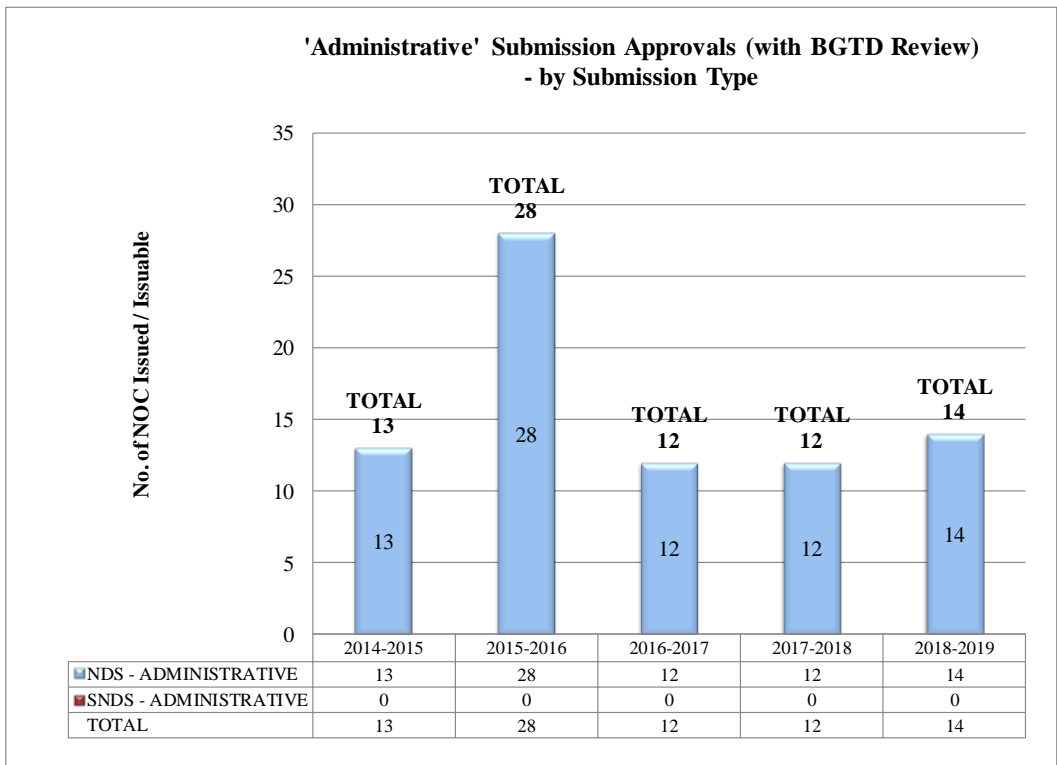
ADMINISTRATIVE SUBMISSIONS (BGTD)

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

Administrative Submissions Received (with BGTD review)

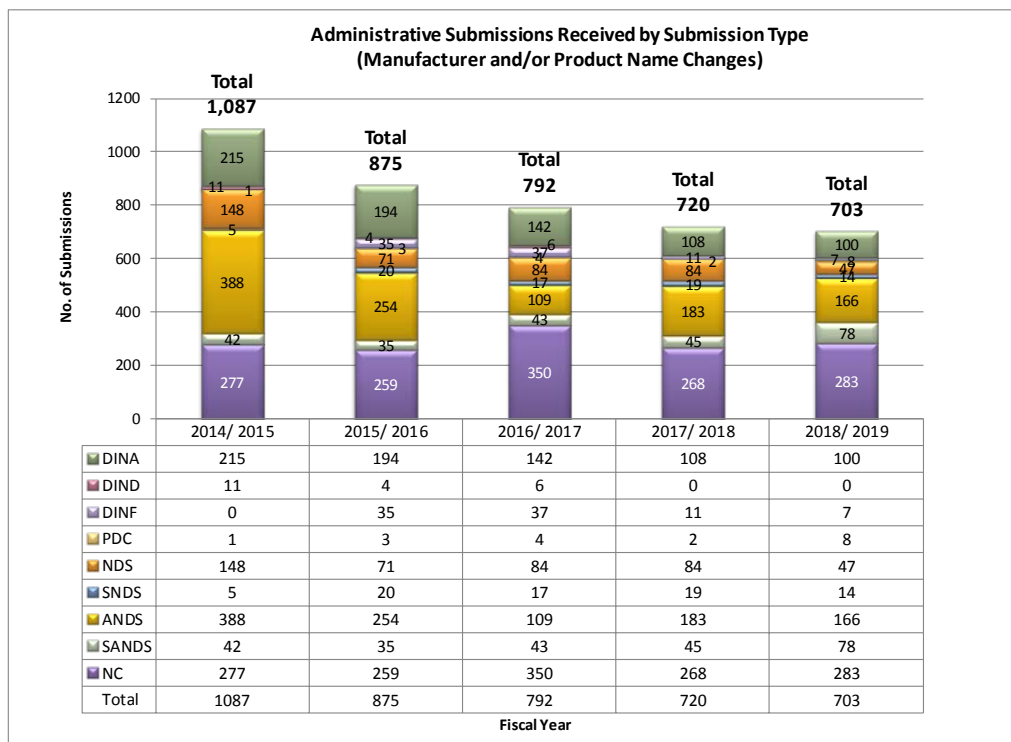


Administrative Submission Approvals (with BGTD Review)

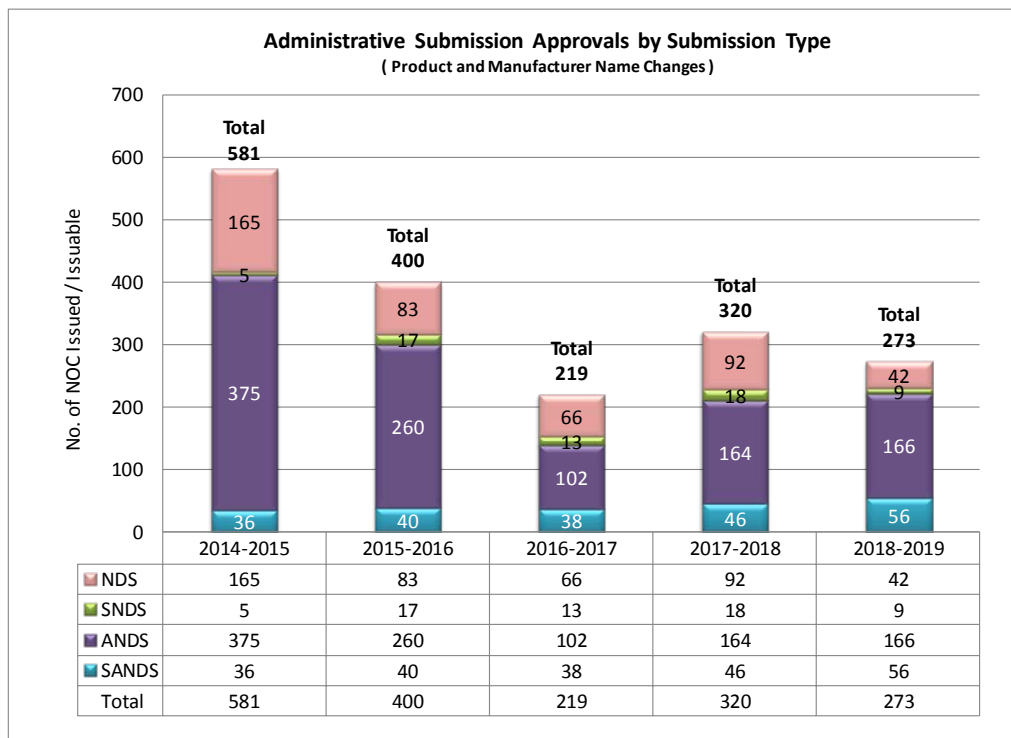


ADMINISTRATIVE SUBMISSIONS (Manufacturer and/or Product Name Changes) ¹³

Administrative Submissions Received by Submission Type



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



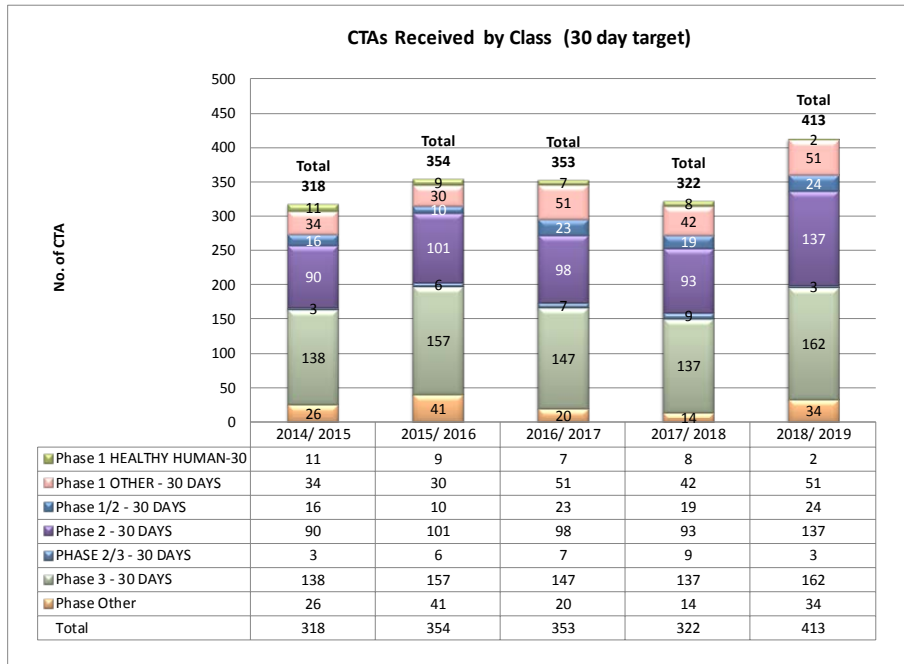
¹³ The screening functions for Administrative submissions and the review functions for Labelling Only submissions with an Administrative component were moved from the Office of Submissions and Intellectual Property (OSIP) to the labelling area of the Bureau of Gastroenterology, Infection and Viral Diseases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

Clinical Trial Applications and Amendments

(CTA & CTA-A)

CLINICAL TRIAL APPLICATIONS

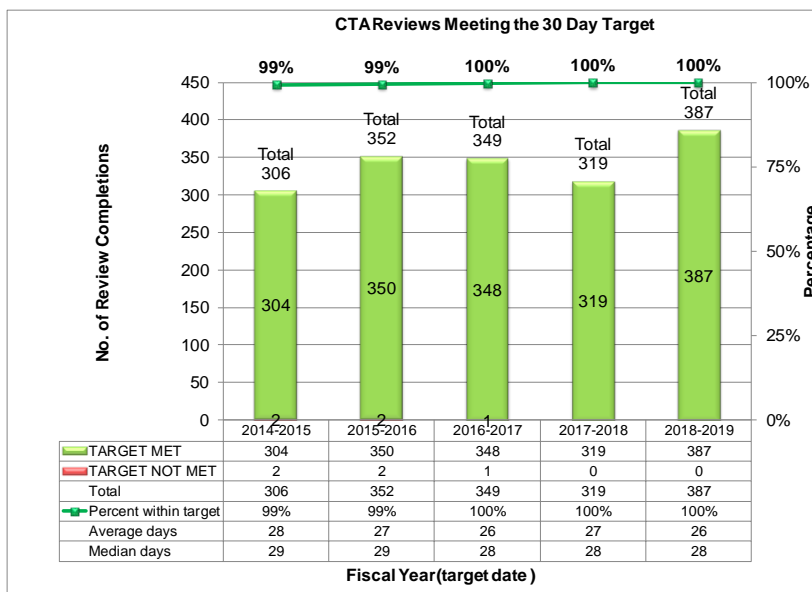
Number Received - Clinical Trial Application (CTA)



Decision Documents - Clinical Trial Application (CTA)

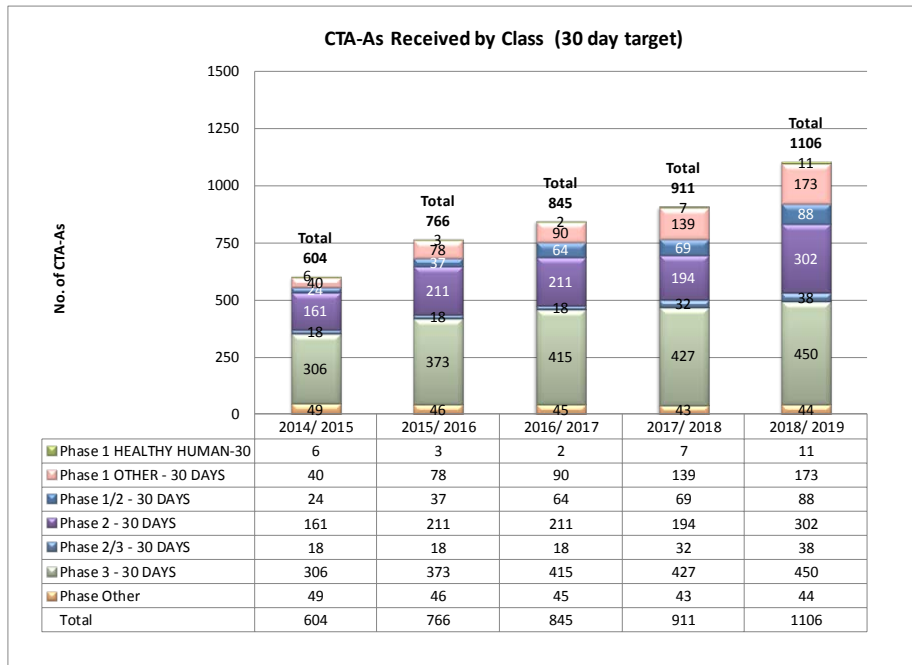
CTA (30 day target)					
DOCUMENT TYPE	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
NO OBJECTION LETTER	283	336	328	307	380
CANCELLED BY COMPANY DURING REVIEW	18	10	21	12	7
CANCELLED BY COMPANY AT PROCESSING	5	2	10	6	6
NOT SATISFACTORY NOTICE	4	3	0	0	1
REJECTION LETTER (SCR)	1	1	1	0	2
SCREENING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

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



CLINICAL TRIAL APPLICATION-AMENDMENTS

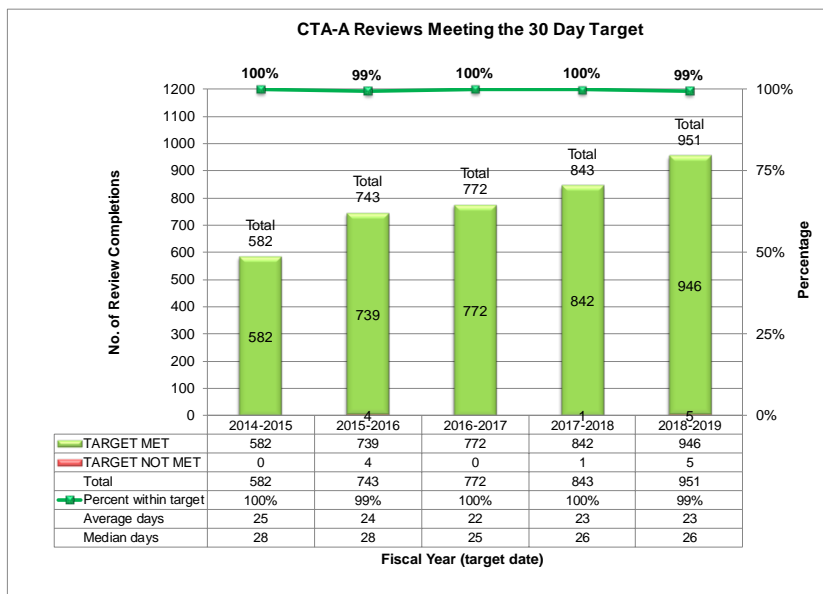
Number Received - Clinical Trial Application-Amendments (CTA-A)



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

CTA-A (30 day target)	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
DOCUMENT TYPE					
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



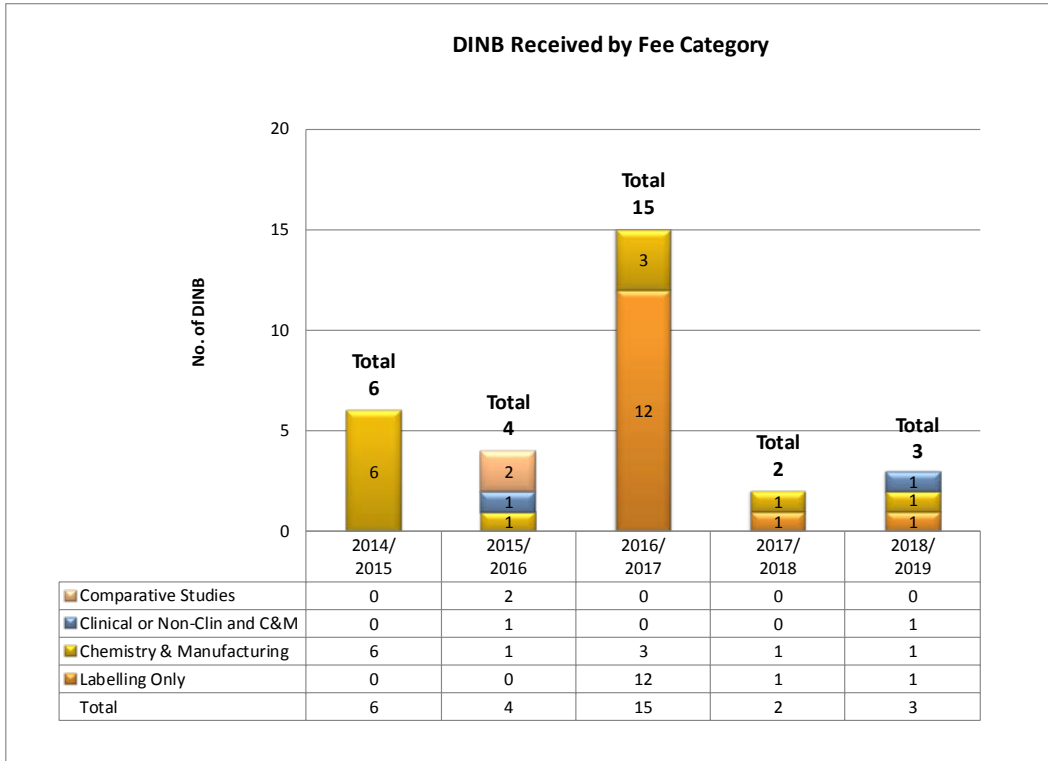
Application for a Drug Identification Number

DINB

Biological Products

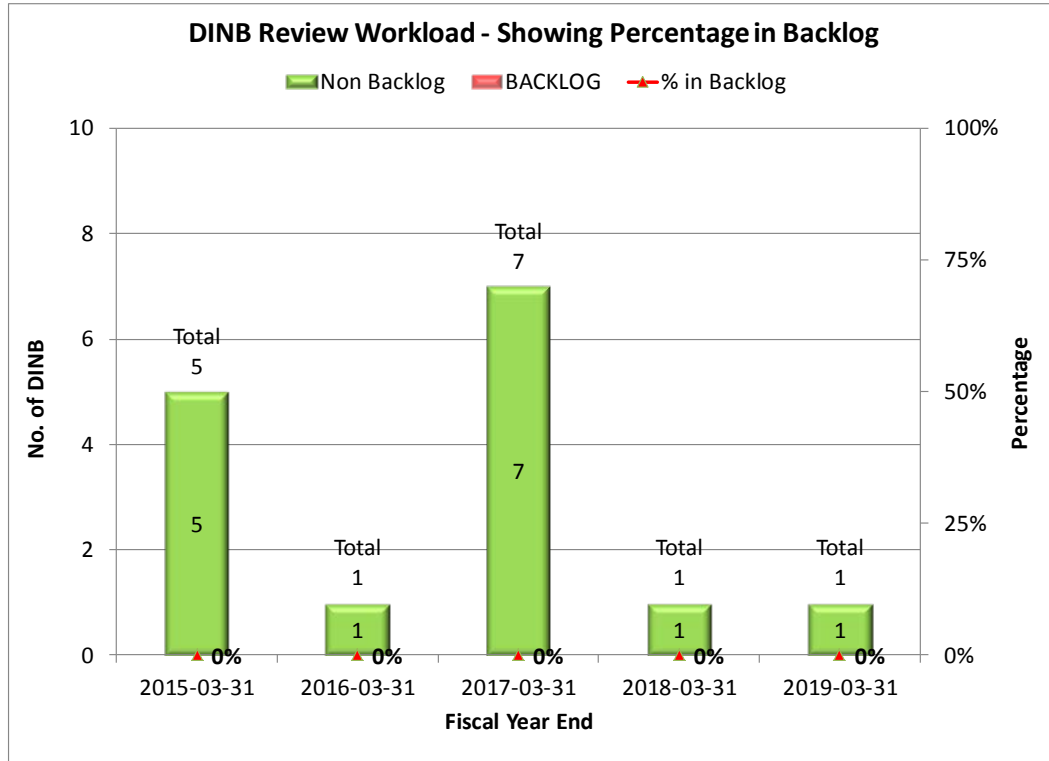
DINB: Application for a Drug Identification Number – BIOLOGICAL Products

DINB: Number Received



REVIEW WORKLOAD

DINB: Review Workload Showing Percentage in Backlog

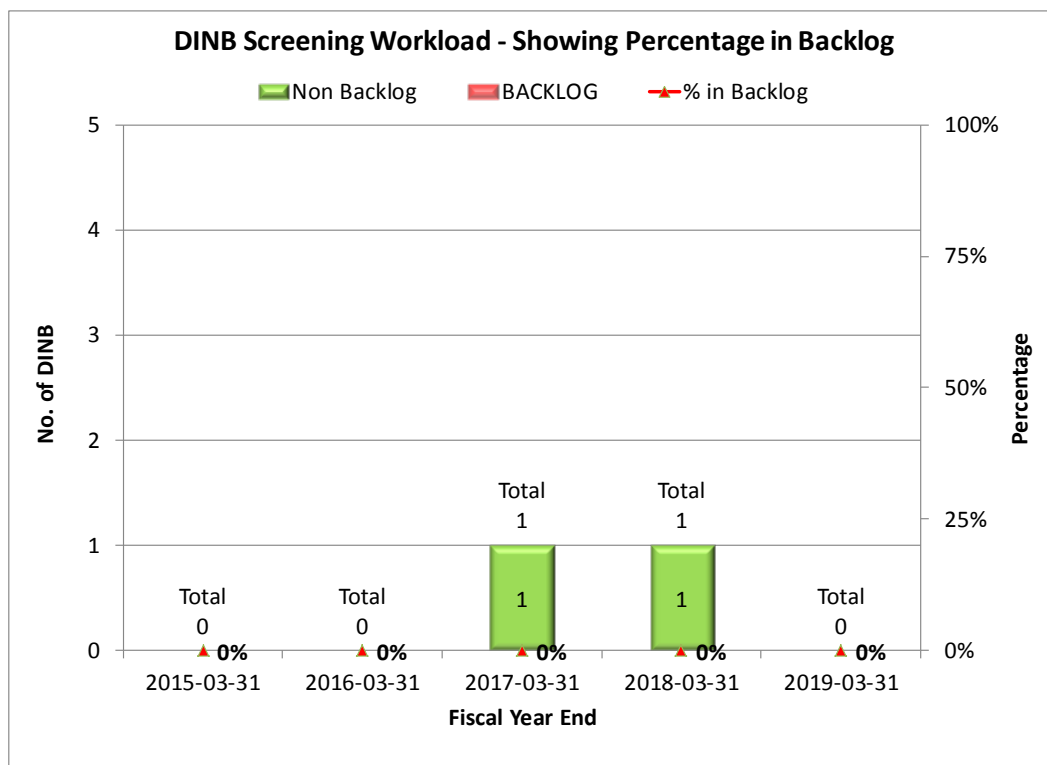


DINB: Review Workload by Class

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
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Chemistry & Manufacturing	5	1	1	0	1
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
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 administrative) 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
<i>Backlog</i>	0	0	0	0	0
Chemistry & Manufacturing	0	0	1	1	0
<i>Backlog</i>	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

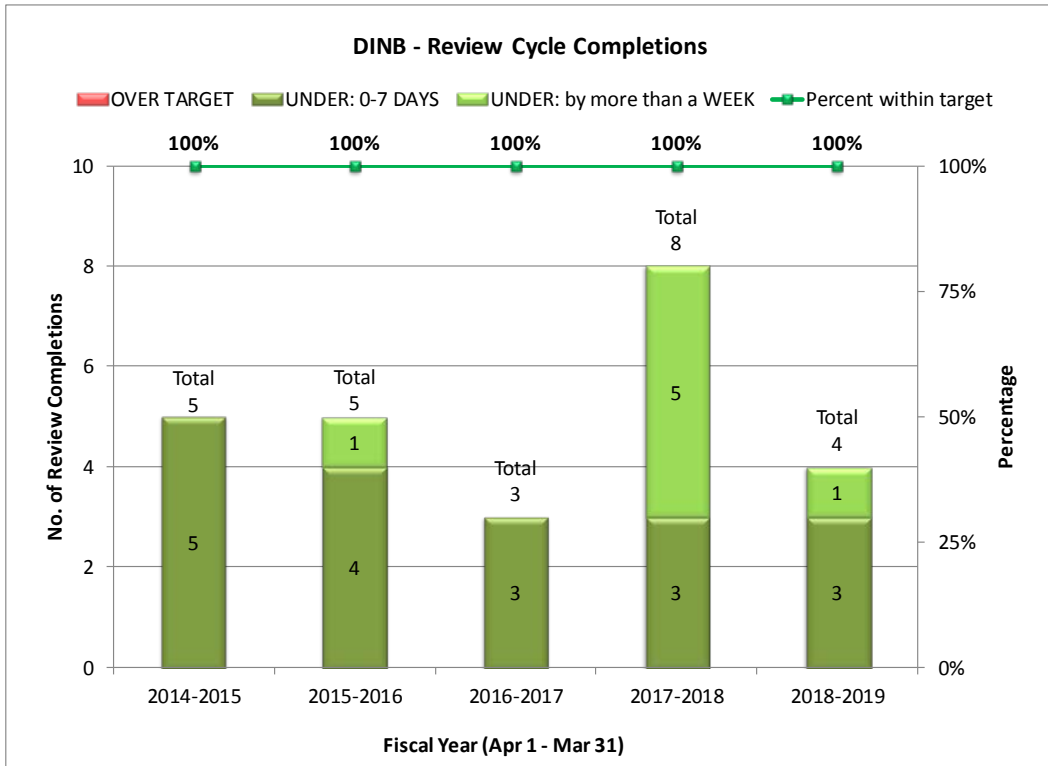
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

DINB: Requests for Reconsideration of Final Decisions

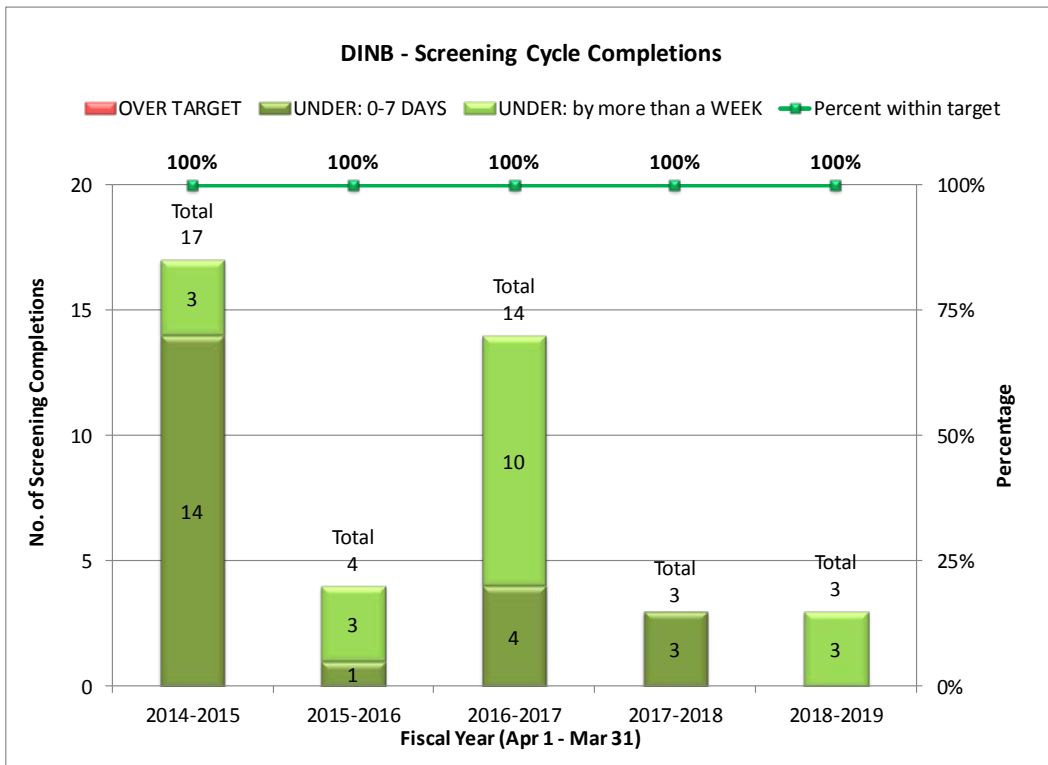
DINB					
Year of Reconsideration Request					
	14-15	15-16	16-17	17-18	18-19
Total	0	0	0	0	0

PERFORMANCE

DINB: Review Cycle Completions

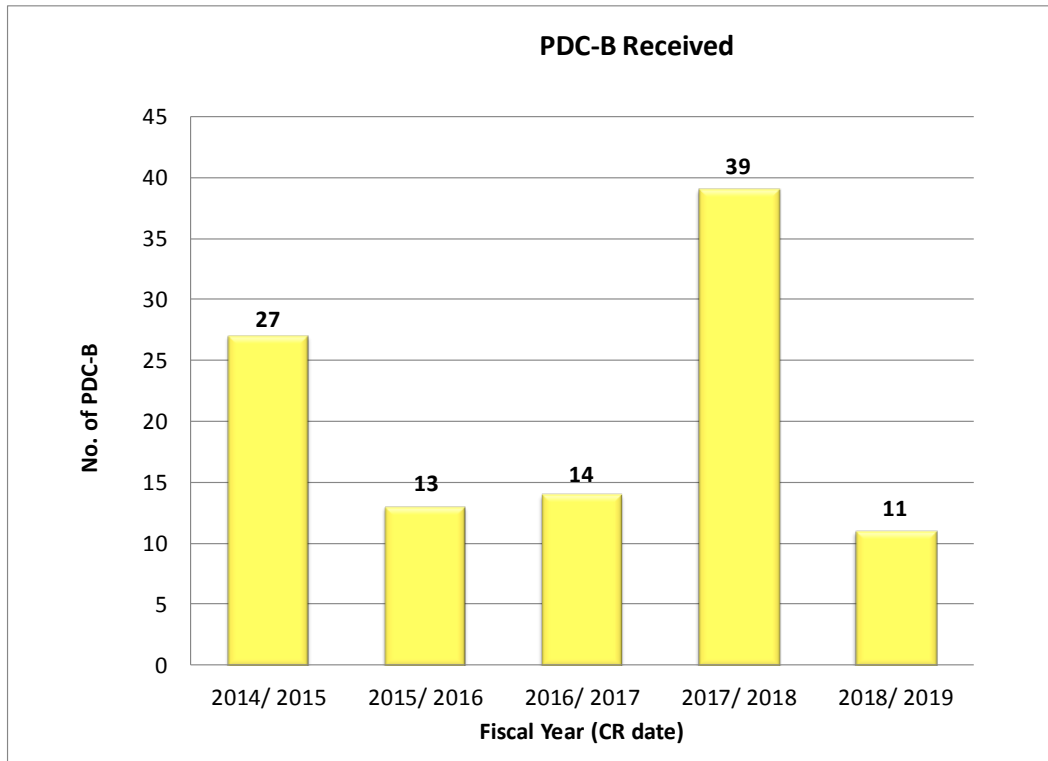


DINB: Screening Cycle Completions



PDC-B: Post Authorization Division 1 Changes - Biologics

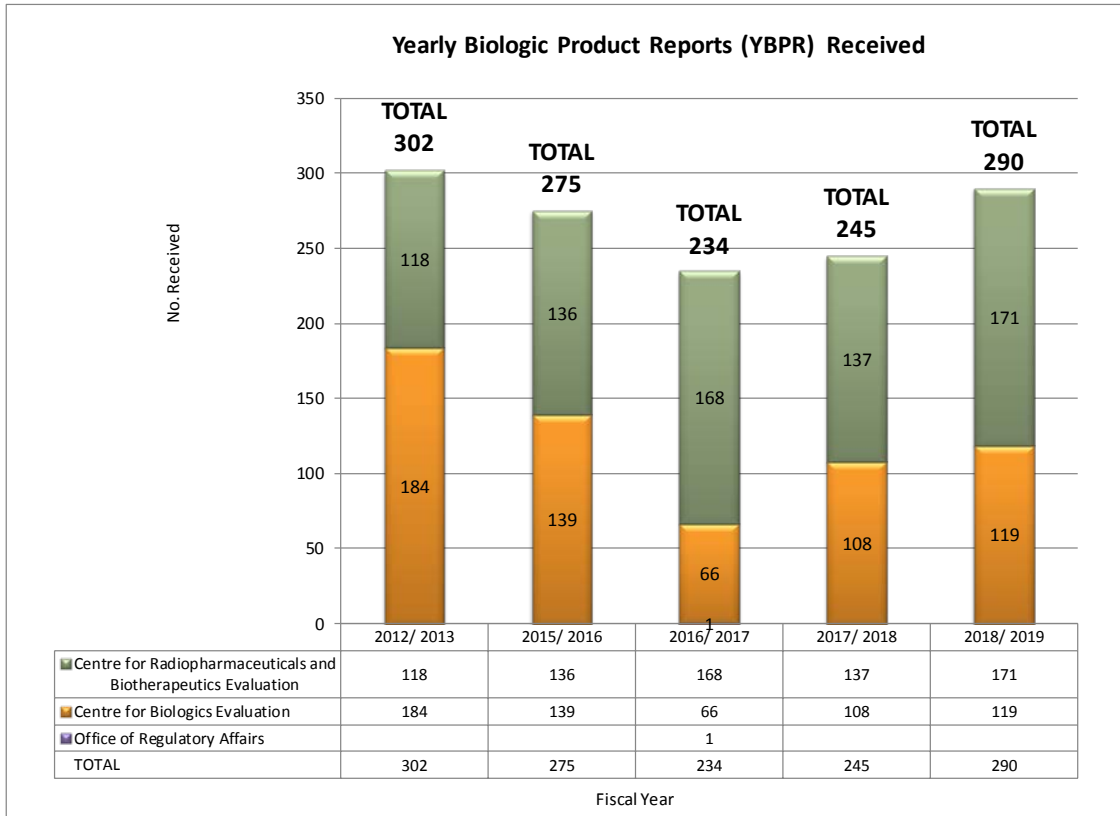
PDC-B: Post Authorization Division 1 Changes- Biologics Received



14

YBPR: Yearly Biologic Product Reports

Yearly Biologic Product Reports (YBPR) Received

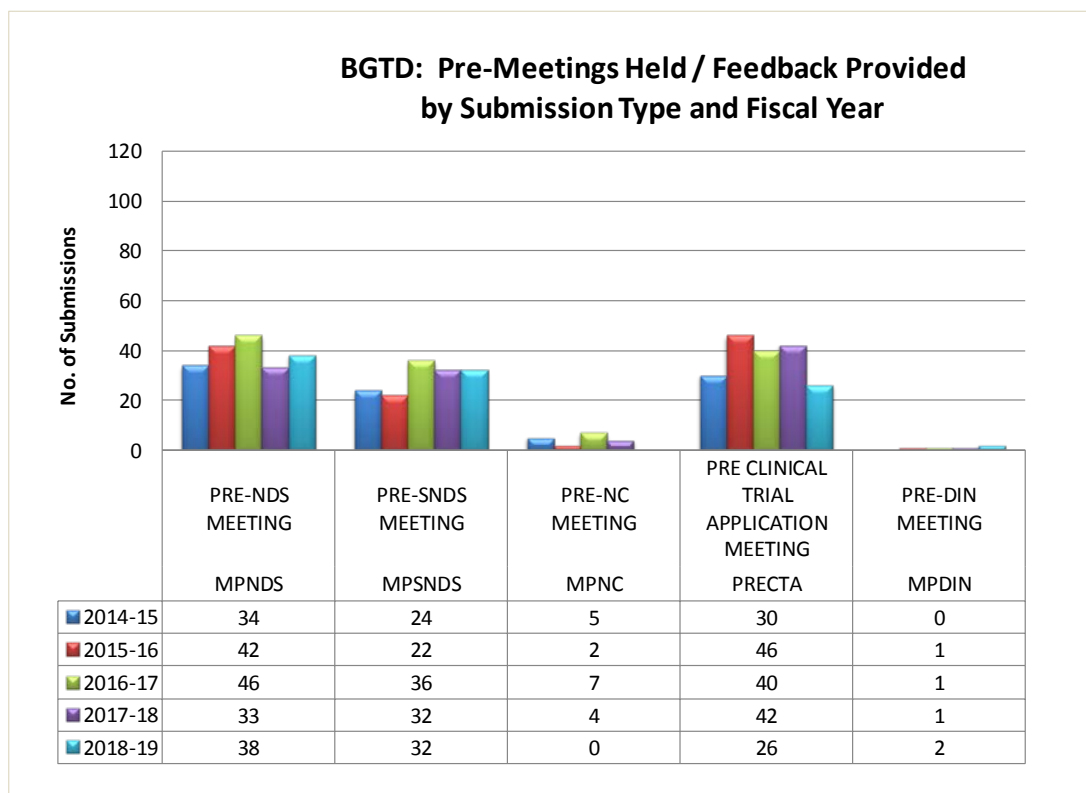


¹⁴ Yearly Biologic Product Report (YBPR), is a report that must be submitted annually by manufacturers of all Schedule D (Biologic) drugs. The report contains production information on both drug substance and drug product lots, including test methods and results, reasons for any recalls and corrective action taken, as well as other pertinent post-market information.

Appendix A: Pre-submission Meetings

15

Pre-submission Meetings Held / Feedback Provided



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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