Santé Canada Health Canada

Biologic and Radiopharmaceutical Drugs Directorate

Drug Submission Performance Annual Report

Fiscal Year

2019-2020

April 1 2019 – March 31 2020

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

Également disponible en français sous le titre :
Direction des médicaments biologiques et radiopharmaceutiques – Rapport annuel du rendement des présentations de drogue – Exercice financier 2019-2020

To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, Ontario K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: hc.publications-publications.sc@canada.ca

Publication date: July 2020

Cat H166-4E-PDF
ISSN 2561-763X
Pub 200109

Table of Contents

OVERVIEW

This year, the Biologics and Genetic Therapies Directorate (BGTD) changed its name to the Biologic and Radiopharmaceutical Drugs Directorate (BRDD). The BRDD's Annual Drug Submission Performance Report reflects biologic and radiopharmaceutical drug submission review activity over five consecutive fiscal years (April 1 to March 31) from 2015-2016 to 2019-2020.

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 April 1 2019 to March 31 2020.

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 and Applications.

[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.

Biosimilar designates 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.

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 and Applications. 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 and Applications

ACRONYMS

Submission Types

ANDS	-	Abbreviated New Drug Submission
CTA	-	Clinical Trial Application
CTA-A	-	Clinical Trial Application-Amendment
DINA	-	Application for a Drug Identification Number for a pharmaceutical product, including non-prescription products attesting to a Labelling Standard
DINB	-	Application for a Drug Identification Number for a biological product
DIND	-	Application for a Drug Identification Number for a disinfectant product
DINF	-	Application for a Drug Identification Number for a Category IV Monograph Product
EUANDS	-	Abbreviated Extraordinary Use New Drug Submission
EUNDS	-	Extraordinary Use New Drug Submission
EUSANDS	-	Supplement to an Abbreviated Extraordinary Use New Drug Submission
EUSNDS	-	Supplement to an Extraordinary Use New Drug Submission
MPNDS	-	Pre-Submission Meeting New Drug Submission
MPSNDS	-	Pre-Submission Meeting Supplement to a New Drug Submission
NC	-	Notifiable Change
NDS	-	New Drug Submission
NDS-D	-	New Drug Submission for disinfectant products
PDC	-	Post-Authorization Division 1 Change for a pharmaceutical product
PDC-B	-	Post-Authorization Division 1 Change for a biologic drug product
PRNDS	-	Request for Priority Review Status: New Drug Submission
PRSNDS	-	Request for Priority Review Status: Supplemental New Drug Submission
SANDS	-	Supplement to an Abbreviated New Drug Submission
SANDS-C	-	Supplement to an Abbreviated New Drug Submission - Confirmatory
SNDS	-	Supplement to a New Drug Submission
SNDS-C	-	Supplement to a New Drug Submission - Confirmatory
SNDS-D	-	Supplement to a New Drug Submission for disinfectant products
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.

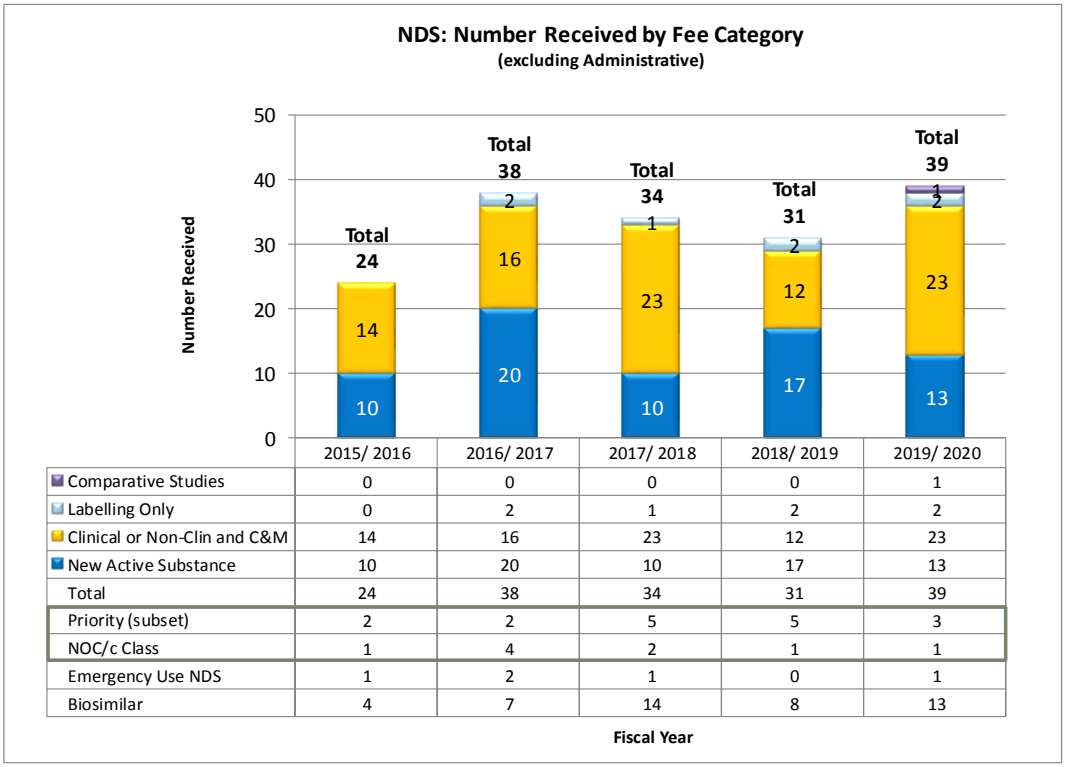
New Drug Submission (NDS)

&

Supplemental New Drug Submission (SNDS)

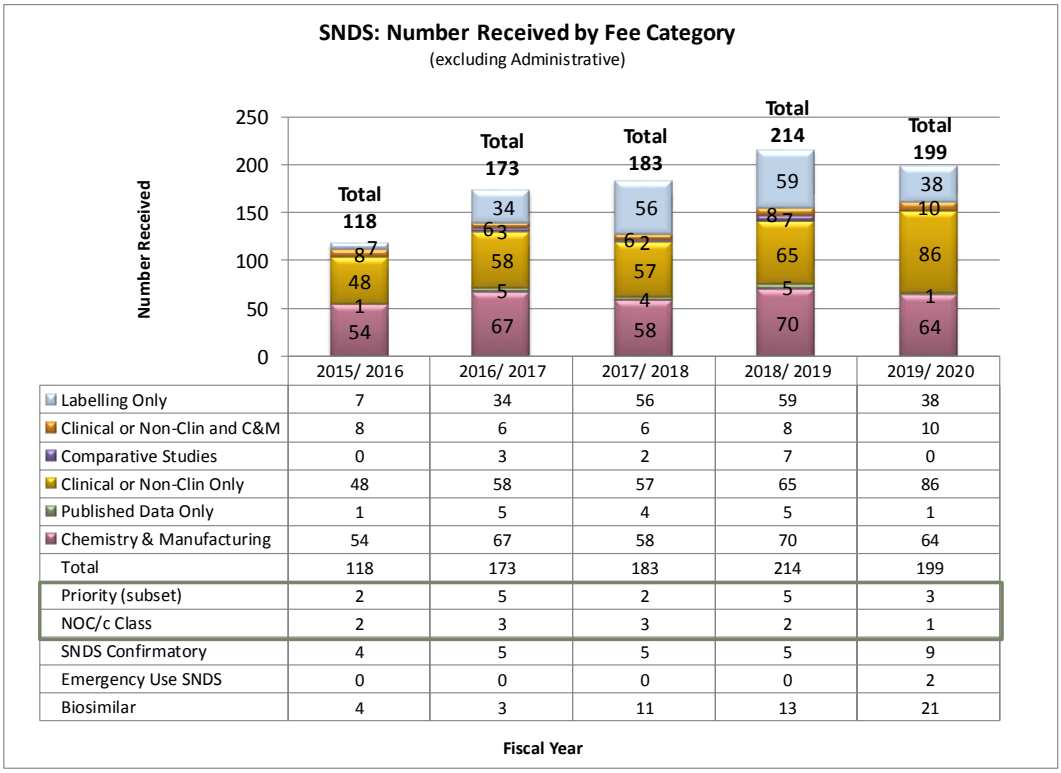
SUBMISSIONS RECEIVED [9]

NDS: Received by Fee Category



	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Comparative Studies	0	0	0	0	1
Labelling Only	0	2	1	2	2
Clinical or Non-Clin and C&M	14	16	23	12	23
New Active Substance	10	20	10	17	13
Total	24	38	34	31	39
Priority (subset)	2	2	5	5	3
NOC/c Class	1	4	2	1	1
Emergency Use NDS	1	2	1	0	1
Biosimilar	4	7	14	8	13

SNDS: Received by Fee Category

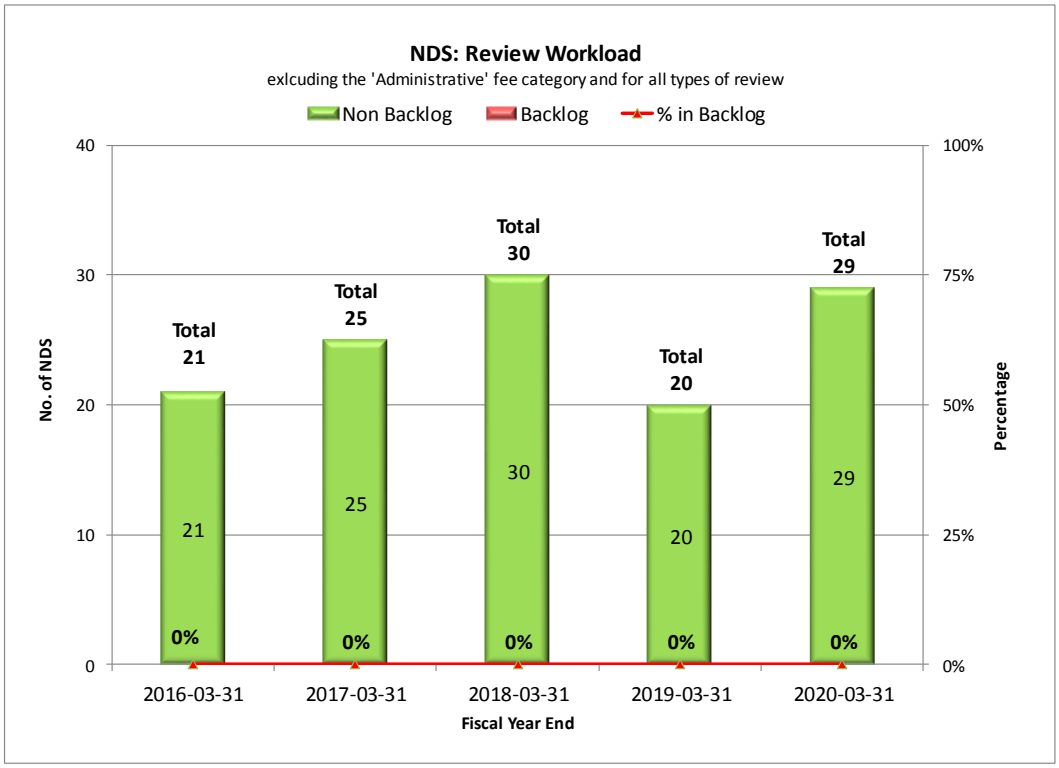


	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Labelling Only	7	34	56	59	38
Clinical or Non-Clin and C&M	8	6	6	8	10
Comparative Studies	0	3	2	7	0
Clinical or Non-Clin Only	48	58	57	65	86
Published Data Only	1	5	4	5	1
Chemistry & Manufacturing	54	67	58	70	64
Total	118	173	183	214	199
Priority (subset)	2	5	2	5	3
NOC/c Class	2	3	3	2	1
SNDS Confirmatory	4	5	5	5	9
Emergency Use SNDS	0	0	0	0	2
Biosimilar	4	3	11	13	21

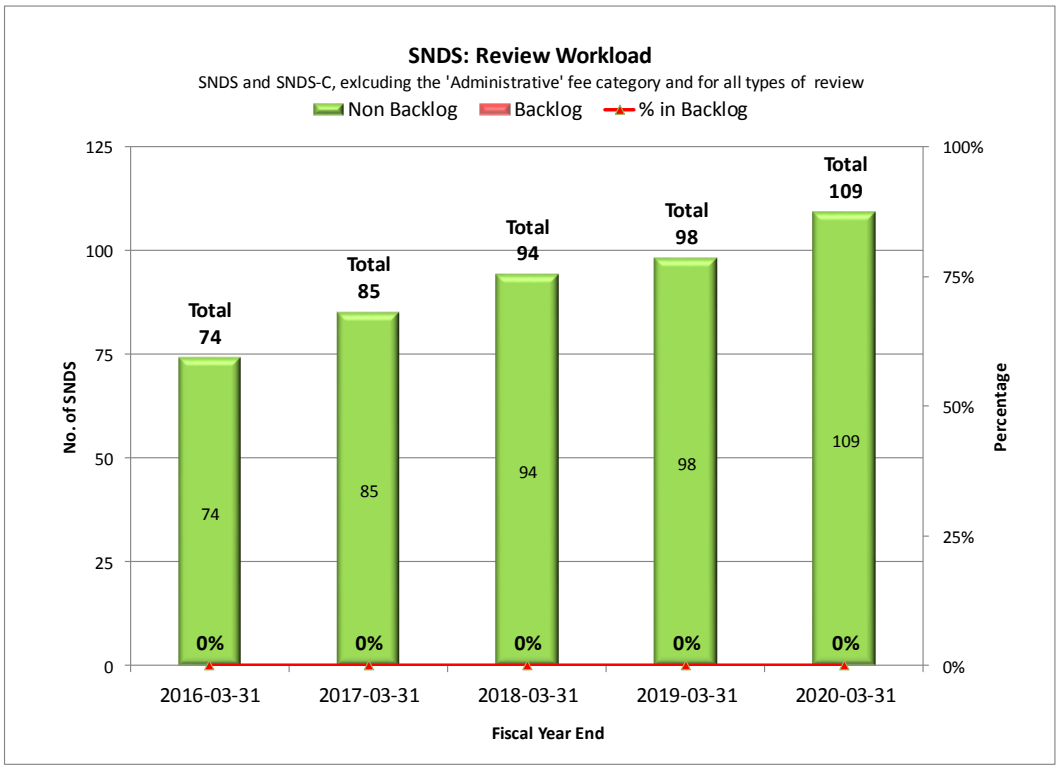
[9] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance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

WORKLOAD

NDS: Review Workload



SNDS: Review Workload



WORKLOAD

NDS: Review Workload by Fee Category

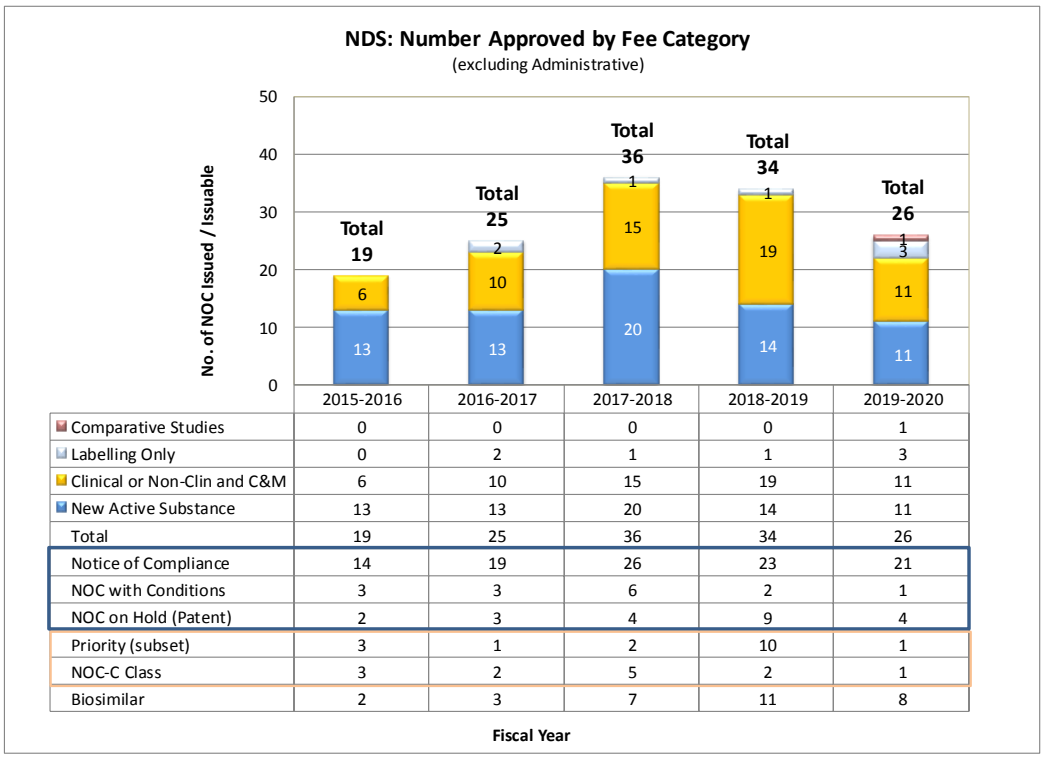
NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Clinical or Non-Clin and C&M	11	11	21	10	18
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	10	14	9	10	11
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**21**	**25**	**30**	**20**	**29**
Non Backlog	21	25	30	20	29
Backlog	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%
Priority (subset)	1	1	5	0	2
Backlog	*0*	*0*	*0*	*0*	*0*

SNDS: Review Workload by Fee Category

SNDS REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Comparative Studies	0	1	1	4	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	25	28	26	26	31
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	37	44	54	49	63
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	1	3	2	3	3
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	10	4	4	6	8
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	1	5	7	10	4
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**74**	**85**	**94**	**98**	**109**
Non Backlog	74	85	94	98	109
Backlog	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%
Priority (subset)	2	3	2	4	0
Backlog	*0*	*0*	*0*	*0*	*0*
SNDS-C (Confirmatory)	3	3	5	5	6
Backlog	*0*	*0*	*0*	*0*	*0*

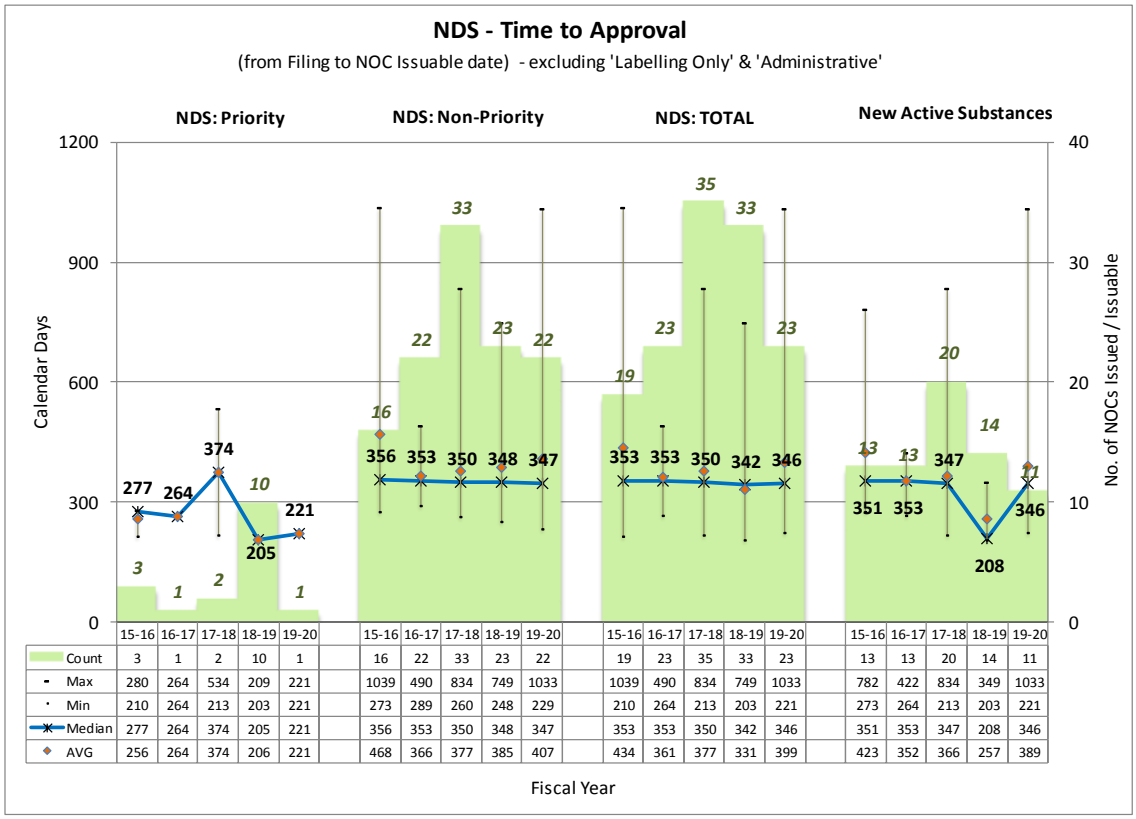
APPROVALS

NDS: Number Approved by Fee Category and by NOC Type



	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
Comparative Studies	0	0	0	0	1
Labelling Only	0	2	1	1	3
Clinical or Non-Clin and C&M	6	10	15	19	11
New Active Substance	13	13	20	14	11
Total	19	25	36	34	26
Notice of Compliance	14	19	26	23	21
NOC with Conditions	3	3	6	2	1
NOC on Hold (Patent)	2	3	4	9	4
Priority (subset)	3	1	2	10	1
NOC-C Class	3	2	5	2	1
Biosimilar	2	3	7	11	8

NDS Approval Times

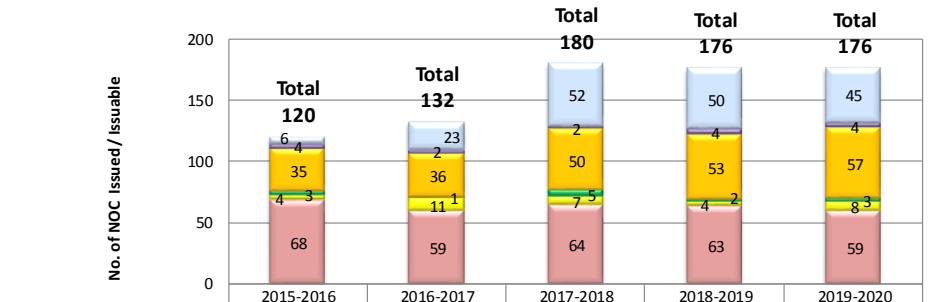


	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20
Count	3	1	2	10	1	16	22	33	23	22	19	23	35	33	23	13	13	20	14	11
Max	280	264	534	209	221	1039	490	834	749	1033	1039	490	834	749	1033	782	422	834	349	1033
Min	210	264	213	203	221	273	289	260	248	229	210	264	213	203	221	273	264	213	203	221
Median	277	264	374	205	221	356	353	350	348	347	353	353	350	342	346	351	353	347	208	346
AVG	256	264	374	206	221	468	366	377	385	407	434	361	377	331	399	423	352	366	257	389

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..

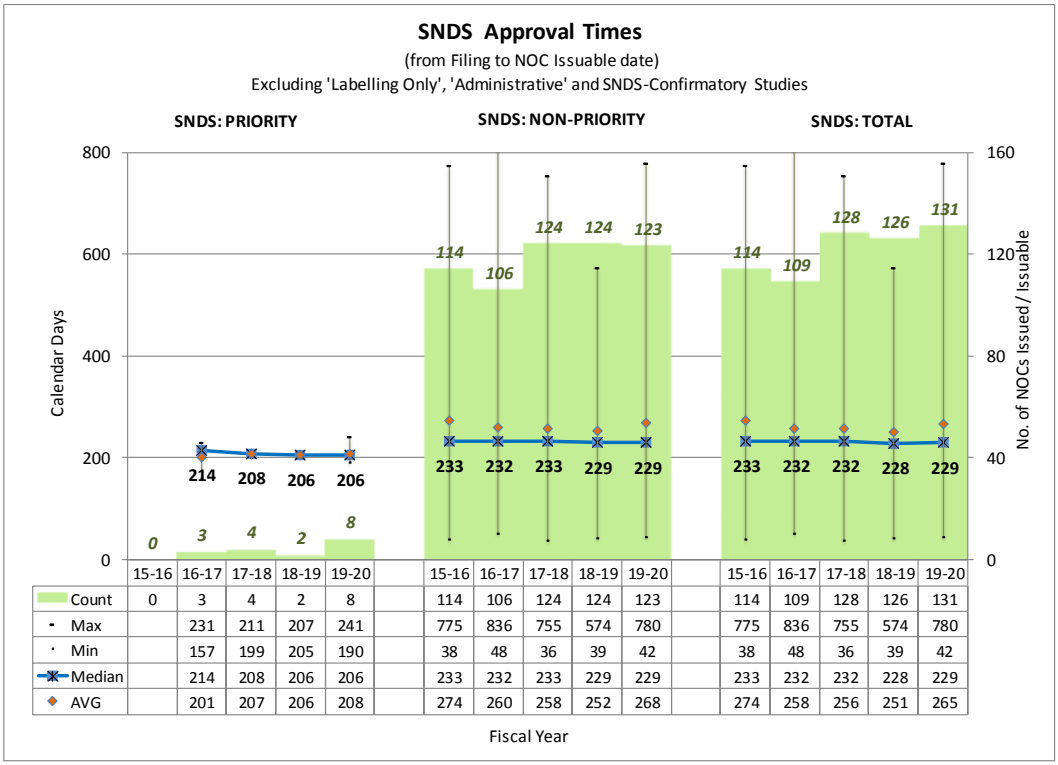
APPROVALS

SNDS: Number Approved by Fee Category and by NOC Type



	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
Labelling Only	6	23	52	50	45
Comparative Studies	4	2	2	4	4
Clinical or Non-Clin Only	35	36	50	53	57
Published Data Only	3	1	5	2	3
Clinical or Non-Clin and C&M	4	11	7	4	8
Chemistry & Manufacturing	68	59	64	63	59
Total	120	132	180	176	176
Notice of Compliance	120	127	175	174	165
NOC with Conditions	0	2	4	1	6
NOC on Hold (Patent)	0	3	1	1	5
Priority (subset)	0	3	4	2	8
NOC-C Class	0	2	4	1	3
Biosimilar	3	6	6	9	18

SNDS Approval Times



	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20
Count	0	3	4	2	8	114	106	124	124	123	114	109	128	126	131
Max		231	211	207	241	775	836	755	574	780	775	836	755	574	780
Min		157	199	205	190	38	48	36	39	42	38	48	36	39	42
Median		214	208	206	206	233	232	233	229	229	233	232	232	228	229
AVG		201	207	206	208	274	260	258	252	268	274	258	256	251	265

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

.

New Active Substance Approvals (NAS) - BRDD - Fiscal Year 2019-2020

New Active Substance Approvals (NAS) - BRDD Fiscal Year 2019-2020 (April 1 2019 to March 31 2020)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
BEOVU (brolucizumab) - is indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD).	NAS	Novartis Pharmaceuticals Canada Inc.	27-Mar 19	12-Mar-20
CABLIVI (caplacizumab) - is indicated for the treatment of adults with acquired thrombotic thrombocytopenic purpura (aTTP) in combination with plasma exchange (PE) and immunosuppressive therapy.	PRIORITY-NAS	Sanofi-Aventis Canada Inc.	22-Jul-19	28-Feb-20
EMGALITY (galcanezumab) - is indicated for the prevention of migraine in adults who have at least 4 migraine days per month.	NAS	Eli Lilly Canada Inc.	21-Aug-18	30-Jul-19
ESPEROCT (Antihemophilic Factor VIII (Recombinant, B-Domain Truncated), PEGylated) - is indicated for use in adults and children with hemophilia A (congenital Factor VIII deficiency) for: • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding.	NAS	Novo Nordisk Canada Inc.	23-Jul-18	4-Jul-19
EVENITY (romosozumab) - is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture.	NAS	Amgen Canada Inc.	18-Aug-16	17-Jun-19

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

New Active Substance Approvals (NAS) - BRDD Fiscal Year 2019-2020 (April 1 2019 to March 31 2020)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
GALLI EO (gallium (68Ga) chloride) - The gallium (68Ga) chloride eluate from the Galli EO™ generator is not intended for direct administration to patients. The gallium (68Ga) chloride eluate is indicated for in vitro radiolabelling of radiopharmaceutical ligands for diagnostic procedures using positron emission tomography (PET).	NAS	Ire Elit S.A.	5-Dec-18	13-Nov-19
LIBTAYO (cemiplimab) - is indicated for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation.	NOC-C-NAS	Sanofi-Aventis Canada Inc.	27-Jul-18	10-Apr-19 NOC-C
MYLOTARG (gemtuzumab ozogamicin) - is indicated for combination therapy with daunorubicin (DNR) and cytarabine (AraC) for the treatment of adult patients with previously untreated, de novo CD33-positive acute myeloid leukemia (AML), except acute promyelocytic leukemia.	NAS	Pfizer Canada ULC	17-Dec-18	28-Nov-19
NETSPOT (dotatate) - after radiolabeling with gallium (68Ga), is indicated for use with positron emission tomography (PET), as an adjunct to other diagnostic tests for localization of somatostatin receptor-positive neuroendocrine tumors (NETs).	NAS	Advanced Accelerator Applications USA, Inc.	20-Jul-18	3-Jul-19
SKYRIZI (risankizumab) - is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.	NAS	Abbvie Corporation	7-May-18	17-Apr-19
ULTOMIRIS (ravulizumab) - is indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).	NAS	Alexion Pharma GMBH	13-Sep-18	28-Aug-19

Priority Submission Approvals – BRDD: Fiscal Year 2019-2020

Priority Submission Approvals - BRDD Fiscal Year 2019-2020 (April 1 2019 to March 31 2020)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[11]) dd-mon-yy**	**Approval Date dd-mon-yy**
ADCETRIS (brentuximab vedotin) - new indication: is indicated for the treatment of previously untreated adult patients with systemic anaplastic large cell lymphoma (sALCL), peripheral T-cell lymphoma-not otherwise specified (PTCL-NOS) or angioimmunoblastic T-cell lymphoma (AITL), whose tumours express CD30, in combination with cyclophosphamide, doxorubicin, and prednisone (CHP).	PRIORITY-CLIN ONLY	Seattle Genetics Inc.	30-Apr-19	22-Nov-19
CABLIVI (caplacizumab) - is indicated for the treatment of adults with acquired thrombotic thrombocytopenic purpura (aTTP) in combination with plasma exchange (PE) and immunosuppressive therapy.	PRIORITY-NAS	Sanofi-Aventis Canada Inc.	22-Jul-19	28-Feb-20
DARZALEX (daratumumab) - extension of an indication: is indicated in combination with lenalidomide and dexamethasone, or with bortezomib, melphalan and prednisone, for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.	PRIORITY-CLIN ONLY	Janssen Inc.	3-Apr-19	25-Oct-19
HEMLIBRA (emicizumab) - addition of a new dosing regimen and new indication: Hemlibra is indicated for hemophilia A (congenital factor VIII deficiency) patients with or without factor VIII inhibitors as routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes.	PRIORITY-CLIN/C&M	Hoffmann La Roche Limited	22-Nov-18	14-Jun-19

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

Priority Submission Approvals - BRDD Fiscal Year 2019-2020 (April 1 2019 to March 31 2020)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[11]) dd-mon-yy**	**Approval Date dd-mon-yy**
KADCYLA (trastuzumab emtansine) - new indication: Early Breast Cancer (EBC) Kadcyla monotherapy is indicated for the adjuvant treatment of HER2-positive early breast cancer patients who have residual invasive disease following neoadjuvant taxane and trastuzumab-based treatment.	PRIORITY-CLIN ONLY	Hoffmann La Roche Limited	1-May-19	25-Nov-19
REVESTIVE (teduglutide) - expansion of indication: for the treatment of adults and pediatric patients 1 year of age and above with Short Bowel Syndrome (SBS) who are dependent on parenteral support.	PRIORITY-CLIN ONLY	Shire Pharmaceuticals Ireland Limited	18-Jan-19	13-Aug-19
SOLIRIS (eculizumab) - new indication: Neuromyelitis Optica Spectrum Disorder (NMOSD): is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. SOLIRIS is not intended for acute treatment of an NMOSD relapse.	PRIORITY-CLIN ONLY	Alexion Pharma GMBH	18-Mar-19	24-Sep-19
TECENTRIQ (atezolizumab) - new indication: First Line Extensive-Stage Small Cell Lung Cancer (ES-SCLC): in combination with carboplatin and etoposide, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).	PRIORITY-CLIN ONLY	Hoffmann La Roche Limited	16-Jan-19	8-Aug-19
TECENTRIQ (atezolizumab) - new indication: Locally Advanced or Metastatic Triple-Negative Breast Cancer (TNBC): in combination with nab-paclitaxel, is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have PD-L1 expression ≥ 1%, and who have not received prior chemotherapy for metastatic disease.	PRIORITY-CLIN/C&M	Hoffmann La Roche Limited	21-Jan-19	19-Sep-19 NOC-C

BIOSIMILARS: MARKET AUTHORIZATIONS

Biosimilars: Number of Market Authorization by Fiscal Year

		Fiscal Year of Market Authorization				
Subm Type	**Class**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**
NDS	CLIN/C&M	2	1	3	5	4
NDS Total		**2**	**1**	**3**	**5**	**4**
SNDS	C&M ONLY	1	2	1	3	5
	C&M/LABELLING	0	1	0	0	0
	CLIN ONLY	0	0	0	2	3
	CLIN/C&M	0	2	0	0	0
	COMP/C&M	0	1	0	1	0
	LABELLING ONLY	1	0	4	2	5
	PUBLISHED DATA ONLY	1	0	0	0	0
SNDS Total		**3**	**6**	**5**	**8**	**13**

Biosimilars: NDS Market Authorizations during Fiscal Year 2019-2020

Brand Name	Class	Company	Active Ingredient(s)	Quarter FY 2019-20	Notice of Compliance (NOC) Date
AVSOLA	CLIN/C&M	AMGEN CANADA INC	INFLIXIMAB	Q4	2020-Mar-12
KANJINTI	CLIN/C&M	AMGEN CANADA INC	TRASTUZUMAB	Q4	2020-Feb-27
OSNUVO	CLIN/C&M	AVIR HARMA INC.	TERIPARATIDE	Q4	2020-Jan-13
ZIRABEV	CLIN/C&M	PFIZER CANADA ULC	BEVACIZUMAB	Q1	2019-Jun-14
New Drug Submission Total					**4**

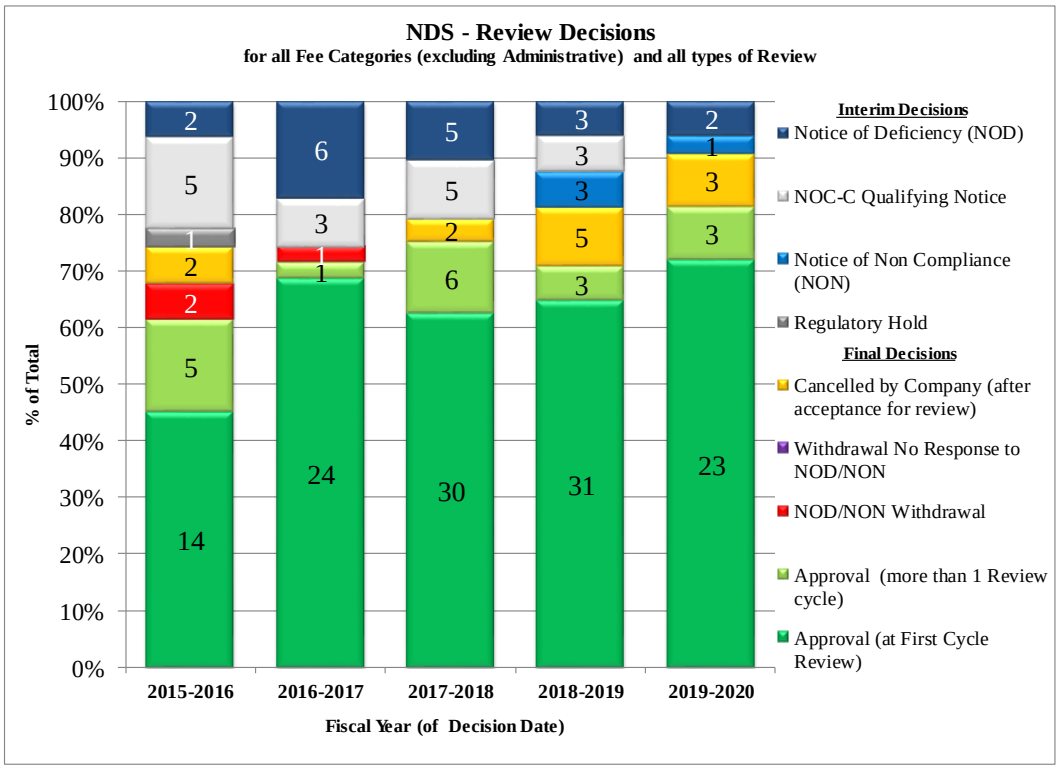
Please note: Approved Biosimilars that remain on Intellectual Property HOLD are not included.

Biosimilars: SNDS Market Authorizations during Fiscal Year 2019-2020

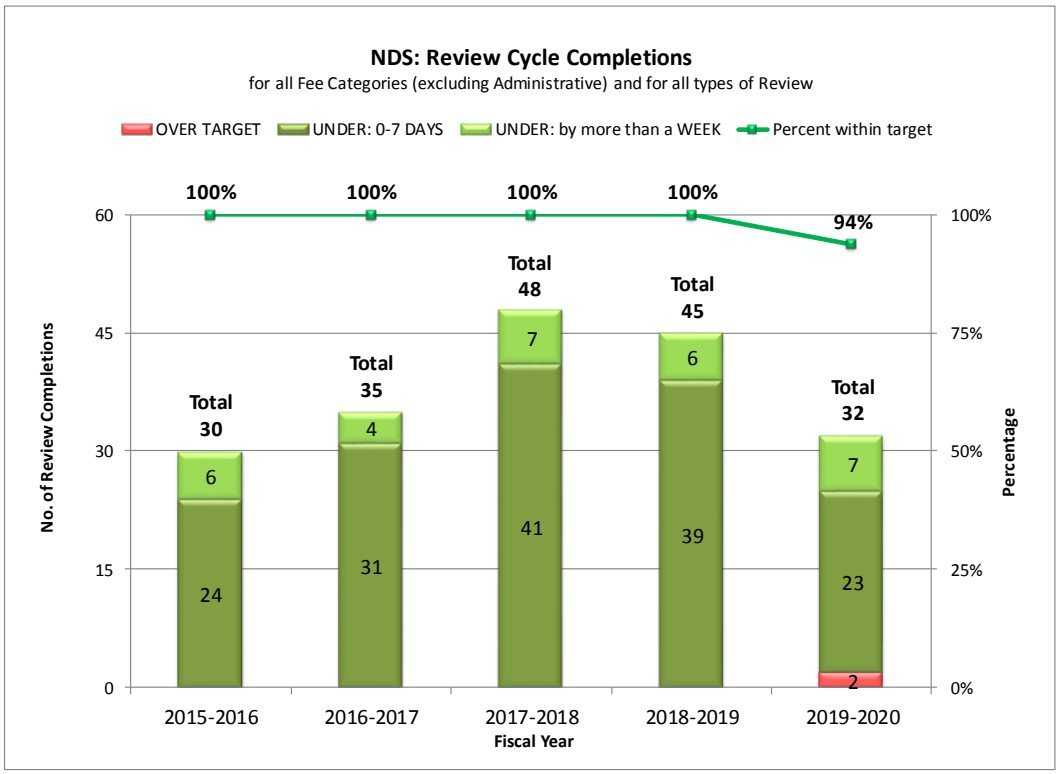
Brand Name	Class	Company	Active Ingredient(s)	Quarter FY 2019-20	Notice of Compliance (NOC) Date
ADMELOG	LABELLING ONLY	SANOFI-AVENTIS CANADA INC.	INSULIN LISPRO	Q3	2019-Oct-18
ADMELOG	LABELLING ONLY	SANOFI-AVENTIS CANADA INC.	INSULIN LISPRO	Q3	2019-Nov-22
BRENZYS (PEN), BRENZYS (PFS)	C&M ONLY	SAMSUNG BIOEPIS CO., LTD	ETANERCEPT	Q3	2019-Oct-23
GRASTOFIL	LABELLING ONLY	APOTEX INC.	FILGRASTIM (R-METHUG-CSF)	Q3	2019-Dec-27
INFLECTRTA	CLIN ONLY	CELLTRION HEALTHCARE CO LTD	INFLIXIMAB	Q2	2019-Sep-28
INFLECTRTA	C&M ONLY	CELLTRION HEALTHCARE CO LTD	INFLIXIMAB	Q2	2019-Sep-18
LAPELGA	LABELLING ONLY	APOTEX INC.	PEGFILGRASTIM	Q3	2019-Dec-27
MVASI	C&M ONLY	AMGEN CANADA INC	BEVACIZUMAB	Q1	2019-Apr-02
MVASI	C&M ONLY	AMGEN CANADA INC	BEVACIZUMAB	Q3	2019-Nov-25
MVASI	CLIN ONLY	AMGEN CANADA INC	BEVACIZUMAB	Q1	2019-Jun-05
MVASI	CLIN ONLY	AMGEN CANADA INC	BEVACIZUMAB	Q4	2020-Feb-21
RENFLEXIS	C&M ONLY	SAMSUNG BIOEPIS CO., LTD	INFLIXIMAB	Q3	2019-Nov-22
TRUXIMA	LABELLING ONLY	CELLTRION HEALTHCARE CO LTD	RITUXIMAB	Q2	2019-Jul-22
Supplemental New Drug Submission Total					**13**

REVIEW PERFORMANCE

NDS: Review Decisions by Type

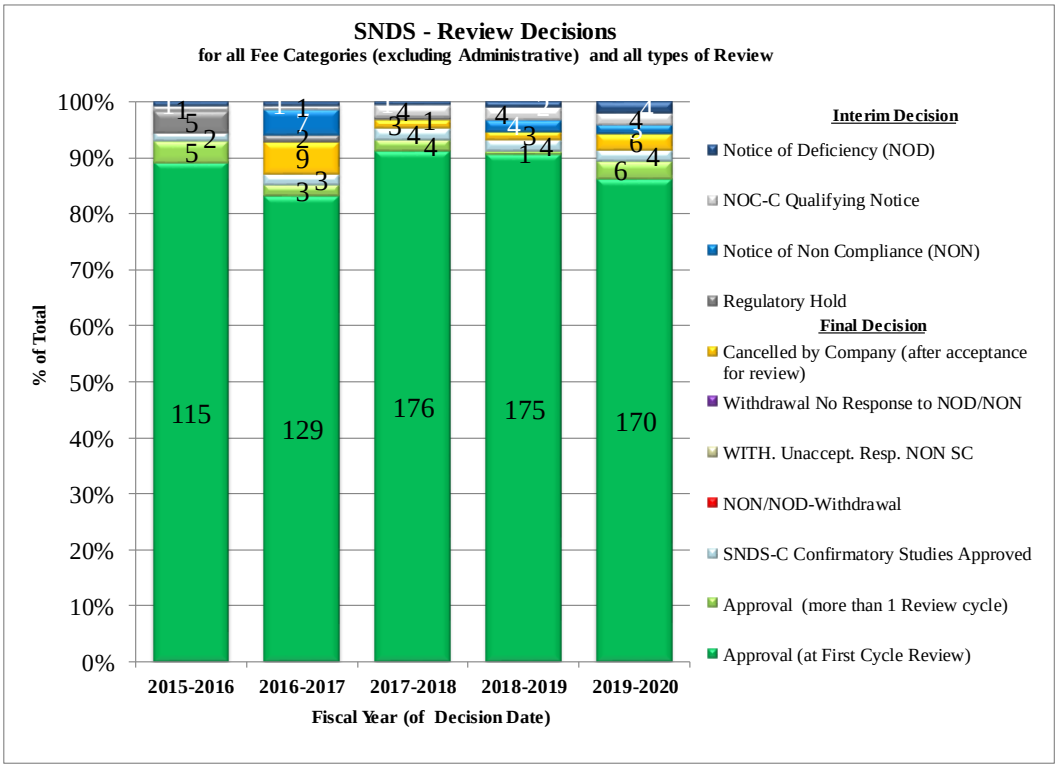


NDS: Review Cycle Completions

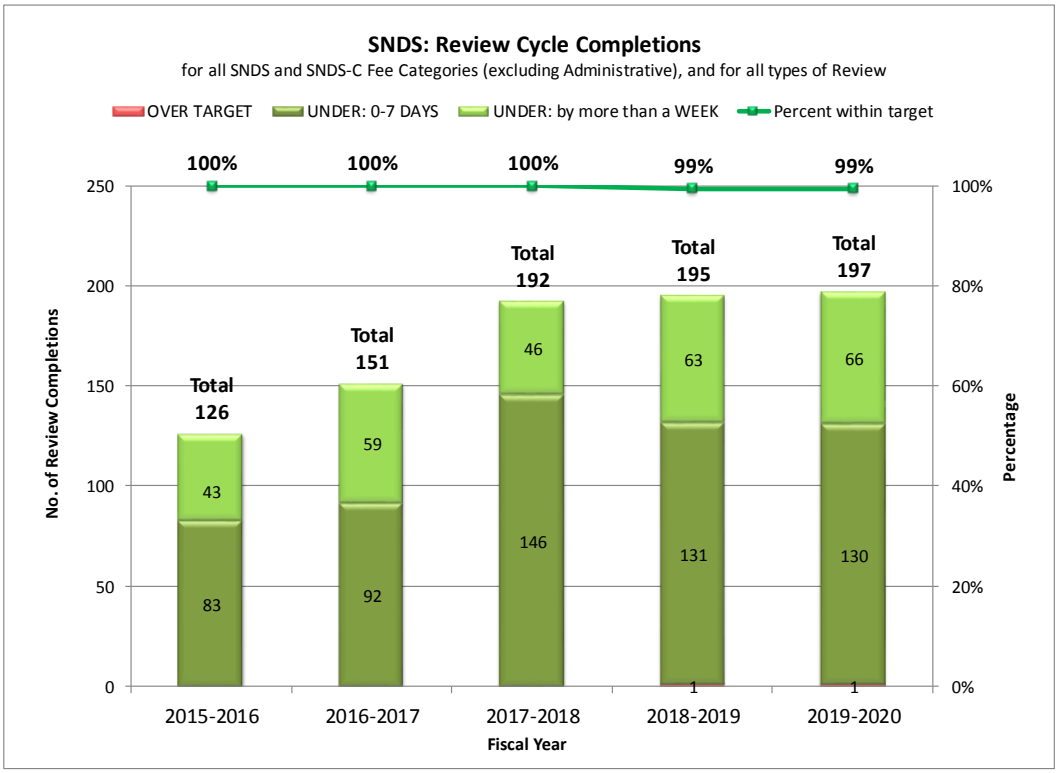


REVIEW PERFORMANCE

SNDS: Review Decisions by Type

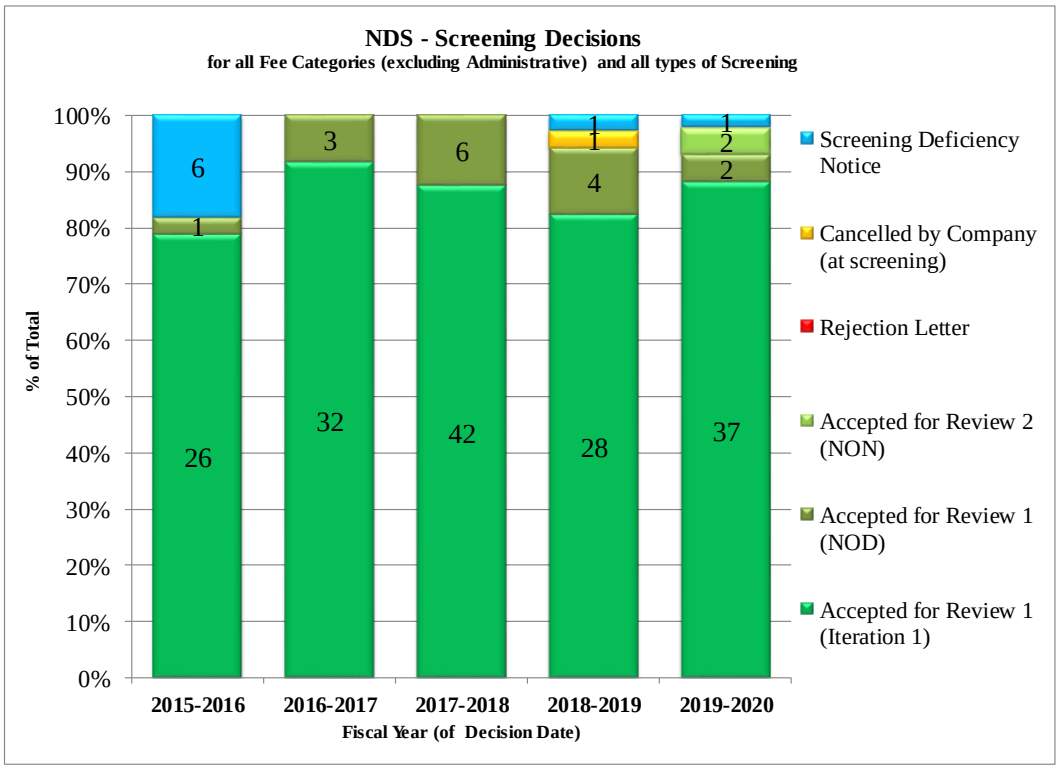


SNDS: Review Cycle Completions

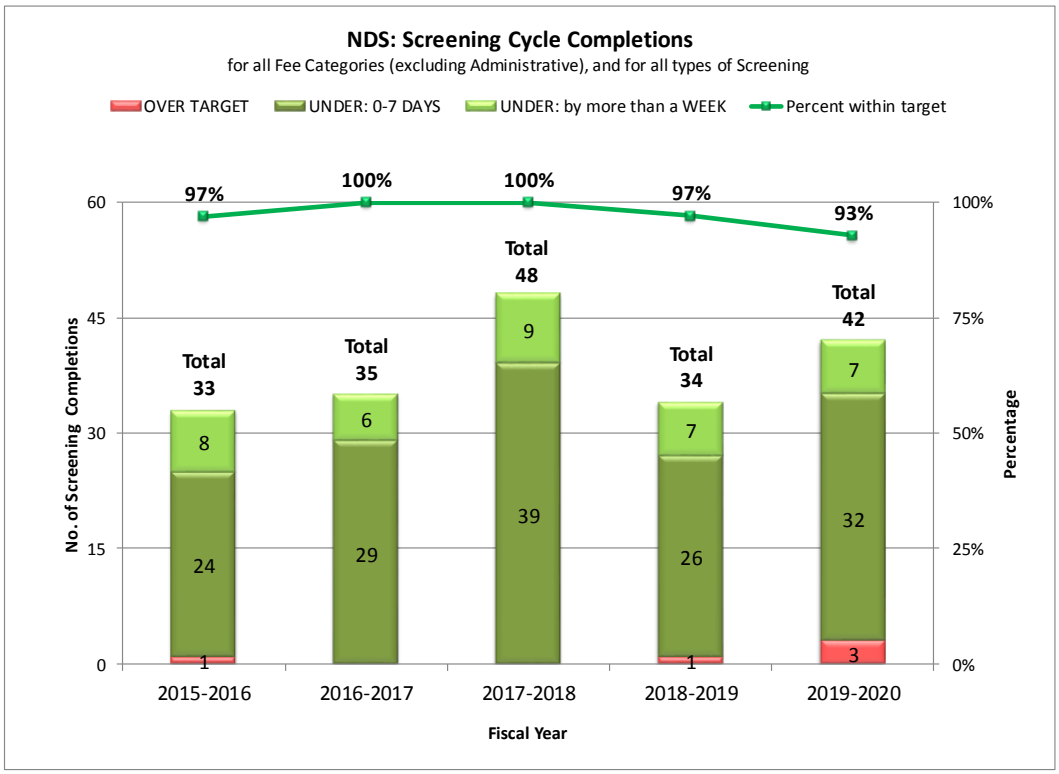


SCREENING PERFORMANCE

NDS: Screening Decisions by Type

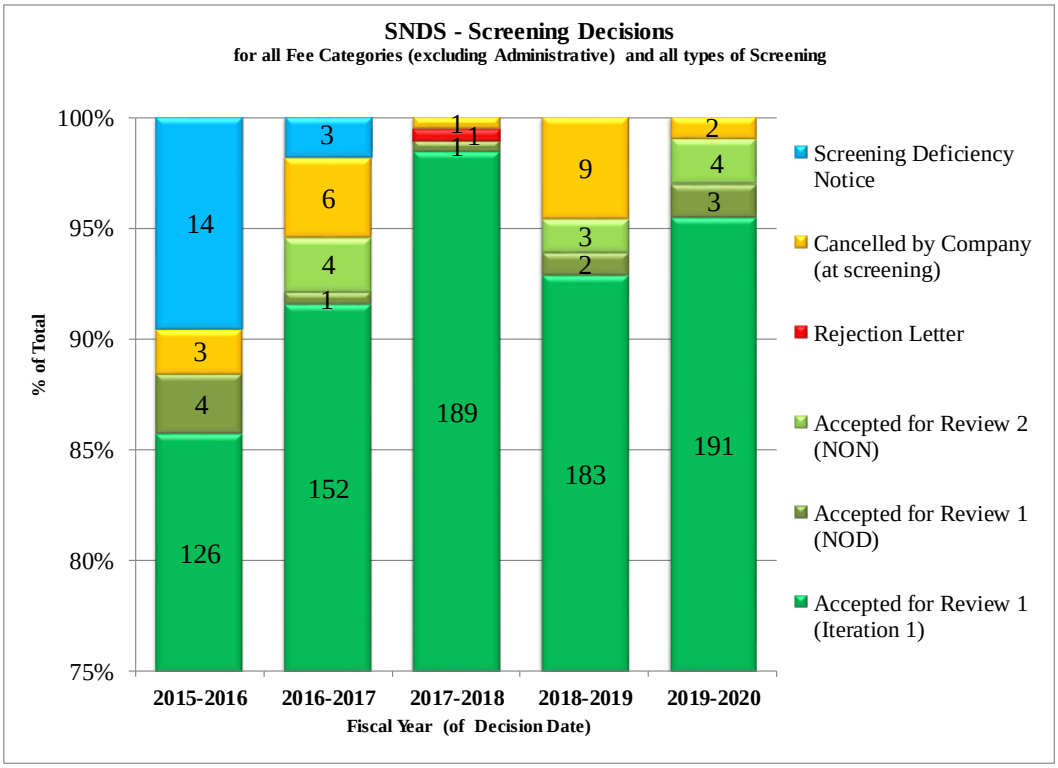


NDS: Screening Cycle Completions

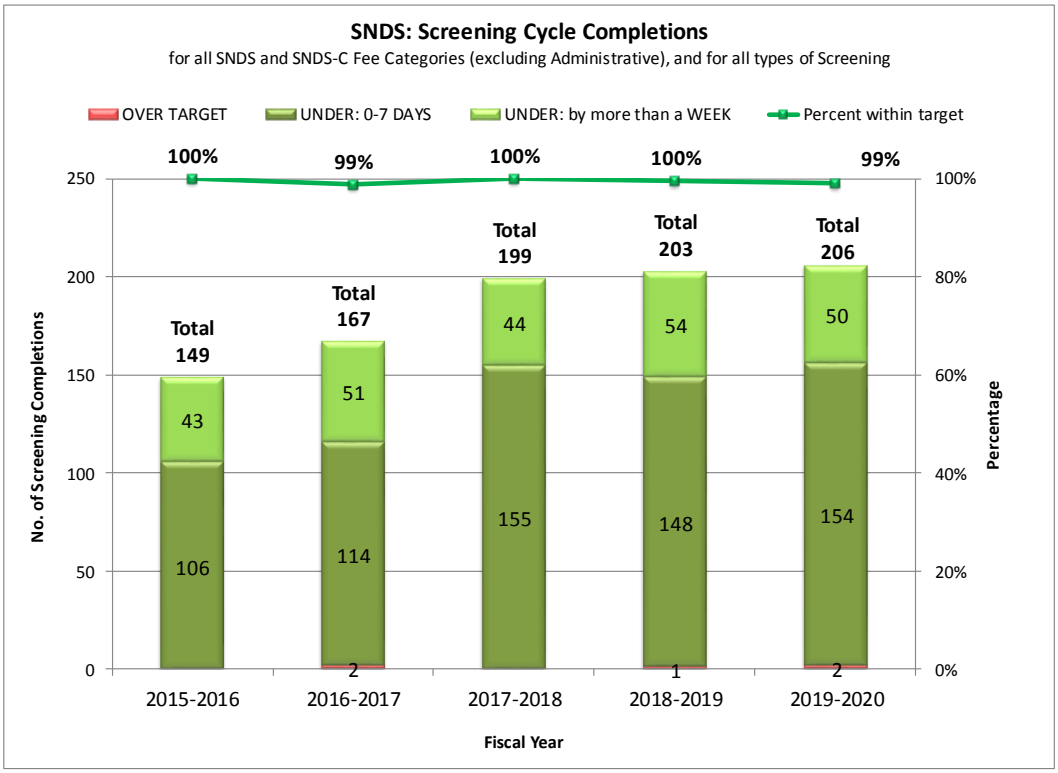


SCREENING PERFORMANCE

SNDS: Screening Decisions by Type



SNDS: Screening Cycle Completions



REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

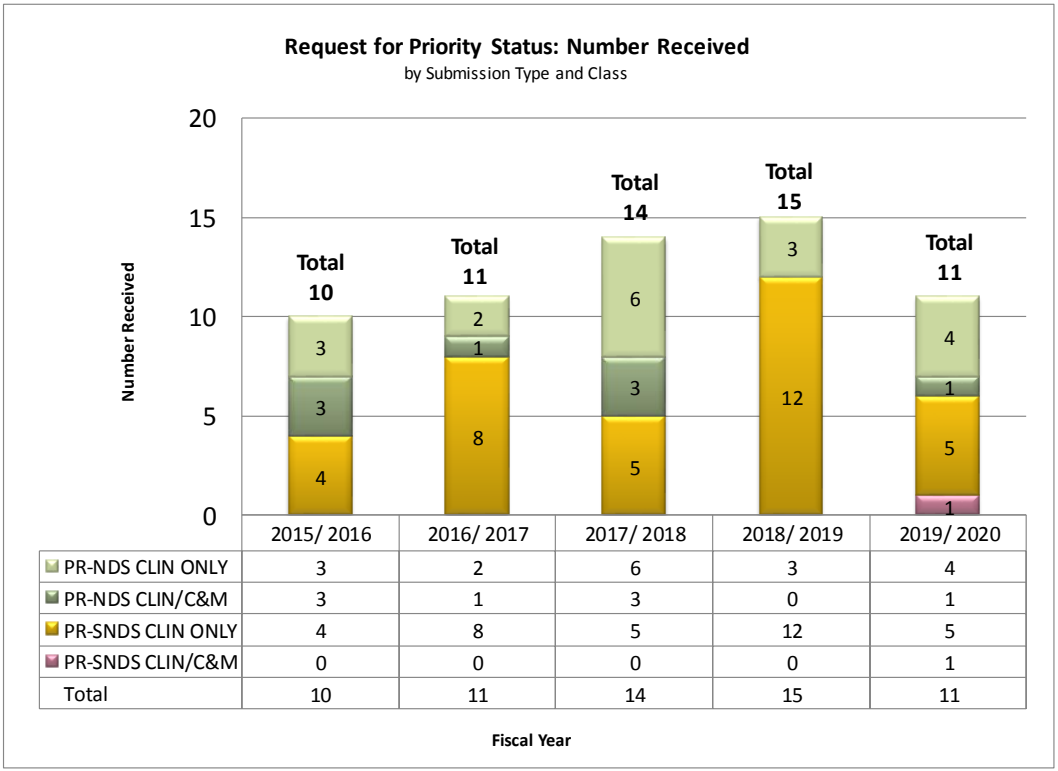
Requests for Reconsideration of Final Decisions - NDS, SNDS & ANDS

Reconsideration of Final Decisions Requests Received NDS, SNDS & ANDS					
Fiscal Year of Request (April 1 - March 31)					
	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
Total Received	0	0	0	0	0

This page is left blank intentionally

REQUEST FOR PRIORITY REVIEW STATUS RECEIVED

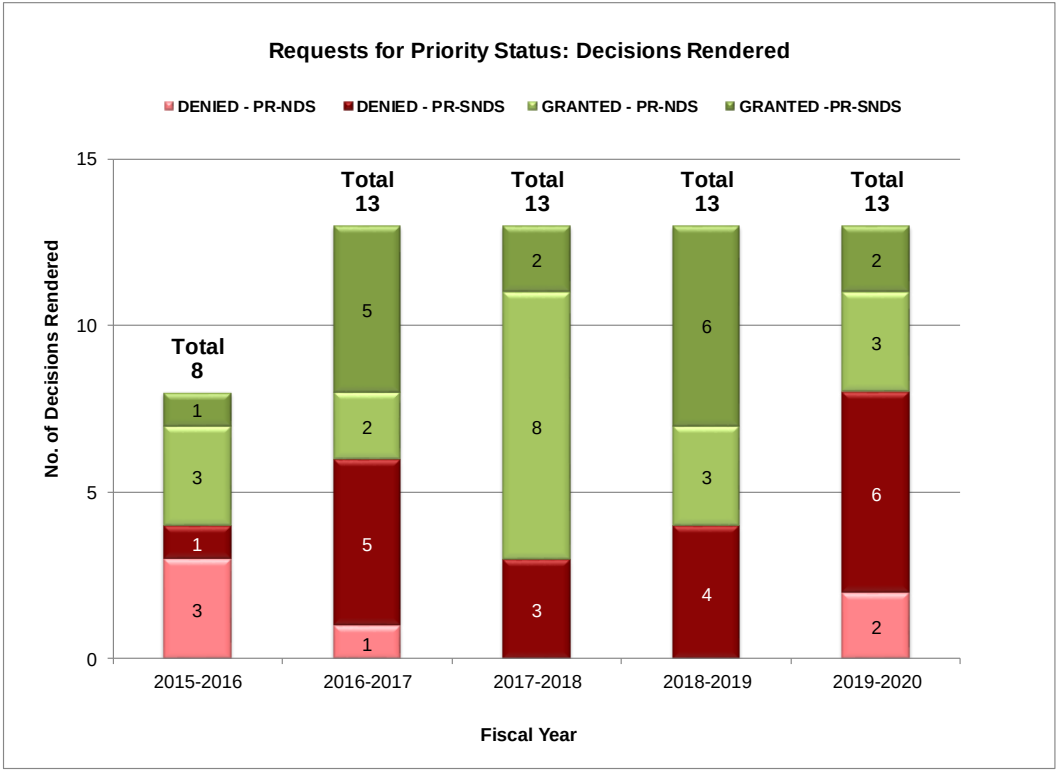
Request for Priority Review Status: Number Received



	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
PR-NDS CLIN ONLY	3	2	6	3	4
PR-NDS CLIN/C&M	3	1	3	0	1
PR-SNDS CLIN ONLY	4	8	5	12	5
PR-SNDS CLIN/C&M	0	0	0	0	1
Total	10	11	14	15	11

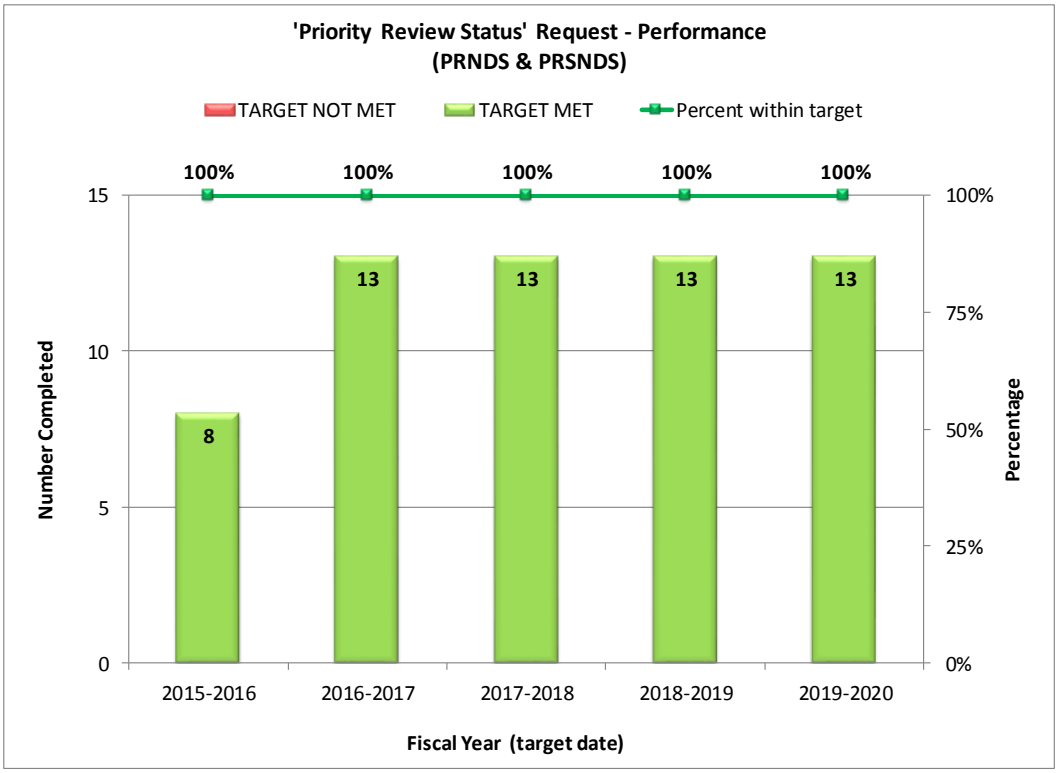
DECISIONS

Request for Priority Review Status: Decisions Rendered



REQUEST FOR PRIORITY REVIEW STATUS PERFORMANCE

Request for Priority Review Status: Performance



REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions - Priority Review Requests

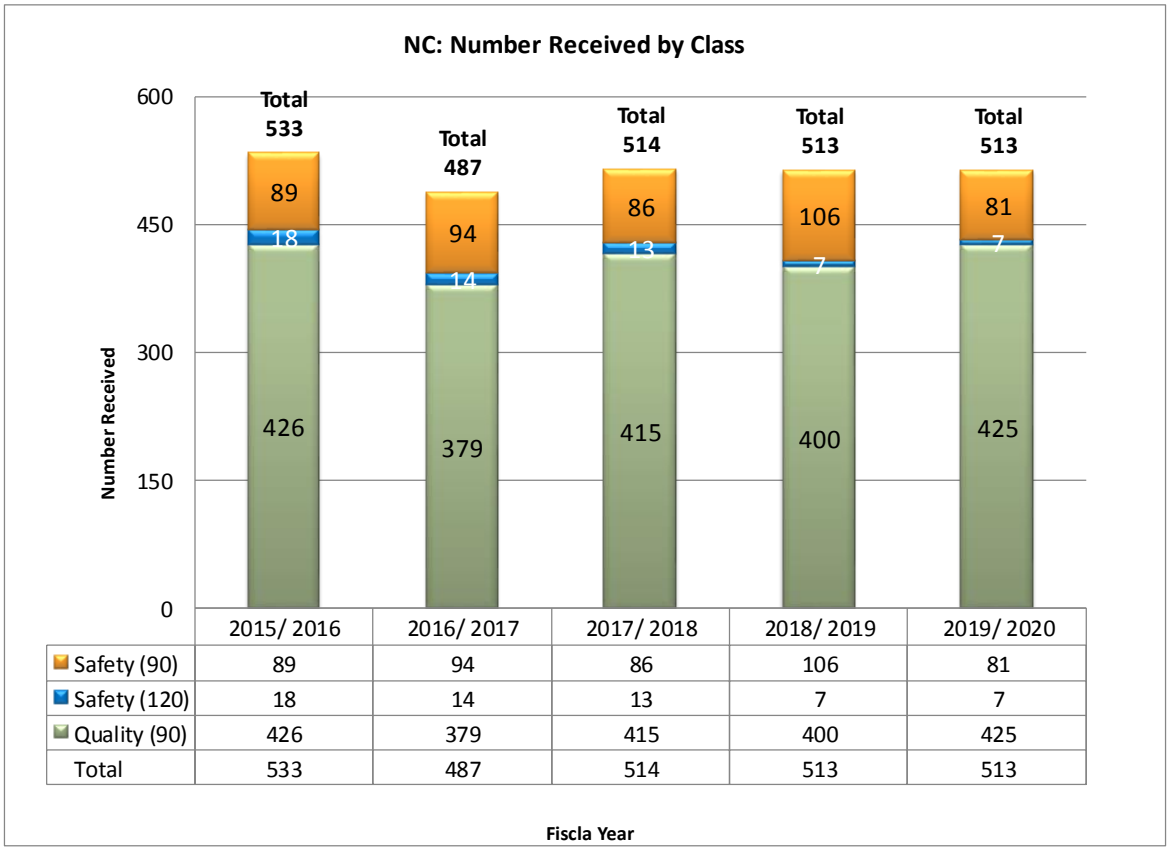
"Priority Review Request" - Requests for Reconsideration of Final Decisions Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020	Final Decision in Dispute	Submission Status (as of May 2020)
Total Received	0	1	0	1	0		
Total Denied	*0*	*1*	*0*	*1*	*0*	PR-SNDS: Priority Review Request Denied	Rejected

NC: NOTIFIABLE CHANGES

NC: NOTIFIABLE CHANGE

RECEIVED

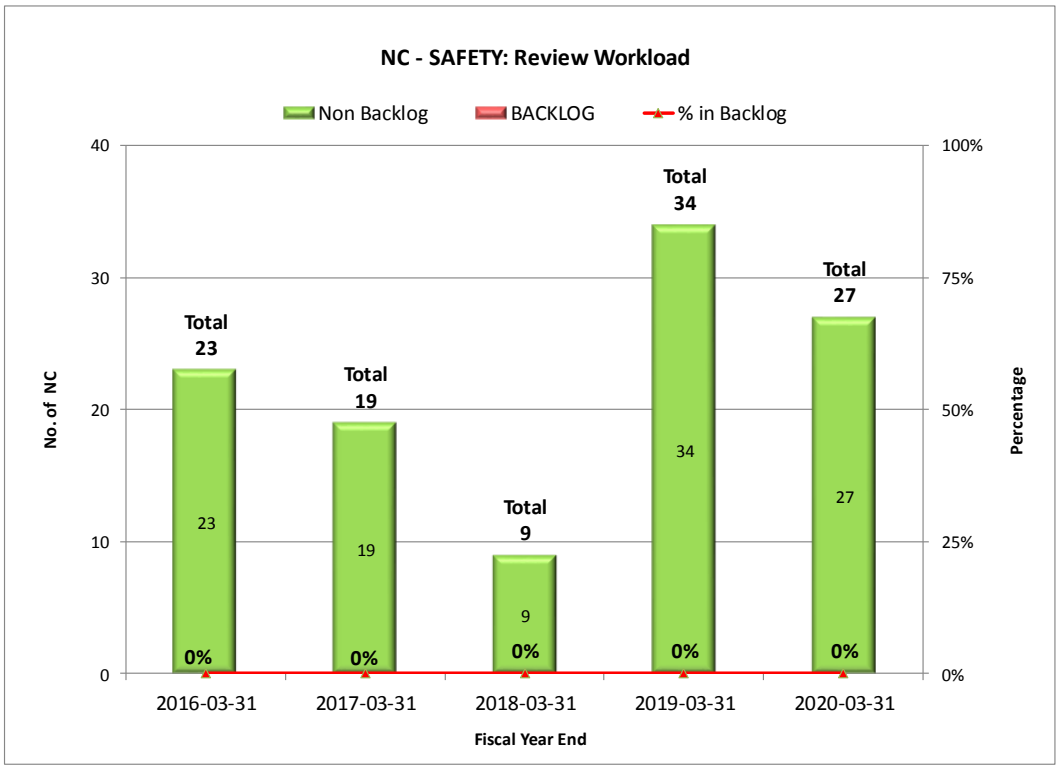
NC: Number Received by Class



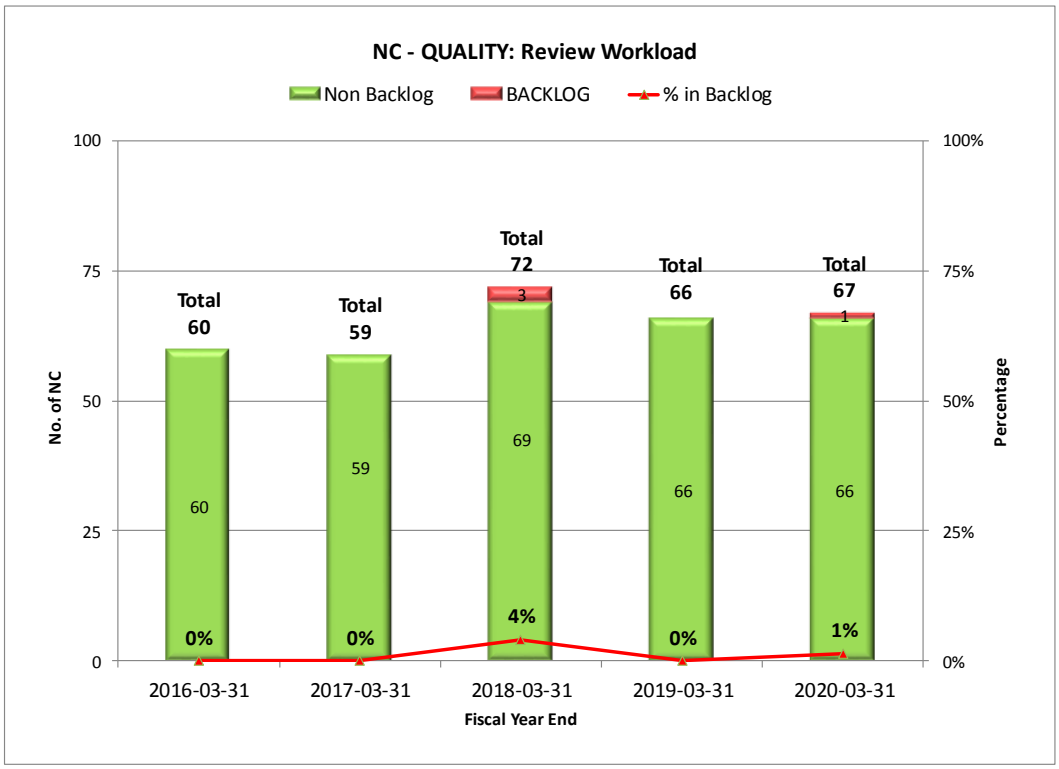
	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Safety (90)	89	94	86	106	81
Safety (120)	18	14	13	7	7
Quality (90)	426	379	415	400	425
Total	533	487	514	513	513

WORKLOAD

NC-SAFETY: Review Workload



NC-QUALITY: Review Workload



WORKLOAD

NC-SAFETY: Review Workload by Class

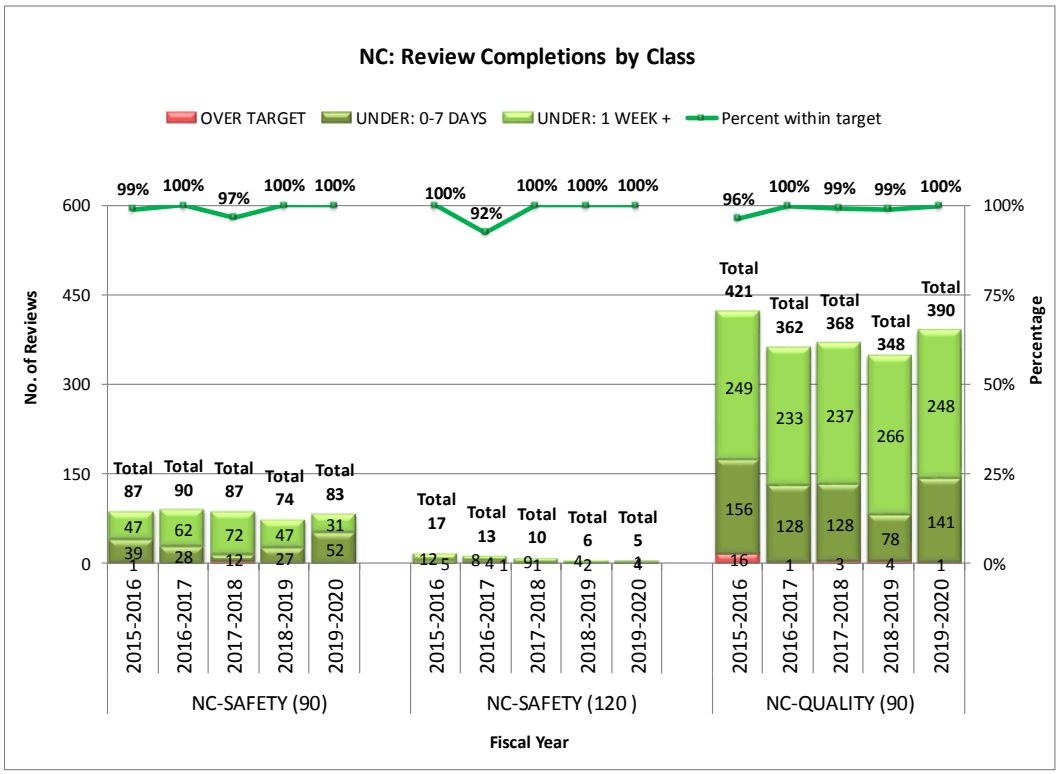
BBRD NC - SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	**2016-03-31**	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**
SAFETY - 90 day	20	15	8	34	24
Backlog	*0*	*0*	*0*	*0*	*0*
SAFETY - 120 day	3	4	1	0	3
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**23**	**19**	**9**	**34**	**27**
Non Backlog	**23**	**19**	**9**	**34**	**27**
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

NC-QUALITY: Review Workload by Class

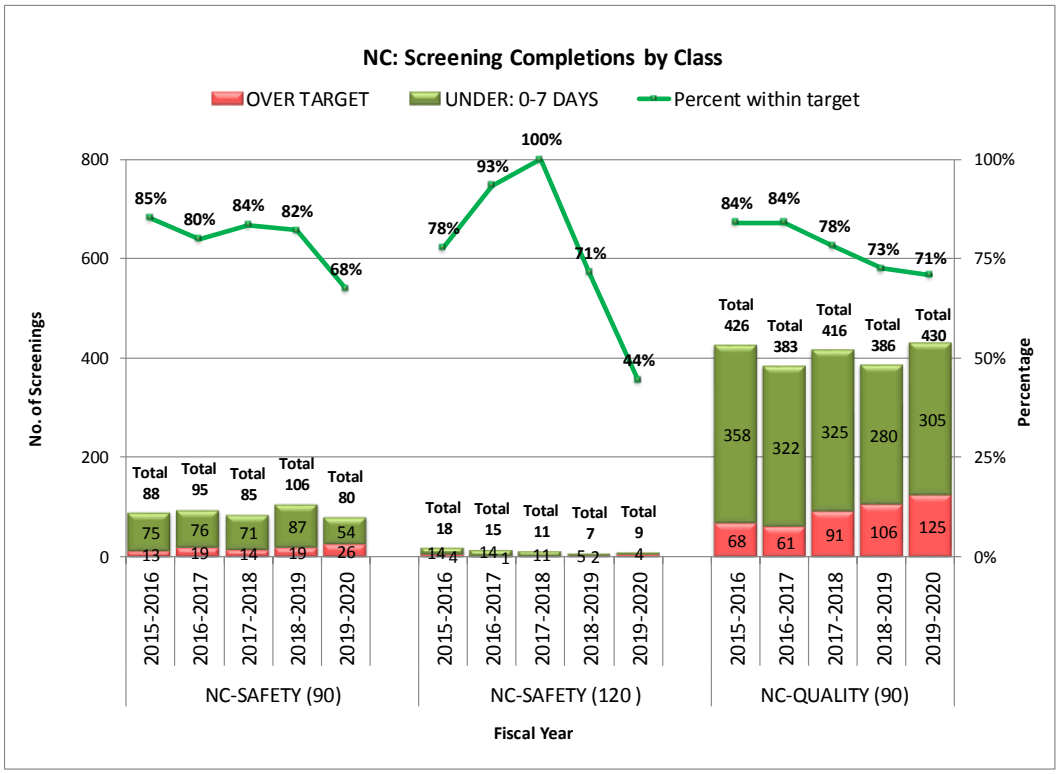
BBRD NC - QUALITY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	**2016-03-31**	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**
QUALITY - 90 day	**60**	**59**	**72**	**66**	**67**
Backlog	*0*	*0*	*3*	*0*	*1*
Total	**60**	**59**	**72**	**66**	**67**
Non Backlog	**60**	**59**	**69**	**66**	**66**
BACKLOG	0	0	3	0	1
% in Backlog	0%	0%	4%	0%	1%

PERFORMANCE

NC: Review Completions by Class



NC: Screening Completions by Class



DECISIONS

NC: Decision Documents by Class

DOCUMENT TYPE	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
NC - QUALITY (90)					
NO OBJECTION LETTER	410	363	381	358	415
NOT SATISFACTORY NOTICE	3	1	0	0	0
REJECTION LETTER (SCR)	33	7	12	16	1
CANCELLED BY COMPANY	6	13	8	16	15
SCREENING DEFICIENCY NOTICE	7	5	2	0	0
NC - HOLD (PATENT)	0	0	0	3	1
NC - SAFETY (90)					
NO OBJECTION LETTER	81	97	88	78	82
NOT SATISFACTORY NOTICE	2	0	0	0	0
REJECTION LETTER (SCR)	1	0	0	0	0
CANCELLED BY COMPANY	4	3	6	5	9
SCREENING DEFICIENCY NOTICE	1	1	1	0	0
NC - HOLD (PATENT)	1	0	0	0	0
NC - SAFETY (120)					
NO OBJECTION LETTER	15	12	12	6	5
NOT SATISFACTORY NOTICE	2	1	0	0	0
REJECTION LETTER (SCR)					
SCREENING DEFICIENCY NOTICE	0	0	1	0	0
CANCELLED BY COMPANY	1	1	2	2	1
NC - ADMINISTRATIVE					
NO OBJECTION LETTER	30	22	9	5	2

REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

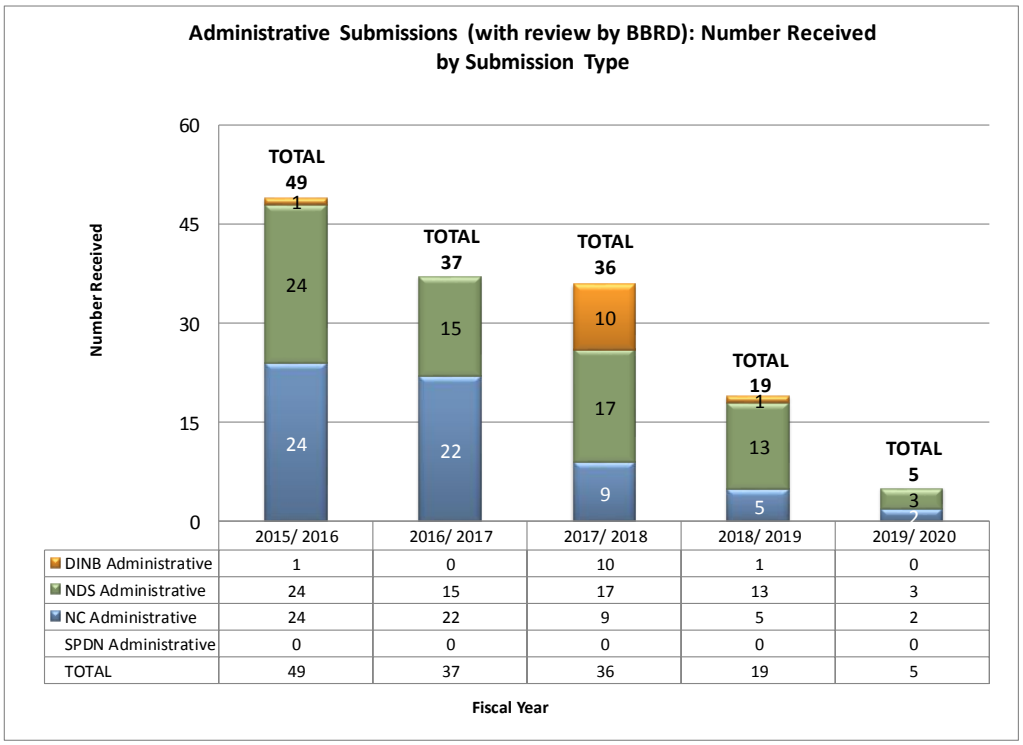
Requests for Reconsideration of Final Decisions- NC

NC - Requests for Reconsideration of Final Decisions					
Fiscal Year of Request (April 1 - March 31)					
	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
Total Received	0	0	0	0	0

ADMINISTRATIVE SUBMISSIONS (processed by BRDD)

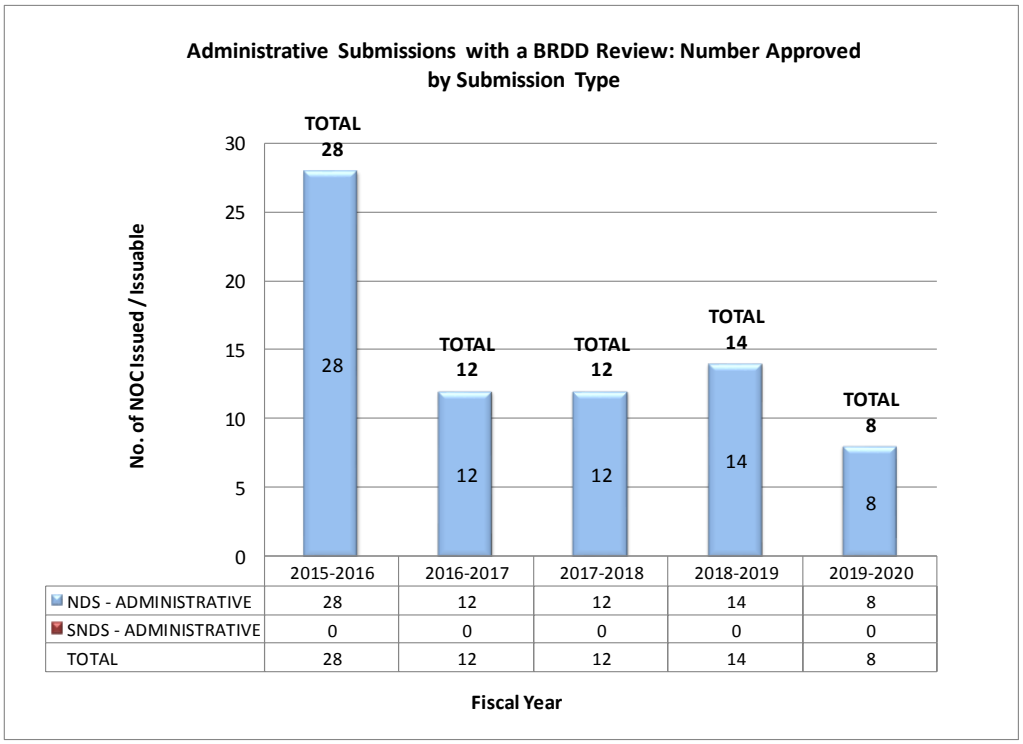
RECEIVED

Administrative Submissions: Number Received



APPROVALS

Administrative Submission: Number Approved

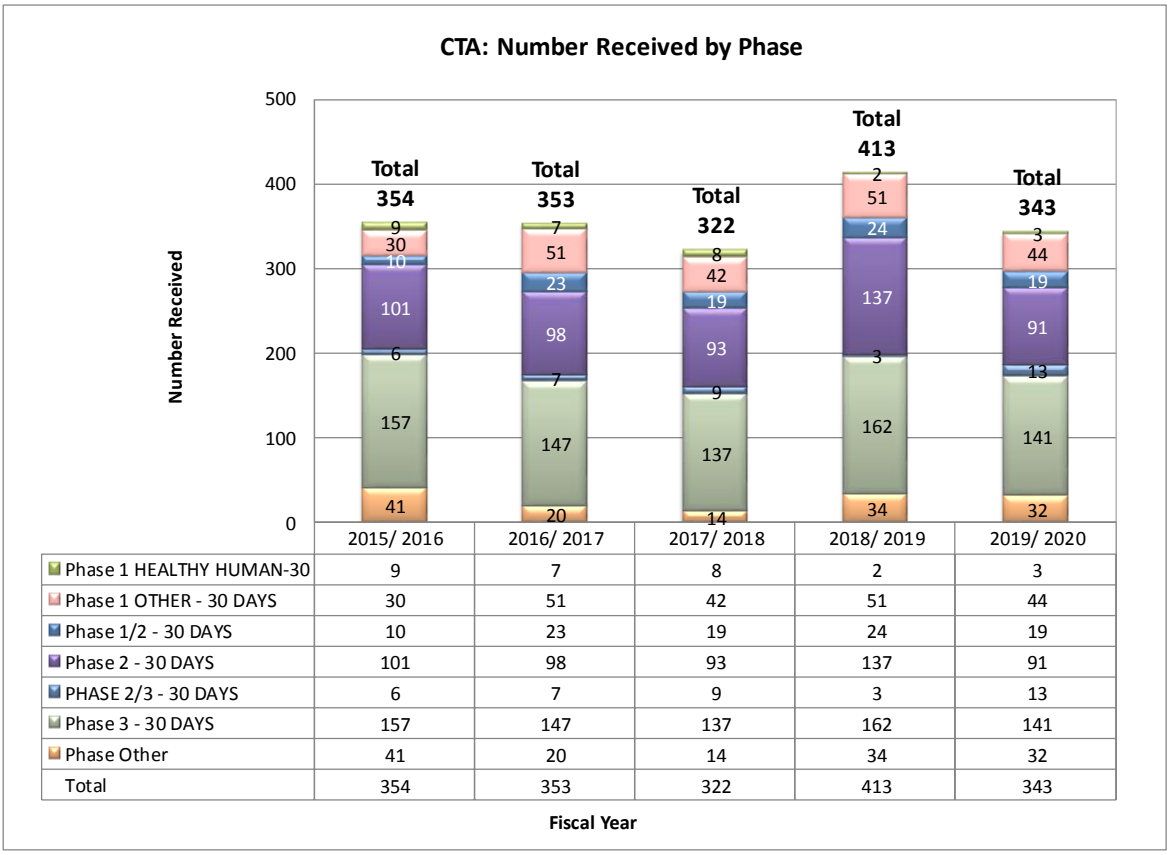


CLINICAL TRIAL APPLICATIONS AND AMENDMENTS

(CTA & CTA-A)

CTA: CLINICAL TRIAL APPLICATIONS RECEIVED

CTA: Number Received by Phase



	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Phase 1 HEALTHY HUMAN-30	9	7	8	2	3
Phase 1 OTHER - 30 DAYS	30	51	42	51	44
Phase 1/2 - 30 DAYS	10	23	19	24	19
Phase 2 - 30 DAYS	101	98	93	137	91
PHASE 2/3 - 30 DAYS	6	7	9	3	13
Phase 3 - 30 DAYS	157	147	137	162	141
Phase Other	41	20	14	34	32
Total	354	353	322	413	343

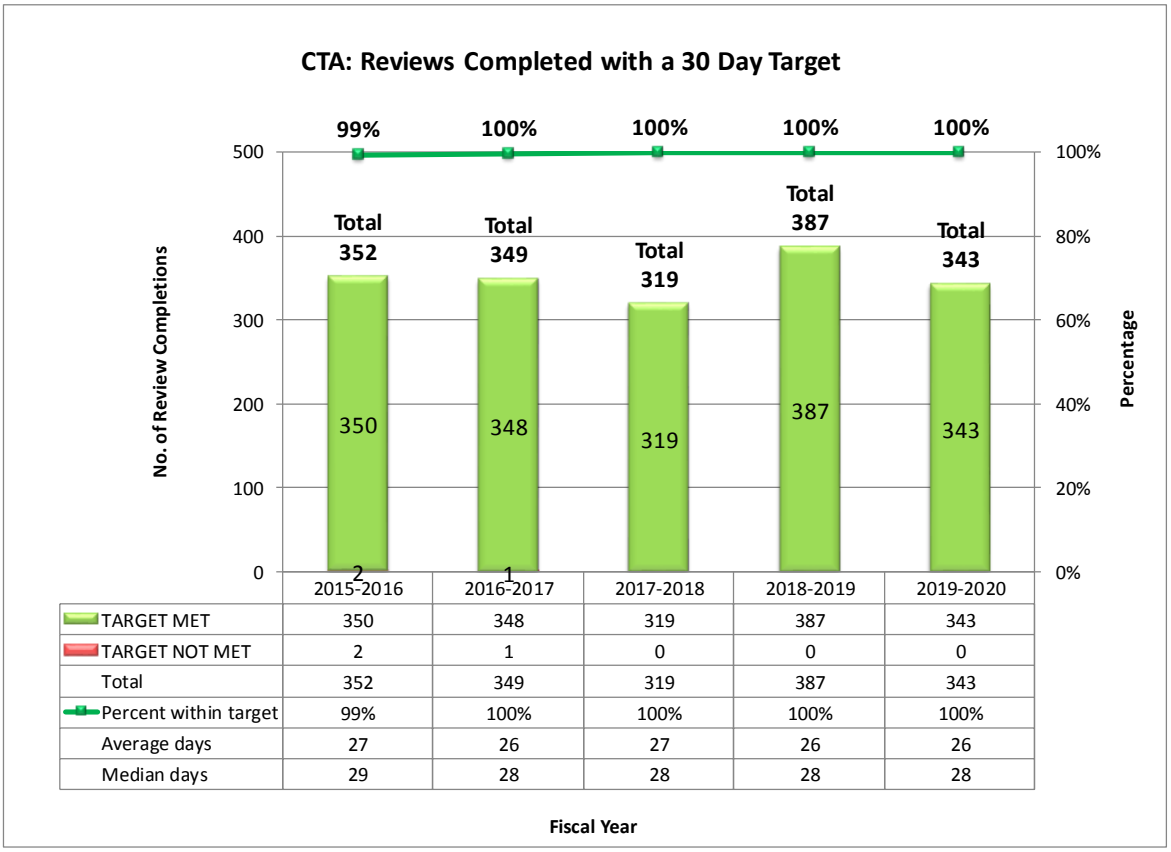
DECISIONS

CTA: Number of Decisions by Type

CTA					
DOCUMENT TYPE	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**
NO OBJECTION LETTER	336	328	307	380	326
CANCELLED BY COMPANY DURING REVIEW	10	21	12	7	17
CANCELLED BY COMPANY AT PROCESSING	2	10	6	6	14
NOT SATISFACTORY NOTICE	3	0	0	1	0
REFUSAL LETTER	0	0	0	0	0
REJECTION LETTER (SCR)	1	1	0	2	5
SCREENING DEFICIENCY NOTICE	3	0	0	0	0

PERFORMANCE

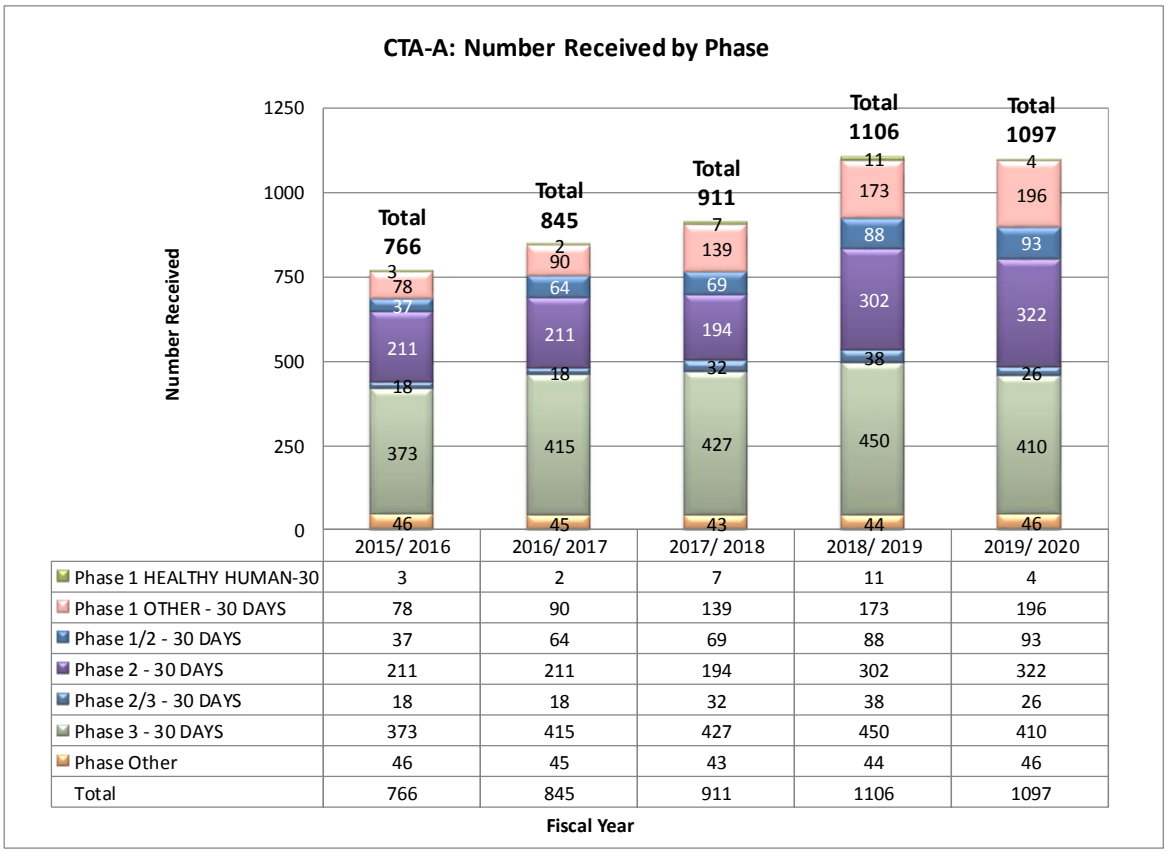
CTA: Reviews Completed with a 30 Day Target



	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
TARGET MET	350	348	319	387	343
TARGET NOT MET	2	1	0	0	0
Total	352	349	319	387	343
Percent within target	99%	100%	100%	100%	100%
Average days	27	26	27	26	26
Median days	29	28	28	28	28

CTA-A: CLINICAL TRIAL APPLICATION-AMENDMENTS RECEIVED

CTA-A: Number Received by Phase



	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Phase 1 HEALTHY HUMAN-30	3	2	7	11	4
Phase 1 OTHER - 30 DAYS	78	90	139	173	196
Phase 1/2 - 30 DAYS	37	64	69	88	93
Phase 2 - 30 DAYS	211	211	194	302	322
Phase 2/3 - 30 DAYS	18	18	32	38	26
Phase 3 - 30 DAYS	373	415	427	450	410
Phase Other	46	45	43	44	46
Total	766	845	911	1106	1097

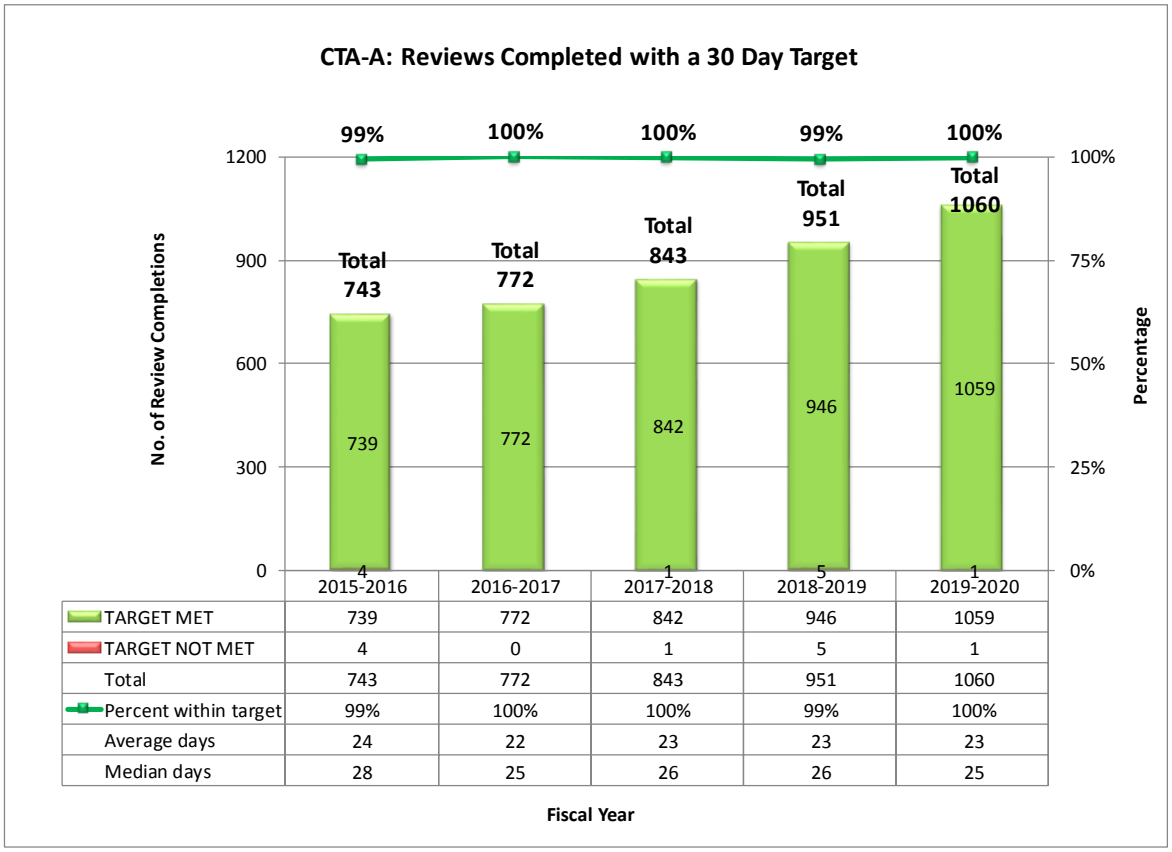
DECISIONS

CTA-A: Number of Decisions by Type

CTA-A					
DOCUMENT TYPE	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
NO OBJECTION LETTER	747	794	869	1048	1080
CANCELLED BY COMPANY DURING REVIEW	5	7	15	4	9
CANCELLED BY COMPANY AT PROCESSING	2	10	9	9	10
NOT SATISFACTORY NOTICE	2	0	0	0	0
REJECTION LETTER (SCR)	10	15	15	20	23

PERFORMANCE

CTA-A: Reviews Completed with a 30 Day Target



	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
TARGET MET	739	772	842	946	1059
TARGET NOT MET	4	0	1	5	1
Total	743	772	843	951	1060
Percent within target	99%	100%	100%	99%	100%
Average days	24	22	23	23	23
Median days	28	25	26	26	25

DINB

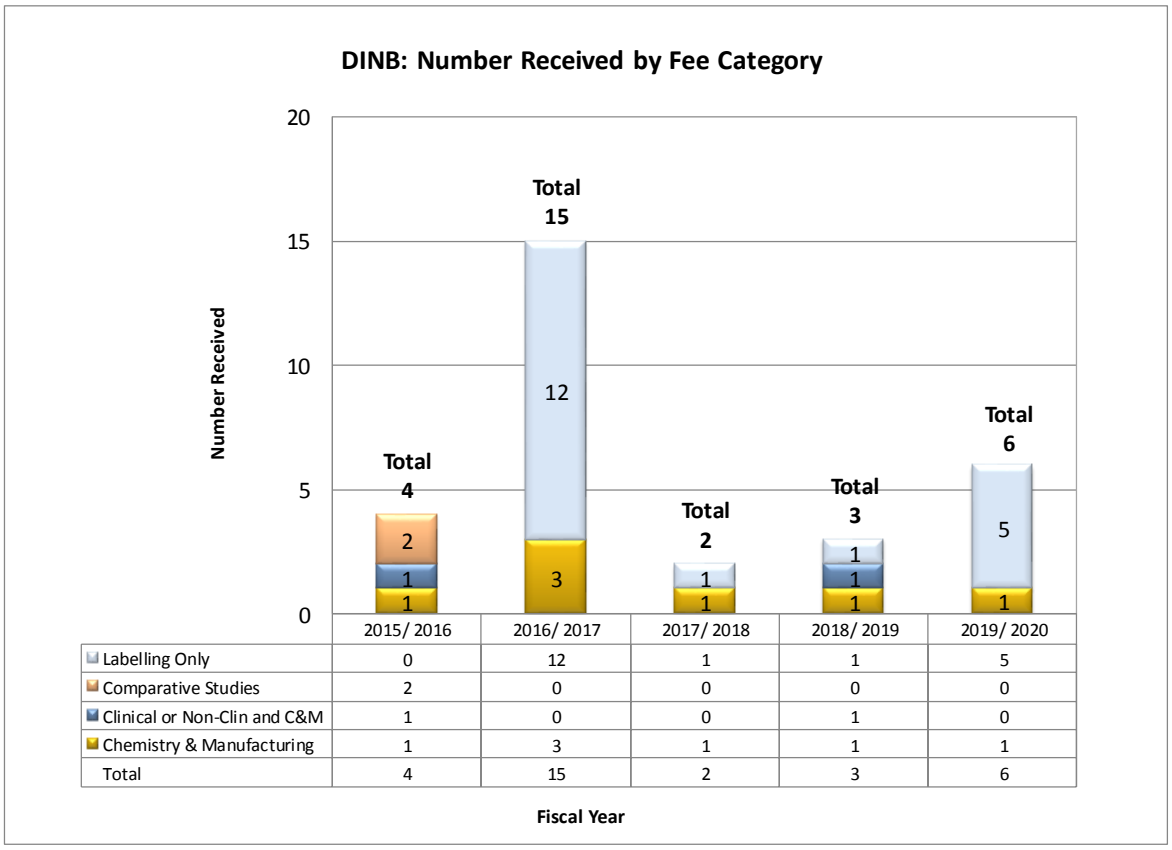
Application for a Drug Identification Number

Biological Products

DINB: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - BIOLOGICAL PRODUCT

RECEIVED

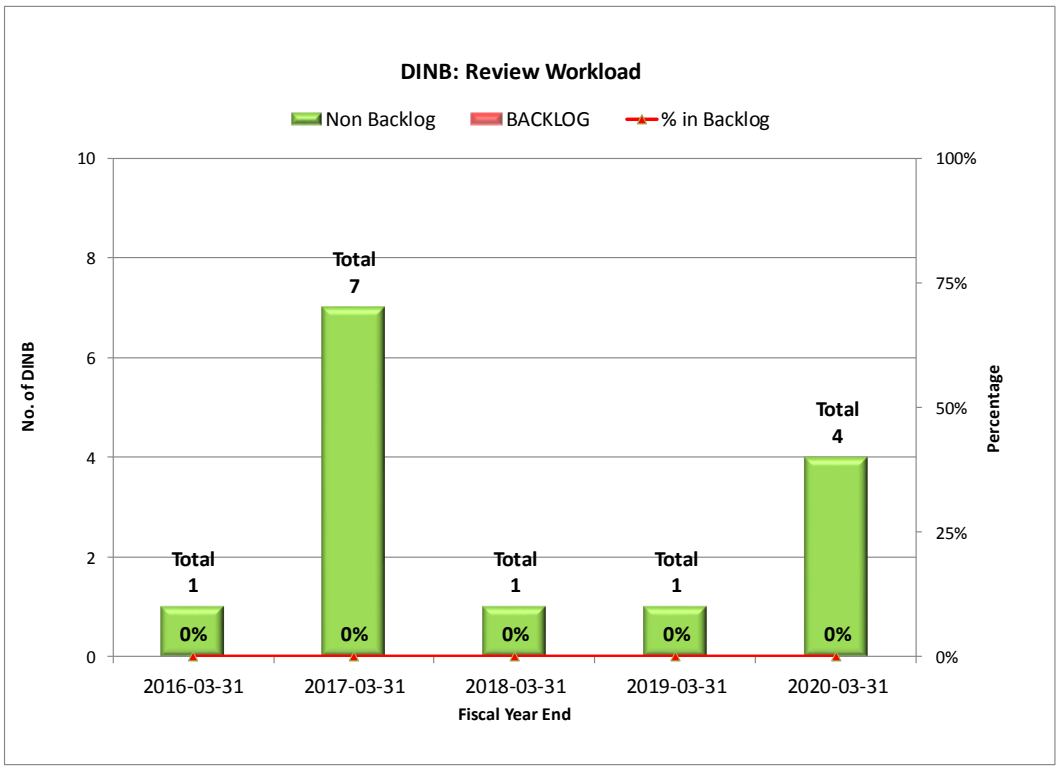
DINB: Number Received by Fee Category



	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Labelling Only	0	12	1	1	5
Comparative Studies	2	0	0	0	0
Clinical or Non-Clin and C&M	1	0	0	1	0
Chemistry & Manufacturing	1	3	1	1	1
Total	4	15	2	3	6

REVIEW WORKLOAD

DINB: Review Workload

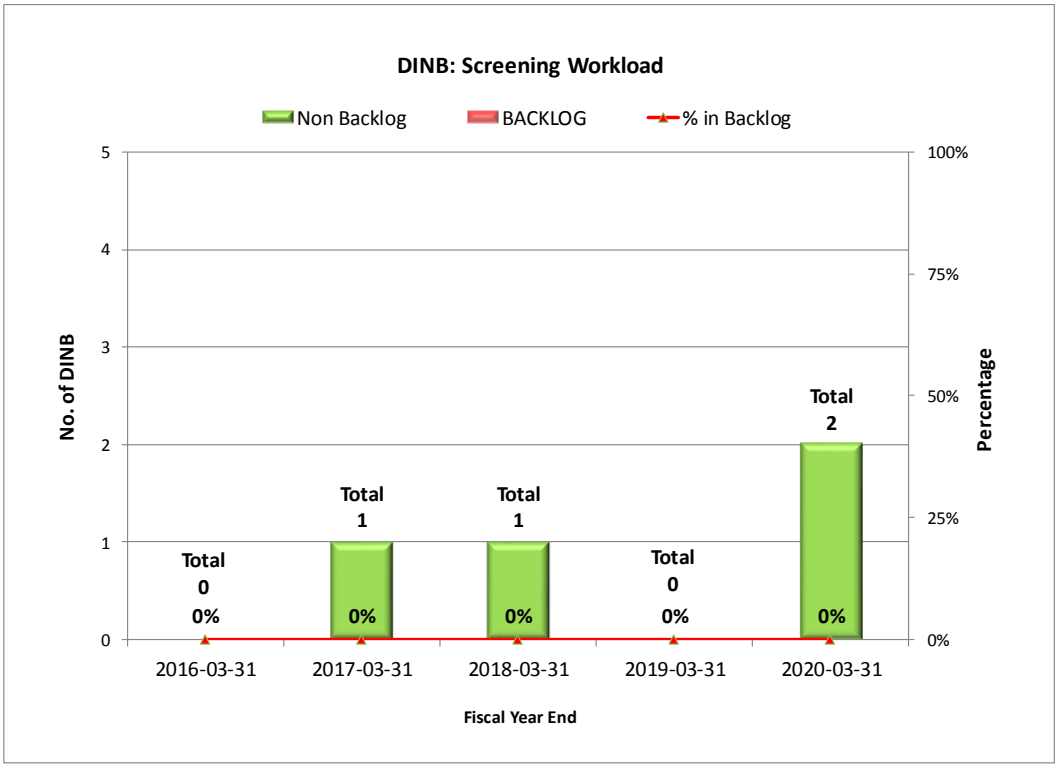


DINB: Review Workload by Fee Category

DINB: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Labelling Only	0	6	1	0	3
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	1	1	0	1	1
Backlog	*0*	*0*	*0*	*0*	*0*
Total	1	7	1	1	4
Non Backlog	1	7	1	1	4
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

SCREENING WORKLOAD

DINB: Screening Workload



DINB: Screening Workload by Fee Category

DINB: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Labelling Only	0	0	0	0	2
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	0	1	1	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	0	1	1	0	2
Non Backlog	0	1	1	0	2
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DECISIONS

DINB: Number of Decisions by Fee Category

DOCUMENT TYPE	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
DINB - LABELLING ONLY					
NO OBJECTION LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
NEW DRUG LETTER SCREEN	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
CANCELLED BY COMPANY	0	6	6	0	0
DINB - CHEMISTRY & MANUFACTURING					
NO OBJECTION LETTER	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTIFICATION FORM DIN SUB	0	0	1	0	0
SCREENING DEFICIENCY NOTICE	0	0	1	0	0
CANCELLED BY COMPANY	0	0	0	0	0
DINB - CLIN/C&M					
NO OBJECTION LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	1	0	0	0	0
DINB - ADMINISTRATIVE					
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
CANCELLED BY COMPANY	0	0	1	0	0
DINB - COMPARATIVE STUDIES					
REJECTION LETTER (SCREENING)	1	0	0	0	0
SCREENING DEFICIENCY NOTICE	1	0	0	0	0

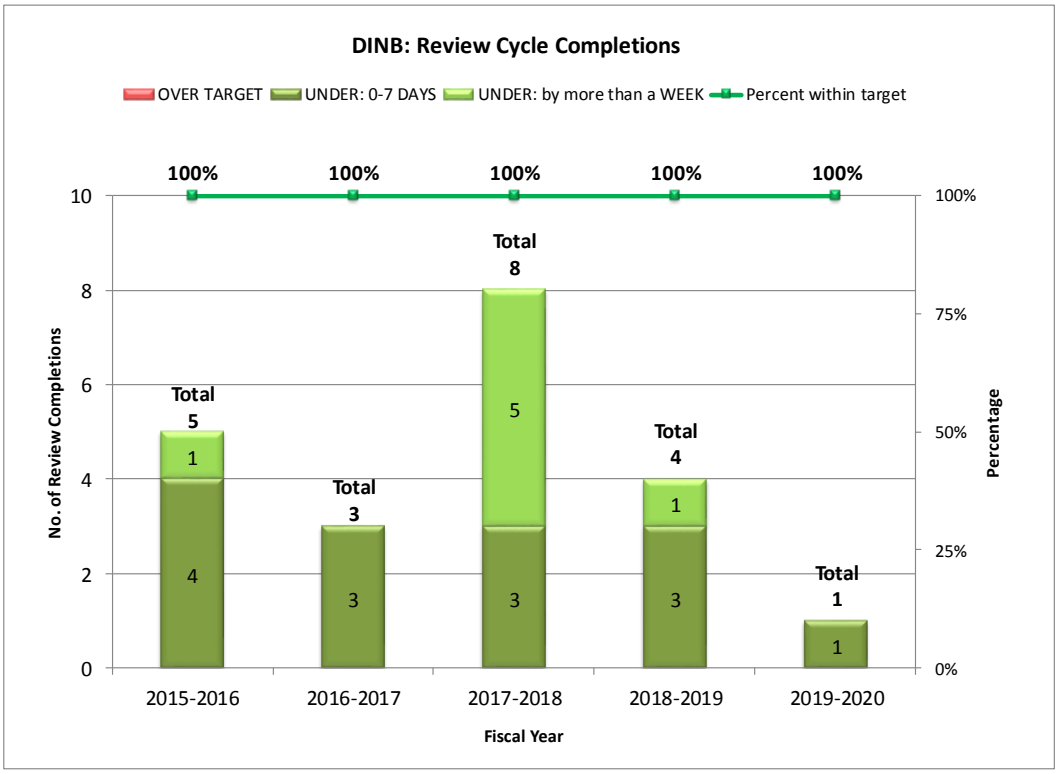
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

DINB: Requests for Reconsideration of Final Decisions

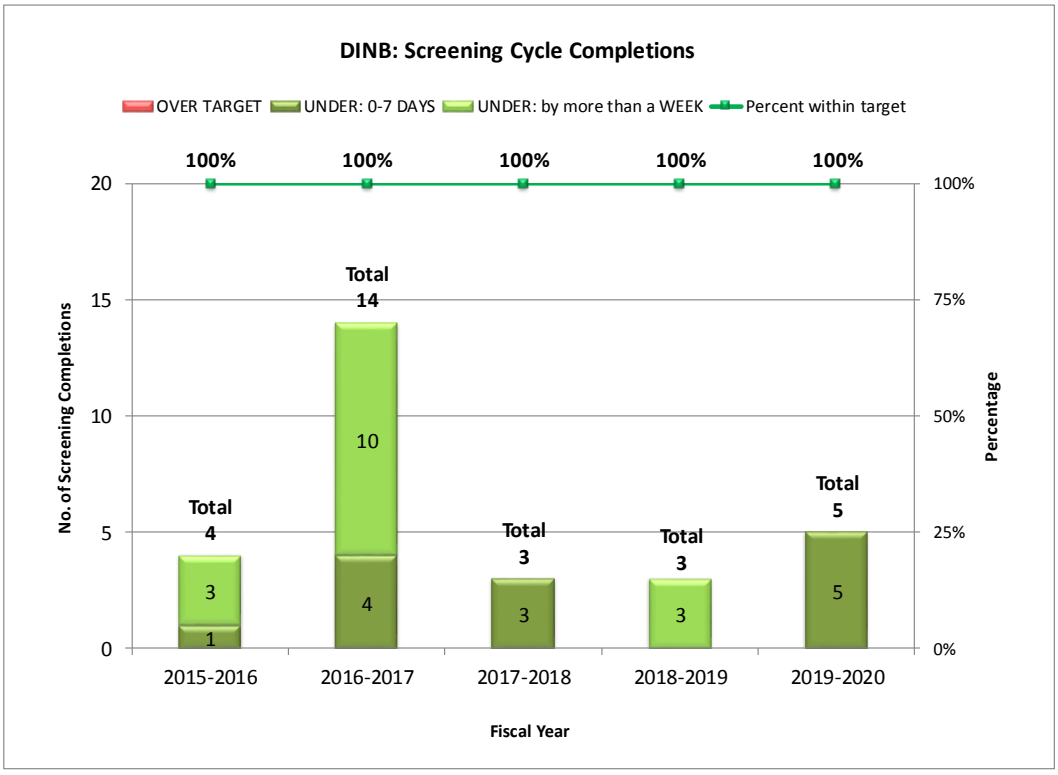
DINB - Requests for Reconsideration of Final Decisions					
Fiscal Year of Request (April 1 - March 31)					
	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
Total	0	0	0	0	0

PERFORMANCE

DINB: Review Cycle Completions



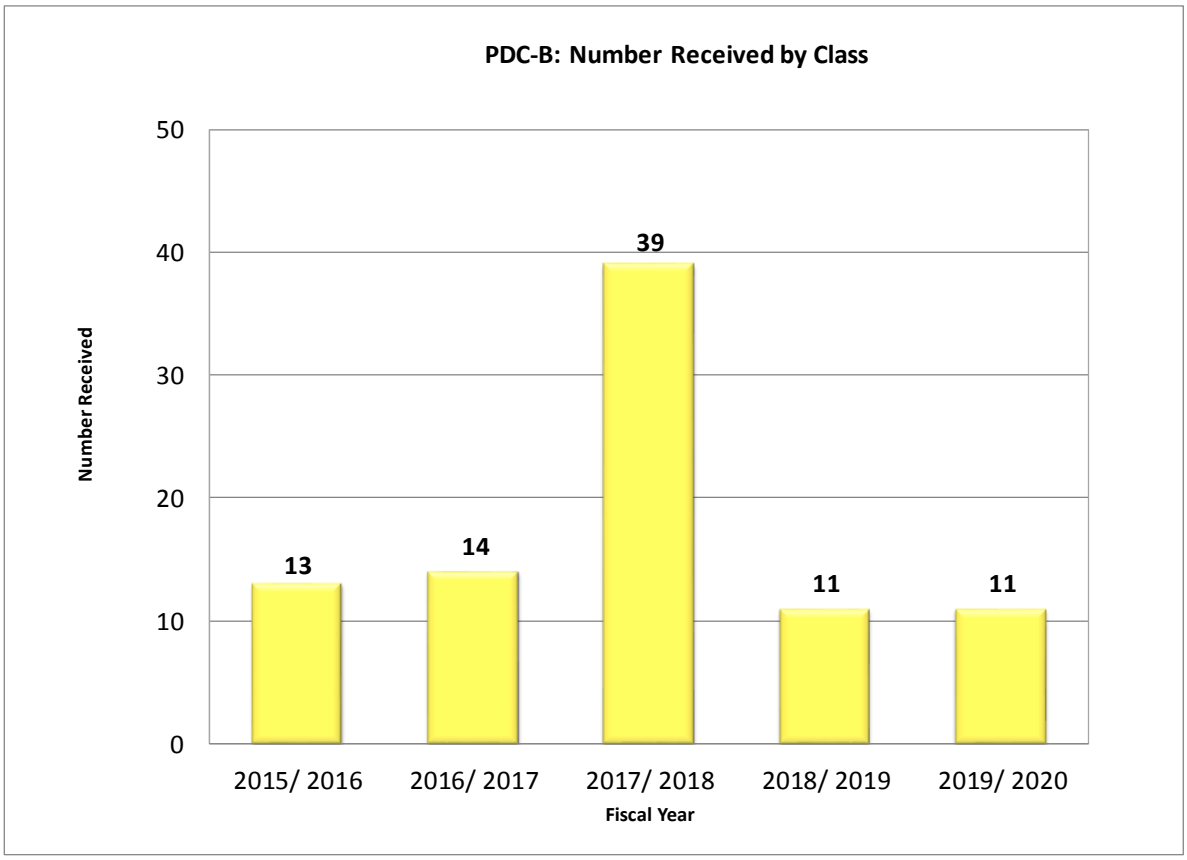
DINB: Screening Cycle Completions



PDC-B: POST AUTHORIZATION DIVISION 1 CHANGE FOR A BIOLOGIC DRUG PRODUCT

RECEIVED

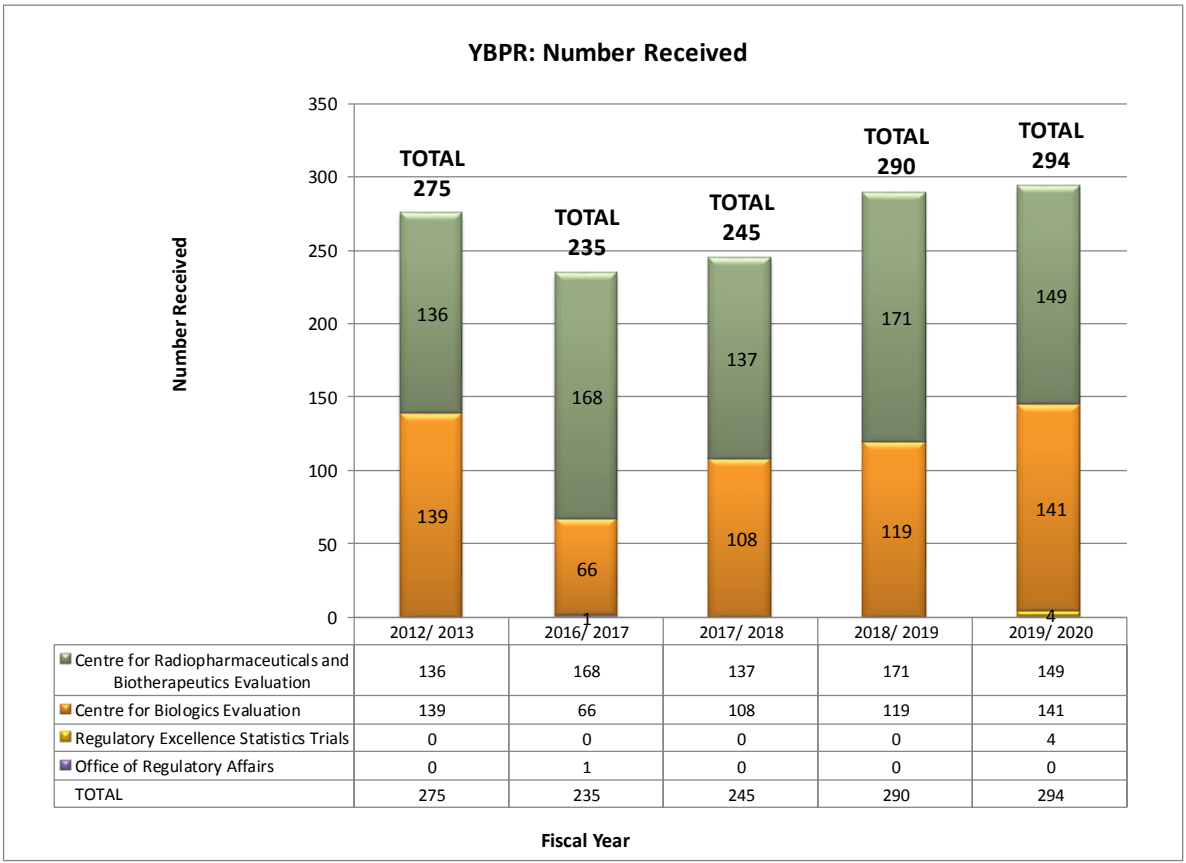
PDC-B: Number Received



YBPR: YEARLY BIOLOGIC PRODUCT REPORTS [12]

RECEIVED

YBPR: Number Received

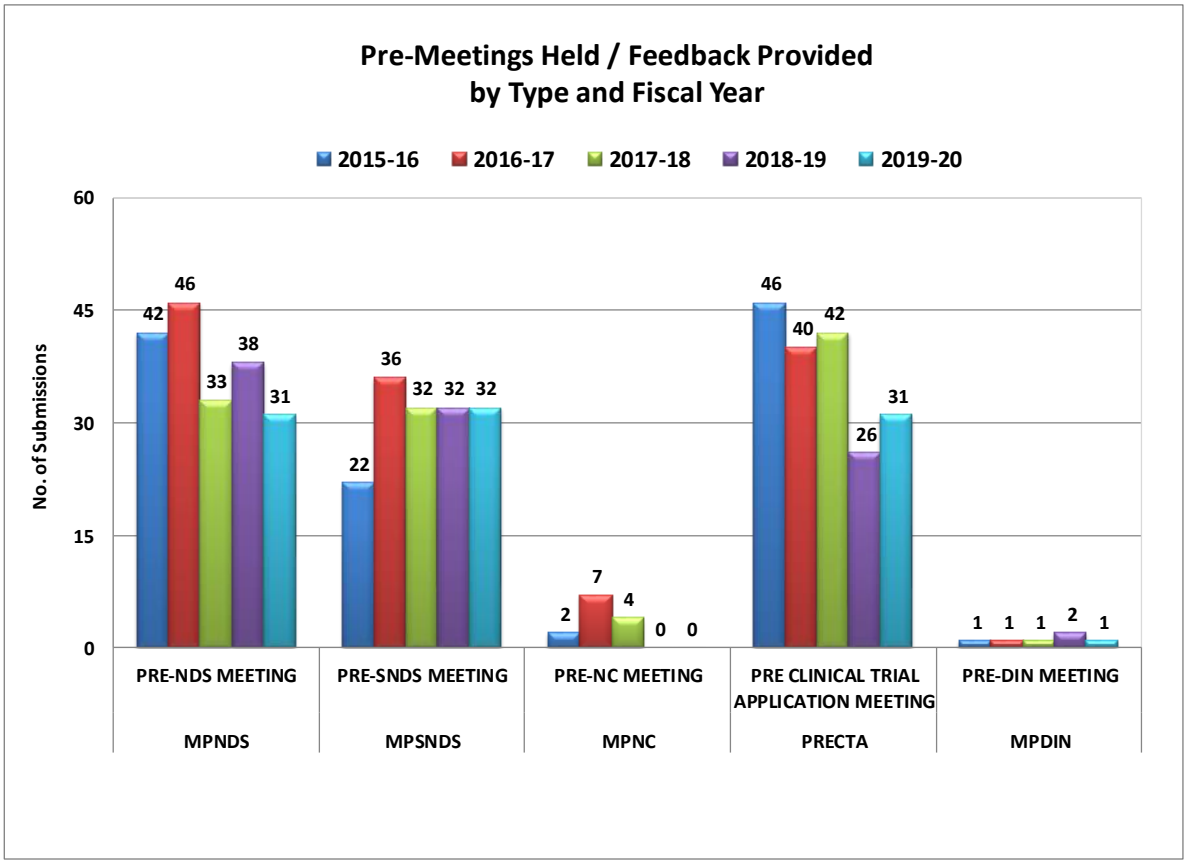


	2012/ 2013	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Centre for Radiopharmaceuticals and Biotherapeutics Evaluation	136	168	137	171	149
Centre for Biologics Evaluation	139	66	108	119	141
Regulatory Excellence Statistics Trials	0	0	0	0	4
Office of Regulatory Affairs	0	1	0	0	0
TOTAL	275	235	245	290	294

[12] 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 [13]

Pre-Submission Meetings Held / Feedback Provided



[13] 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 and Applications

This page is left blank intentionally.