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# Biologic and Radiopharmaceutical Drugs Directorate

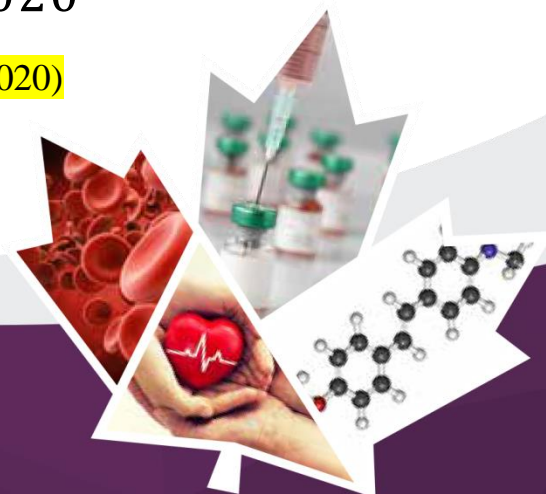
Drug Submission Performance Annual  
Report

Fiscal Year

2019-2020

April 1 2019 – March 31 2020

(Revisions to pages 22-24 – September 1, 2020)



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# 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<sup>1</sup> 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**<sup>2</sup> 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.

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<sup>1</sup> For further clarification refer to the [Guidance for Industry: Management of Drug Submissions and Applications](#).

<sup>2</sup> 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**<sup>3</sup> 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](#)<sup>4</sup> 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”<sup>5</sup> 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  
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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](mailto:hc.osip-bppi.sc@canada.ca)

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<sup>3</sup> 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.

<sup>4</sup> 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).

<sup>5</sup> 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
<b>New Active Substance (NAS)</b>	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.
<b>Clinical or Non-Clinical Data and Chemistry and Manufacturing data</b>	Submissions based on clinical or non-clinical data <b>and</b> chemistry and manufacturing data for a drug that does not include a NAS.
<b>Clinical or Non-Clinical Data Only</b>	Submissions based only on clinical or non-clinical data for a drug that does not include a NAS.
<b>Comparative Studies</b>	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.
<b>Chemistry and Manufacturing Data Only</b>	Submissions based only on chemistry and manufacturing data for a drug that does not include a NAS.
<b>Published Data Only</b>	Submissions based only on published clinical or non-clinical data for a drug that does not include a NAS.
<b>Switch from Prescription to Nonprescription Status</b>	Submissions based only on data that support the modification or removal of a medicinal ingredient on the <a href="#">Prescription Drug List</a> . This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug.
<b>Labelling Only<sup>6</sup></b>	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
<b>Administrative Submission<sup>7</sup></b>	Submissions in support of a manufacturer or product name change.
<b>Disinfectants<sup>8</sup></b>	Submissions and applications that include data in support of a disinfectant.
<b>Drug Identification Number (DIN) - Labelling Standards</b>	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](#)

<sup>6</sup> For more information, please consult the [Guidance Document: Question and Answers about Plain Language Labelling](#)

<sup>7</sup> For additional information, please consult the "[Changes in Manufacturer and/or Product Name Policy](#)" (2015)

<sup>8</sup> 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.

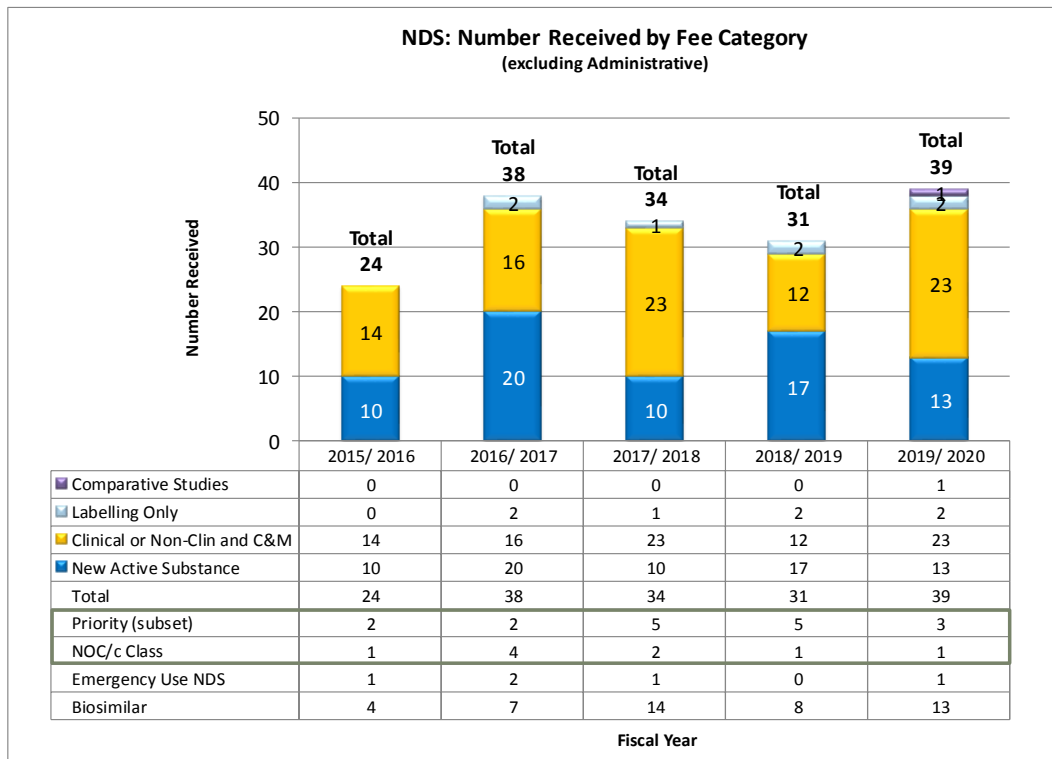
**New Drug Submission  
(NDS)**

**&**

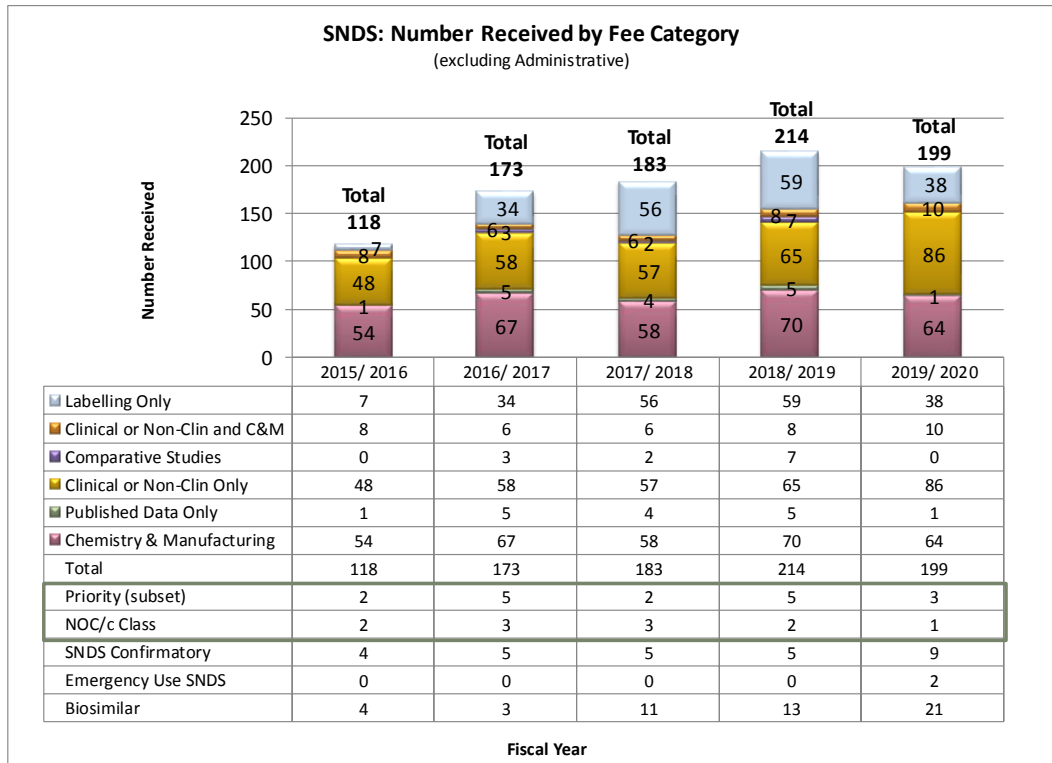
**Supplemental New Drug Submission  
(SNDS)**

## SUBMISSIONS RECEIVED <sup>9</sup>

### NDS: Received by Fee Category



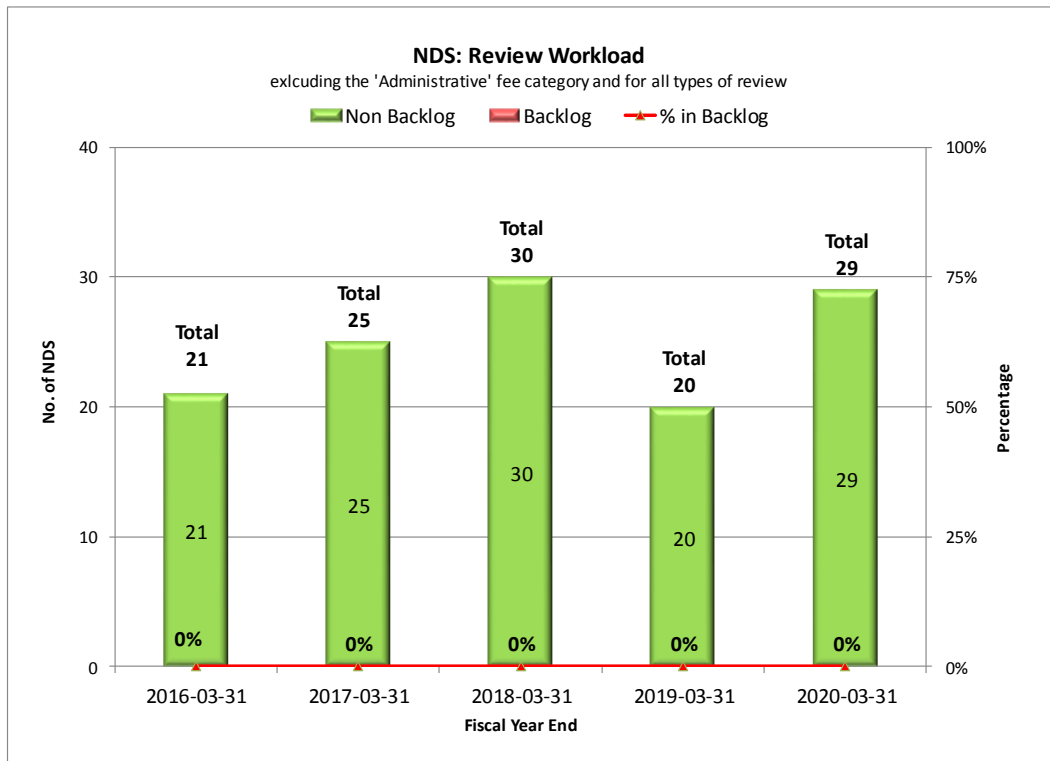
### SNDS: Received by Fee Category



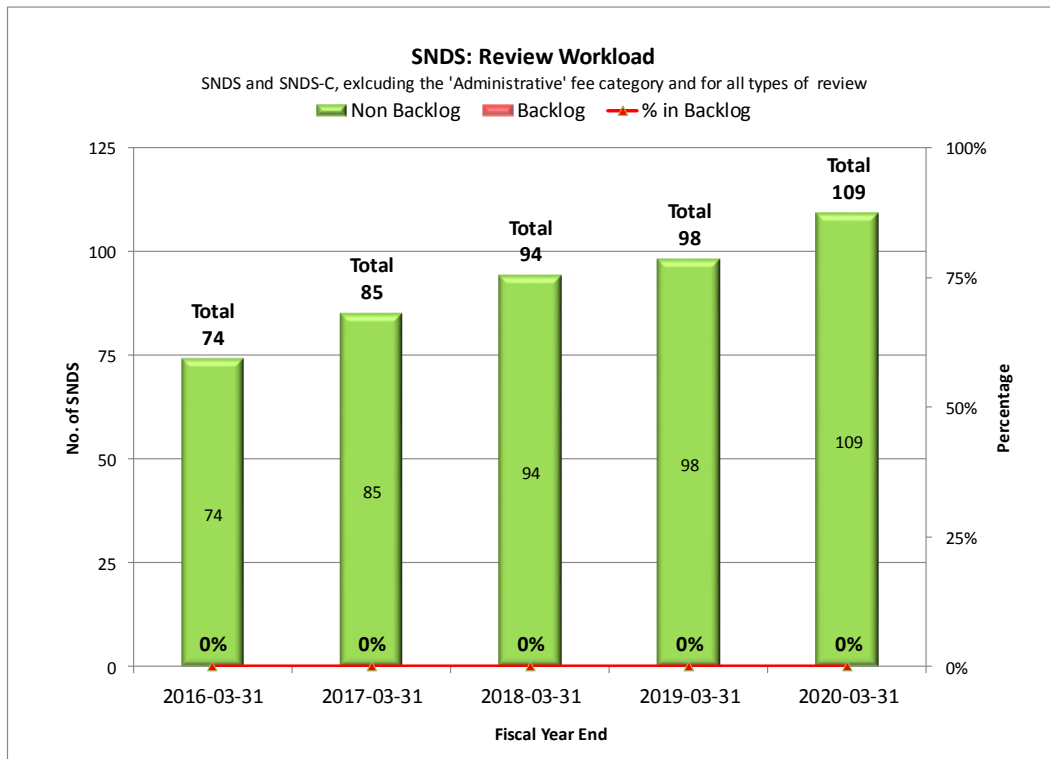
<sup>9</sup> Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the [Priority Review of Drug Submissions Policy](#), the [Notice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

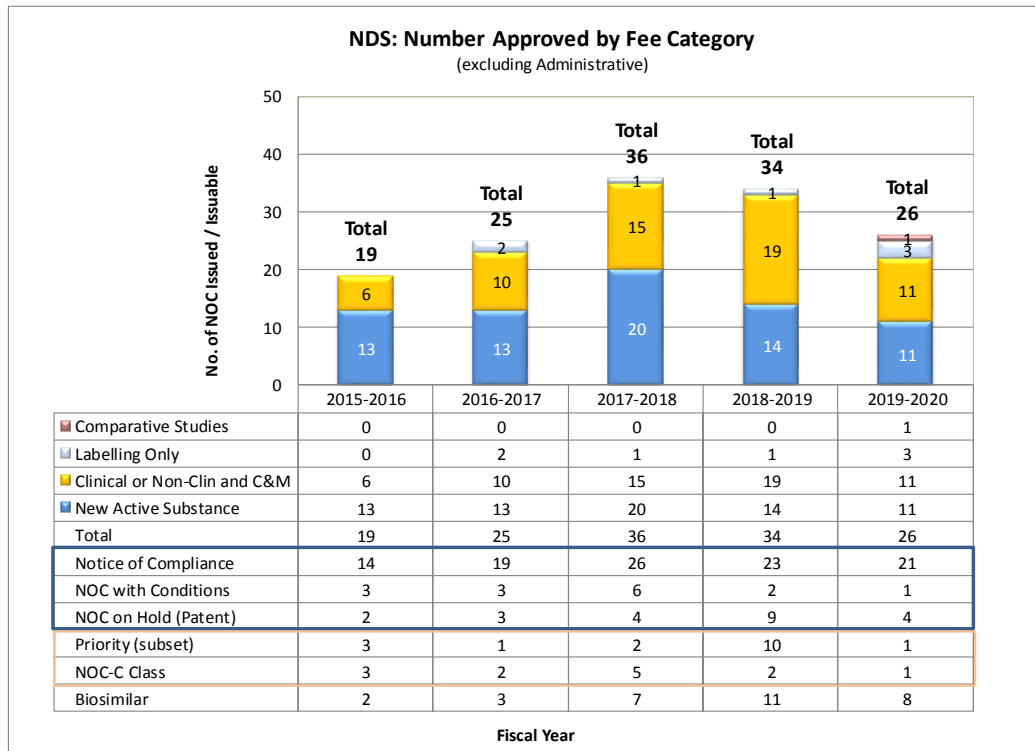
NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Clinical or Non-Clin and C&M	11	11	21	10	18
<i>Backlog</i>	0	0	0	0	0
New Active Substance	10	14	9	10	11
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>21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

### SNDS: Review Workload by Fee Category

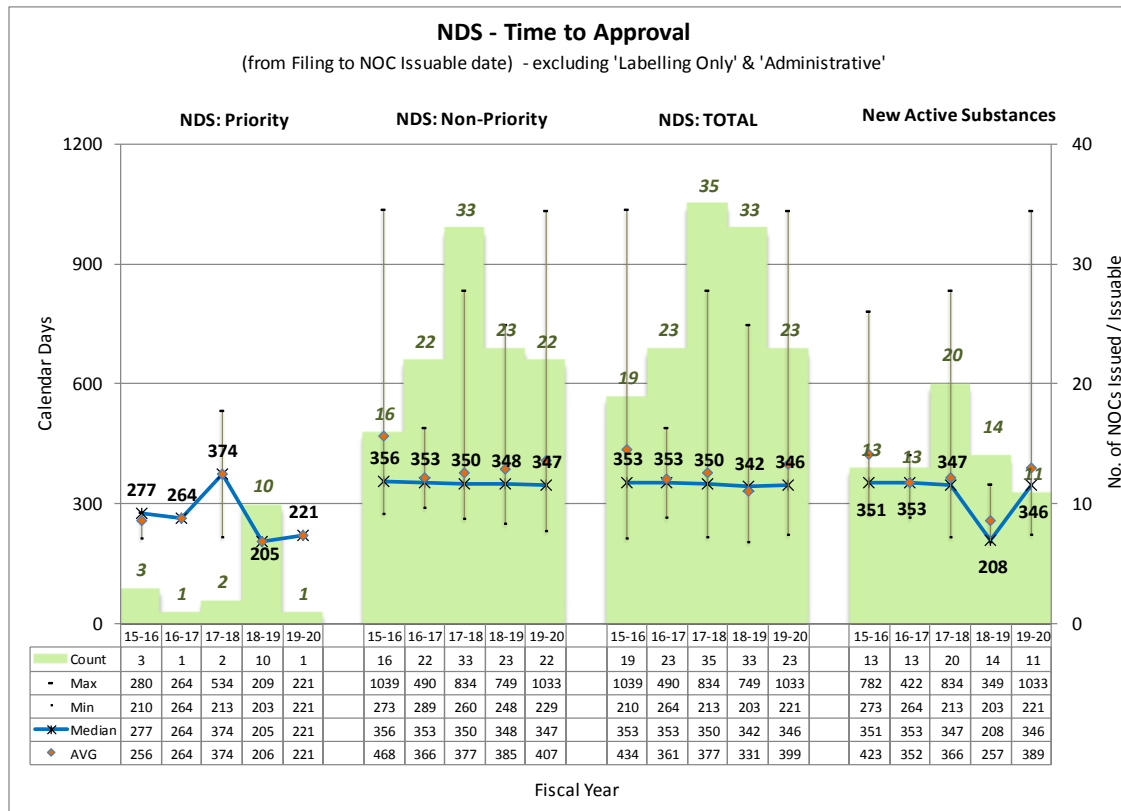
SNDS REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Comparative Studies	0	1	1	4	0
<i>Backlog</i>	0	0	0	0	0
Chemistry & Manufacturing	25	28	26	26	31
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clin Only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

## APPROVALS

### NDS: Number Approved by Fee Category and by NOC Type



### NDS Approval Times

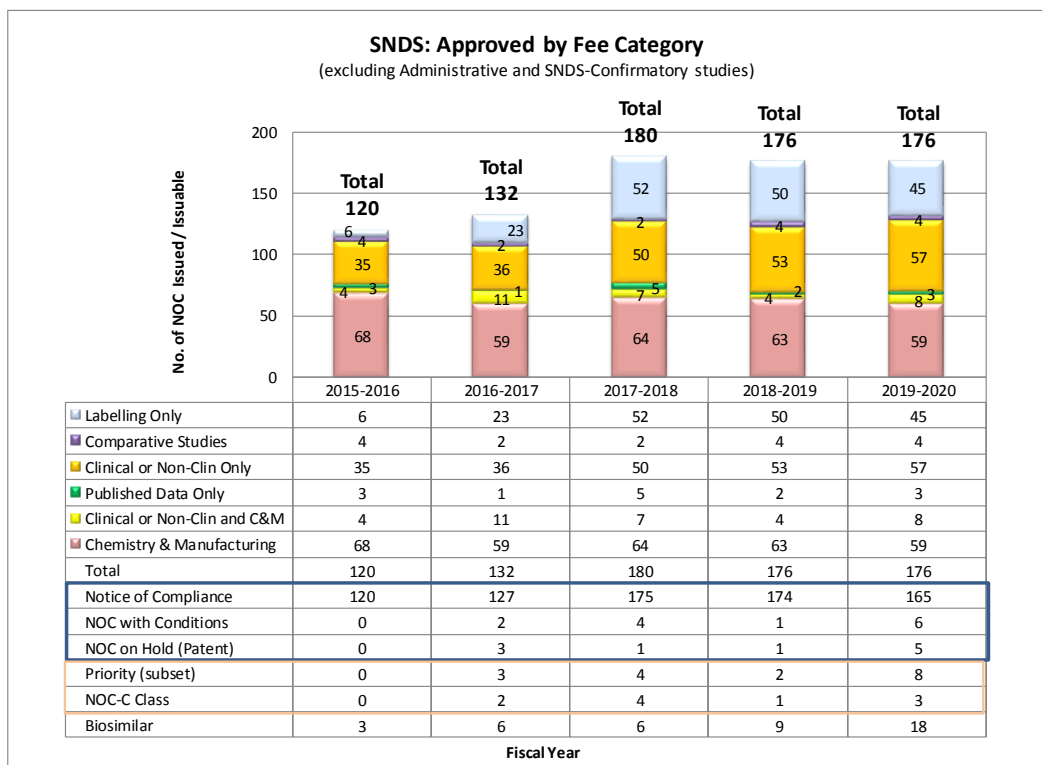


Approval Time is the total number of calendar days between the date a submission is filed (CR date) and the date it is approved (NOC Issuable). This includes time in processing, screening, review and any time taken by the company to respond to notices of deficiency or non-compliance..

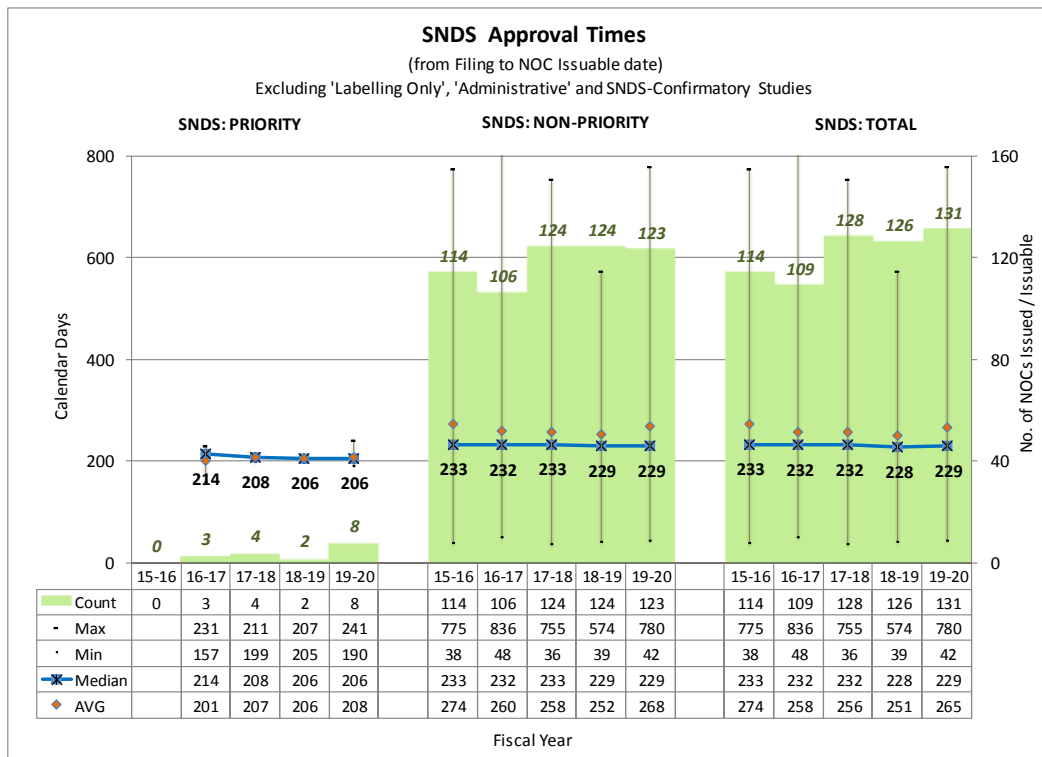


## APPROVALS

### SNDS: Number Approved 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.

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

<b>New Active Substance Approvals (NAS) - BRDD Fiscal Year 2019-2020 (April 1 2019 to March 31 2020)</b>				
<b>Brand Name (Active Ingredient(s)) - Indication(s)</b>	<b>Class</b>	<b>Company</b>	<b>Filing (CR Date<sup>10</sup>) dd-mon-yy</b>	<b>Approval Date dd-mon-yy</b>
<b>BEOVU (brolocizumab)</b> - is indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD).	NAS	Novartis Pharmaceuticals Canada Inc.	27-Mar 19	12-Mar-20
<b>CABLIVI (caplacizumab)</b> - 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
<b>EMGALITY (galcanezumab)</b> - 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
<b>ESPEROCT (Antihemophilic Factor VIII (Recombinant, B-Domain Truncated), PEGylated)</b> - is indicated for use in adults and children with hemophilia A (congenital Factor VIII deficiency) for: <ul style="list-style-type: none"> <li>• Routine prophylaxis to prevent or reduce the frequency of bleeding episodes</li> <li>• On-demand treatment and control of bleeding episodes</li> <li>• Perioperative management of bleeding.</li> </ul>	NAS	Novo Nordisk Canada Inc.	23-Jul-18	4-Jul-19
<b>EVENITY (romosozumab)</b> - 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

<sup>10</sup> The CR Date is the date the submission is received and considered administratively complete by Health Canada

<b>New Active Substance Approvals (NAS) - BRDD</b> <b>Fiscal Year 2019-2020</b> <b>(April 1 2019 to March 31 2020)</b>				
Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date <sup>10</sup> ) dd-mon-yy	Approval Date dd-mon-yy
<b>GALLI EO (gallium (68Ga) chloride)</b> - 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
<b>LIBTAYO (cemiplimab)</b> - 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
<b>MYLOTARG (gemtuzumab ozogamicin)</b> - 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
<b>NETSPOT (dotatate)</b> - 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
<b>SKYRIZI (risankizumab)</b> - 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
<b>ULTOMIRIS (ravulizumab)</b> - 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

<b>Priority Submission Approvals - BRDD</b> <b>Fiscal Year 2019-2020</b> <b>(April 1 2019 to March 31 2020)</b>				
<b>Brand Name (Active Ingredient(s))</b> <b>- Indication(s)</b>	<b>Class</b>	<b>Company</b>	<b>Filing</b> <b>(CR Date<sup>11</sup>)</b> <b>dd-mon-yy</b>	<b>Approval</b> <b>Date</b> <b>dd-mon-yy</b>
<b>ADCETRIS (brentuximab vedotin)</b> - 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
<b>CABLIVI (caplacizumab)</b> - 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
<b>DARZALEX (daratumumab)</b> - 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
<b>HEMLIBRA (emicizumab)</b> - 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

<sup>11</sup> The CR Date is the date the submission is received and considered administratively complete by Health Canada

<b>Priority Submission Approvals - BRDD</b> <b>Fiscal Year 2019-2020</b> <b>(April 1 2019 to March 31 2020)</b>				
<b>Brand Name (Active Ingredient(s))</b> <b>- Indication(s)</b>	<b>Class</b>	<b>Company</b>	<b>Filing</b> <b>(CR Date<sup>11</sup>)</b> <b>dd-mon-yy</b>	<b>Approval</b> <b>Date</b> <b>dd-mon-yy</b>
<b>KADCYLA (trastuzumab emtansine)</b> - 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
<b>REVESTIVE (teduglutide)</b> - 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
<b>SOLIRIS (eculizumab)</b> - 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
<b>TECENTRIQ (atezolizumab)</b> - 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
<b>TECENTRIQ (atezolizumab)</b> - 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 $\geq 1\%$ , 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 (Revised Sept 1, 2020)

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	*8
<b>NDS Total</b>		<b>2</b>	<b>1</b>	<b>3</b>	<b>5</b>	<b>*8</b>
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	*7
	PUBLISHED DATA ONLY	1	0	0	0	0
<b>SNDS Total</b>		<b>3</b>	<b>6</b>	<b>5</b>	<b>8</b>	<b>*15</b>

**Biosimilars: NDS Market Authorizations during Fiscal Year 2019-2020 (Revised Sept 1, 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
*HERZUMA	CLIN/C&M	CELLTRION HEALTHCARE CO. LTD.	TRASTUZUMAB	Q2	2019-Sep-3
KANJINTI	CLIN/C&M	AMGEN CANADA INC	TRASTUZUMAB	Q4	2020-Feb-27
*OGIVRI	CLIN/C&M	BGP PHARMA ULC	TRASTUZUMAB	Q1	2019-May-3
OSNUVO	CLIN/C&M	AVIR HARMA INC.	TERIPARATIDE	Q4	2020-Jan-13
*TRUXIMA	CLIN/C&M	CELLTRION HEALTHCARE CO. LTD.	RITUXIMAB	Q1	2019-Apr-4
*TRAZIMERA	CLIN/C&M	PFIZER CANADA ULC	TRASTUZUMAB	Q2	2019-Aug-15
ZIRABEV	CLIN/C&M	PFIZER CANADA ULC	BEVACIZUMAB	Q1	2019-Jun-14
<b>New Drug Submission Total</b>					<b>*8</b>

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

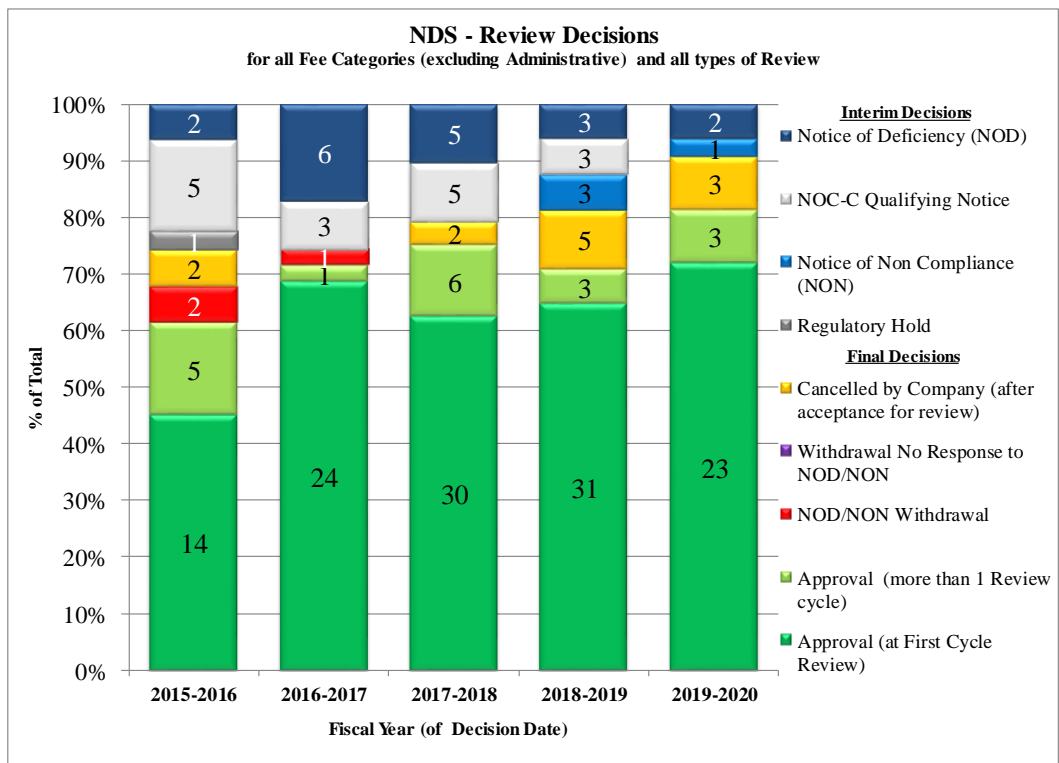
**Biosimilars: SNDS Market Authorizations during Fiscal Year 2019-2020 (Revised Sept 1, 2020)**

<b>Brand Name</b>	<b>Class</b>	<b>Company</b>	<b>Active Ingredient(s)</b>	<b>Quarter FY 2019-20</b>	<b>Notice of Compliance (NOC) Date</b>
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
*HERZUMA	LABELLING ONLY	CELLTRION HEALTHCARE CO. LTD.	TRASTUZUMAB	Q1	2019-May-16
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
*TRAZIMERA	LABELLING ONLY	PFIZER CANADA ULC	TRASTUZUMAB	Q2	2019-Aug-15
TRUXIMA	LABELLING ONLY	CELLTRION HEALTHCARE CO LTD	RITUXIMAB	Q2	2019-Jul-22
<b>Supplemental New Drug Submission Total</b>					<b>*15</b>

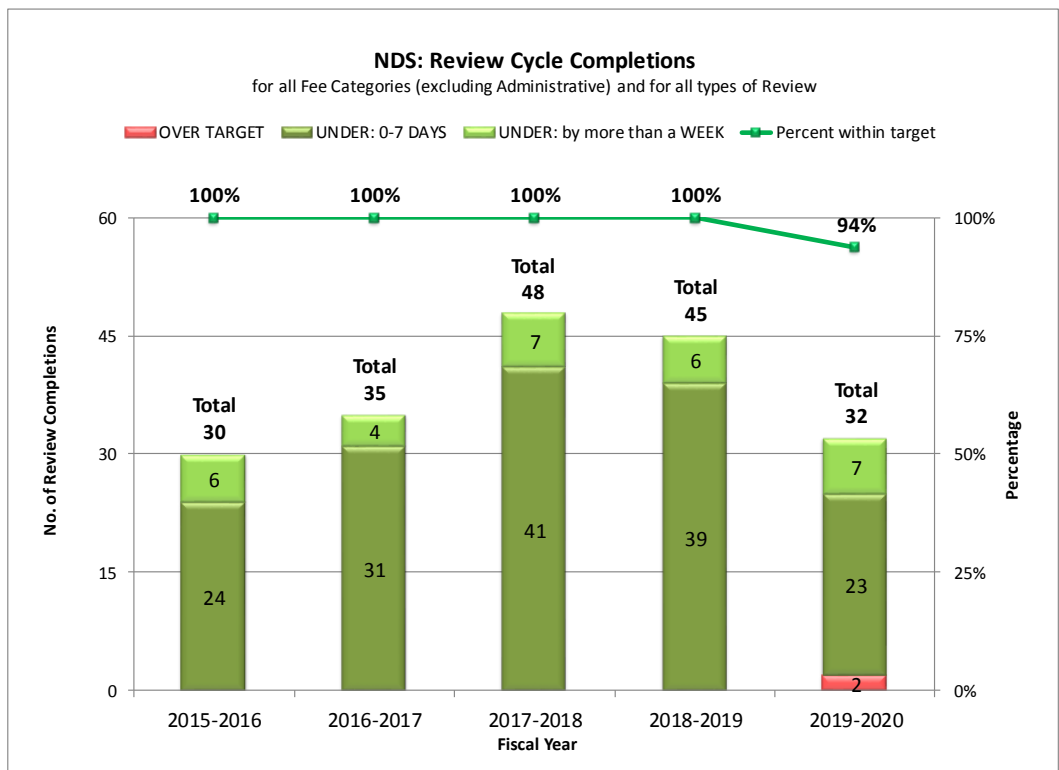


## REVIEW PERFORMANCE

### NDS: Review Decisions by Type

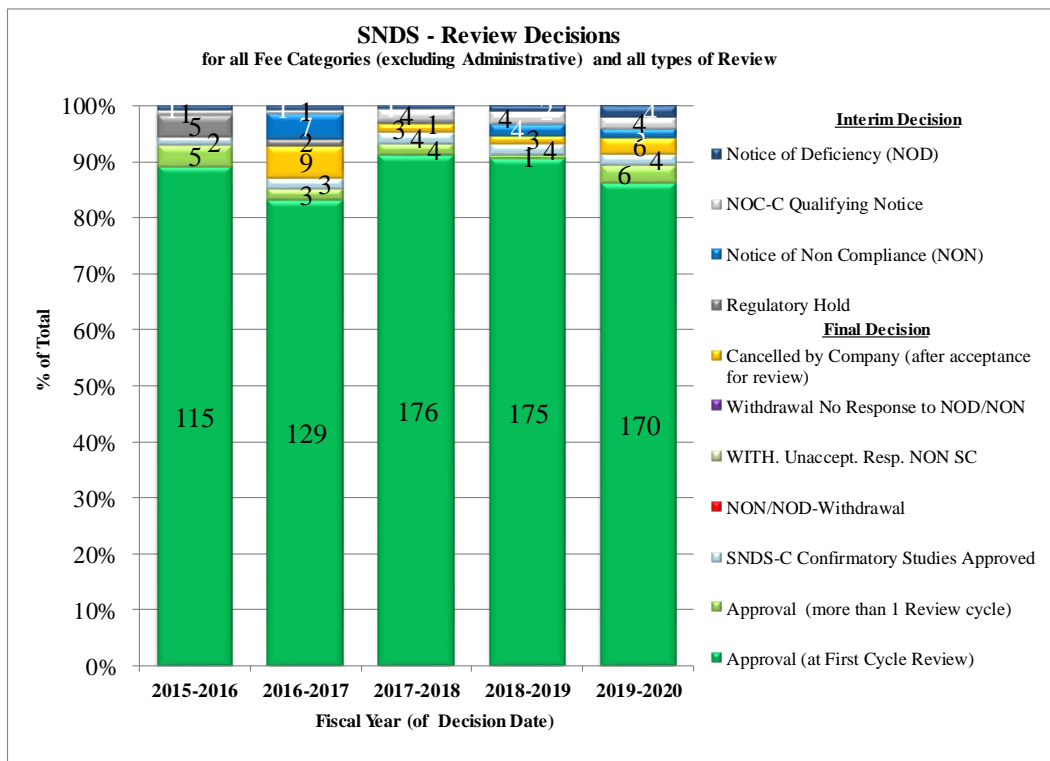


### NDS: Review Cycle Completions

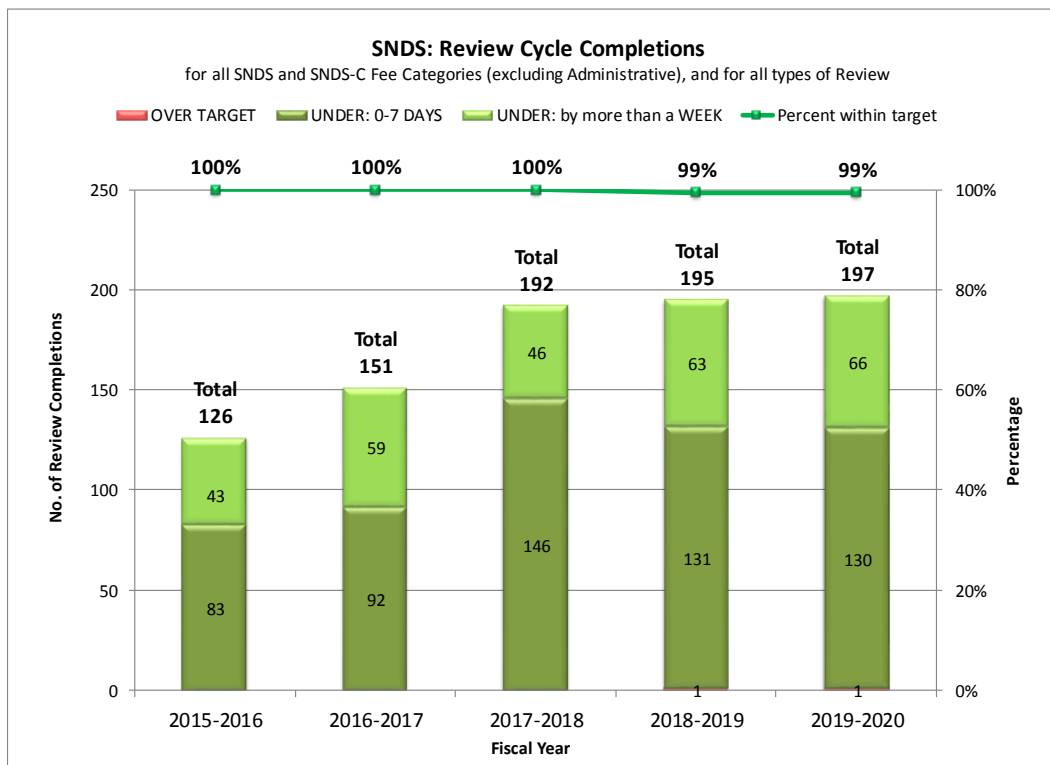


## REVIEW PERFORMANCE

### SNDS: Review Decisions by Type

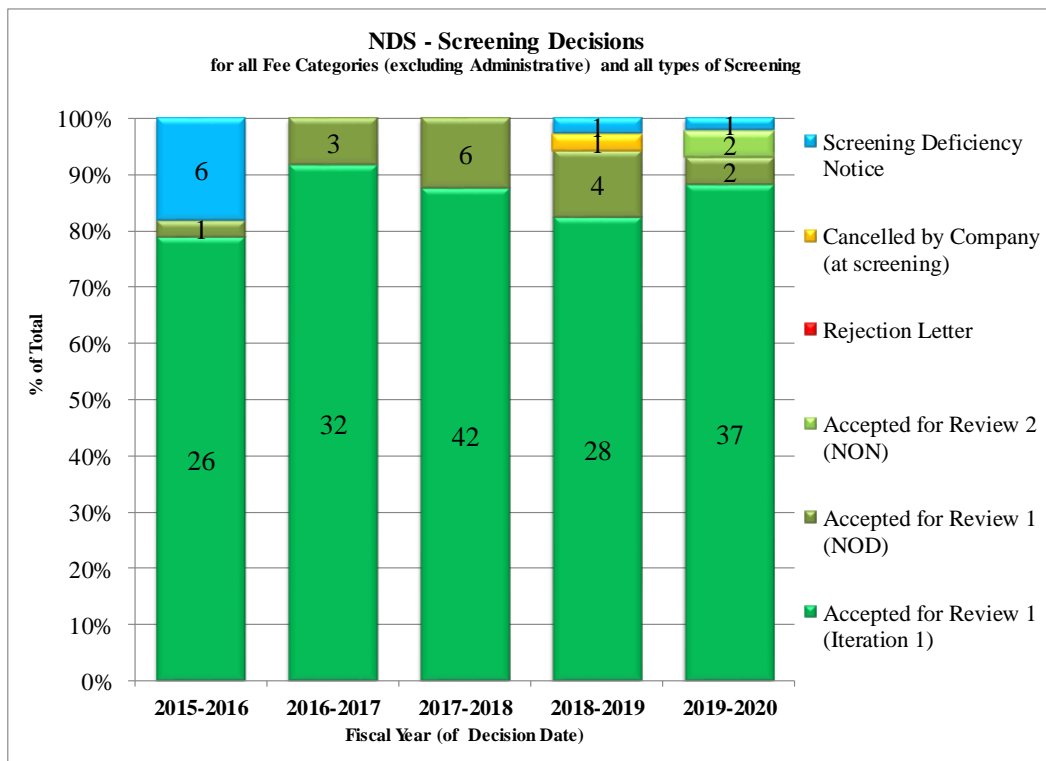


### SNDS: Review Cycle Completions

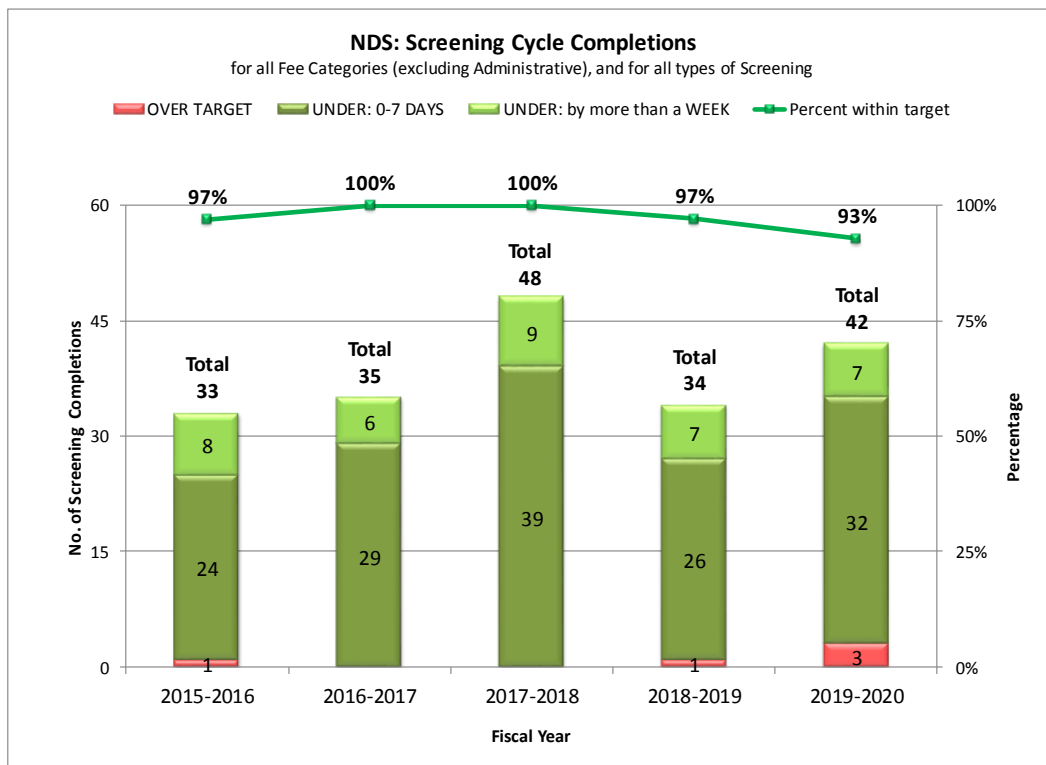


## SCREENING PERFORMANCE

### NDS: Screening Decisions by Type

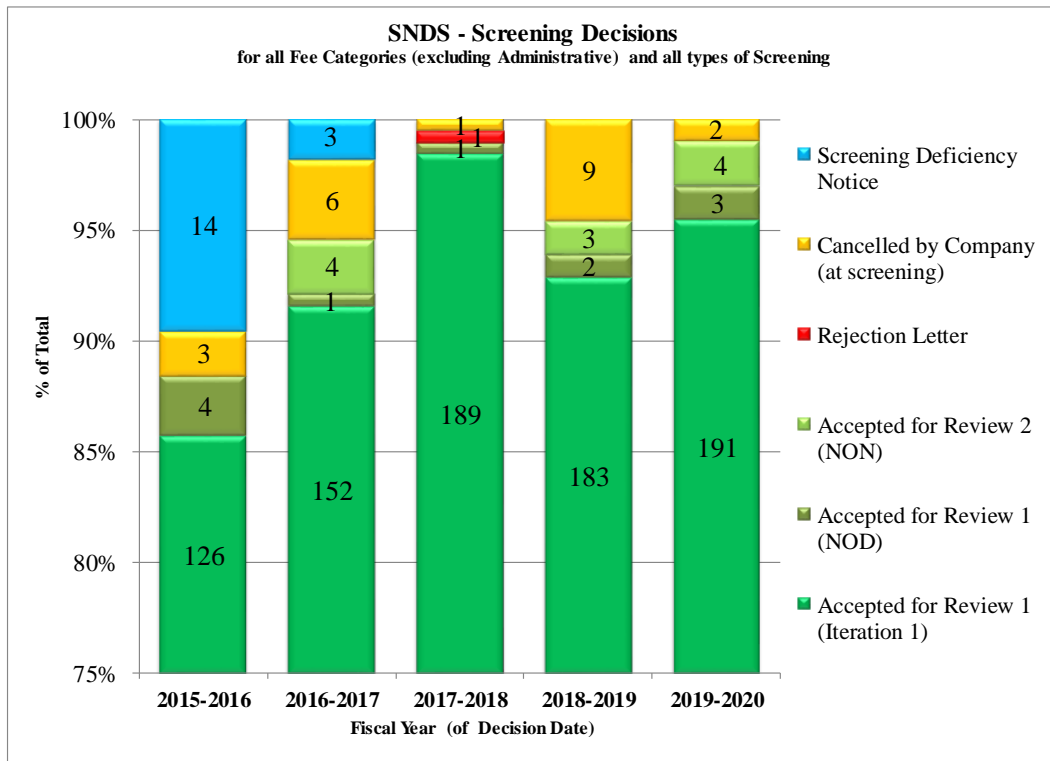


### NDS: Screening Cycle Completions

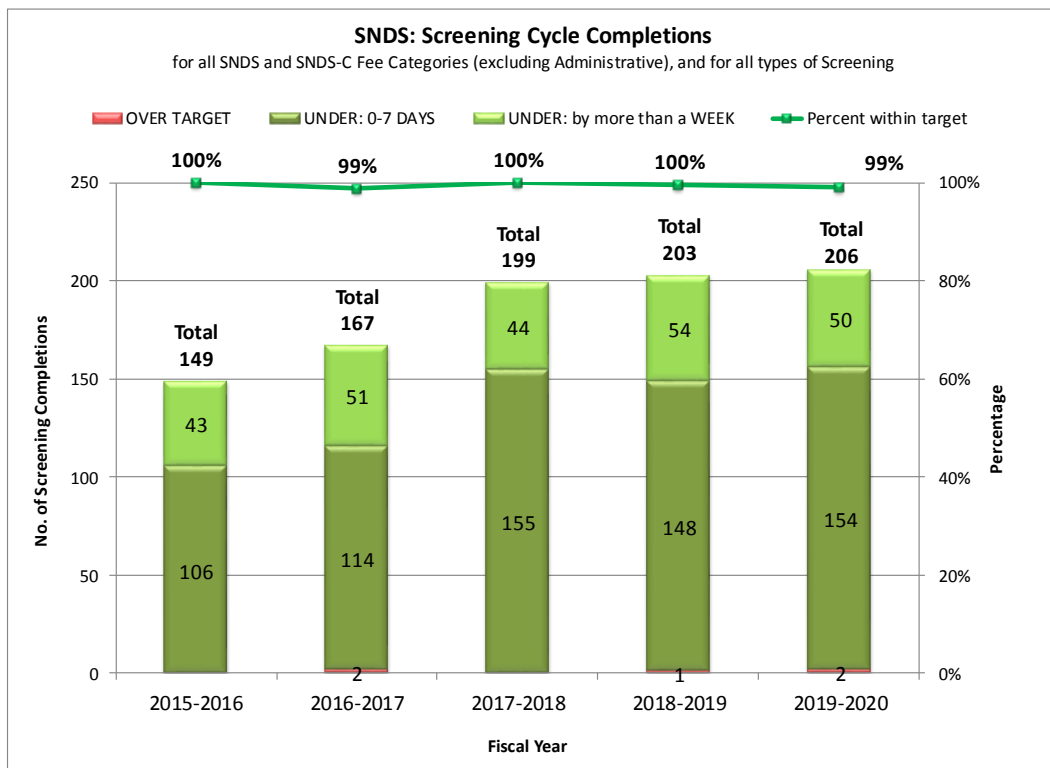


### SCREENING PERFORMANCE

#### SNDS: Screening Decisions by Type



#### SNDS: Screening Cycle Completions



## REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

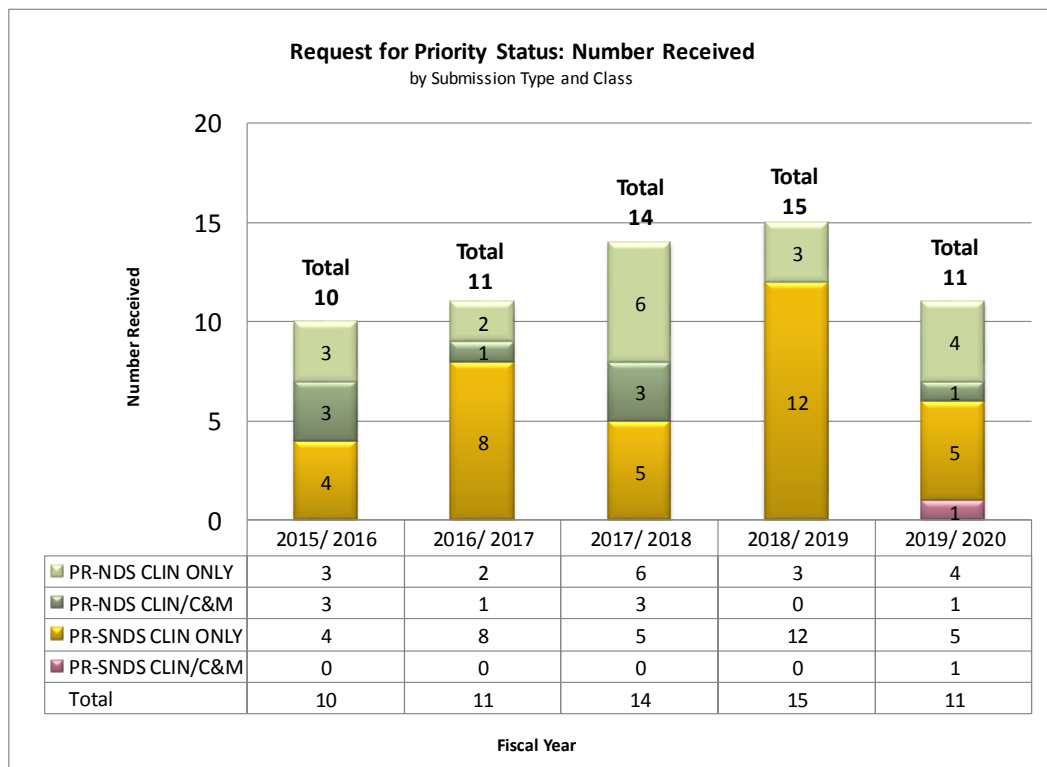
### Requests for Reconsideration of Final Decisions - NDS, SNDS & ANDS

<b>Reconsideration of Final Decisions Requests Received NDS, SNDS &amp; ANDS</b>					
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

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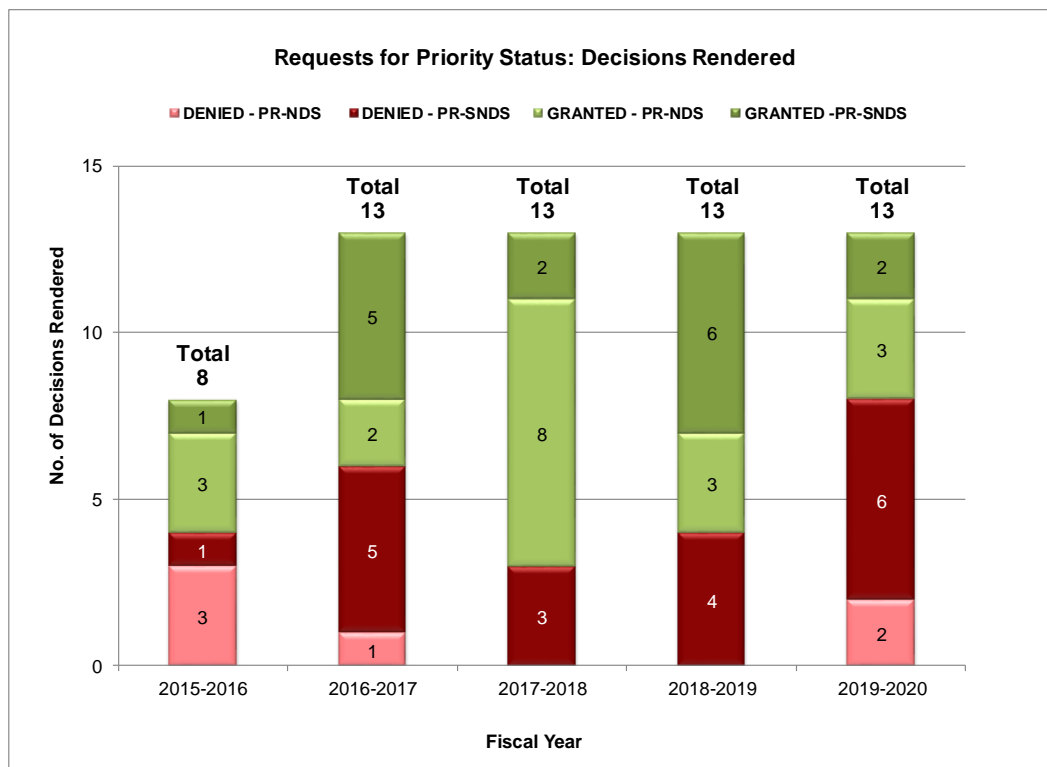
## REQUEST FOR PRIORITY REVIEW STATUS RECEIVED

### Request for Priority Review Status: Number Received



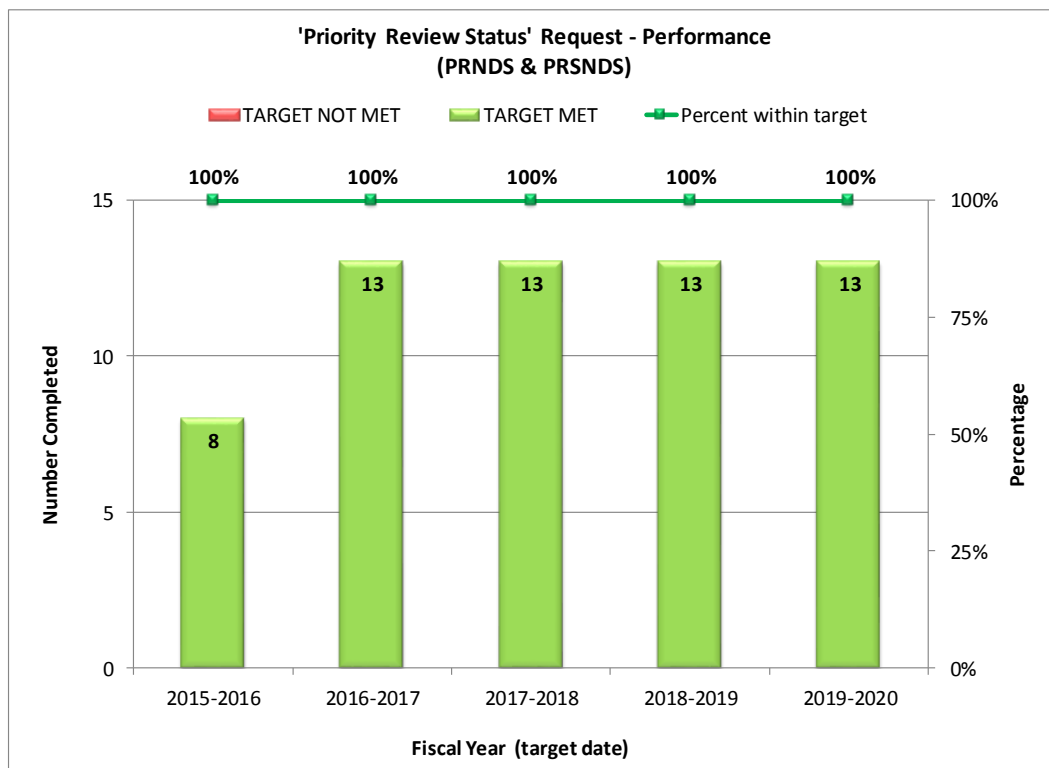
## DECISIONS

### 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

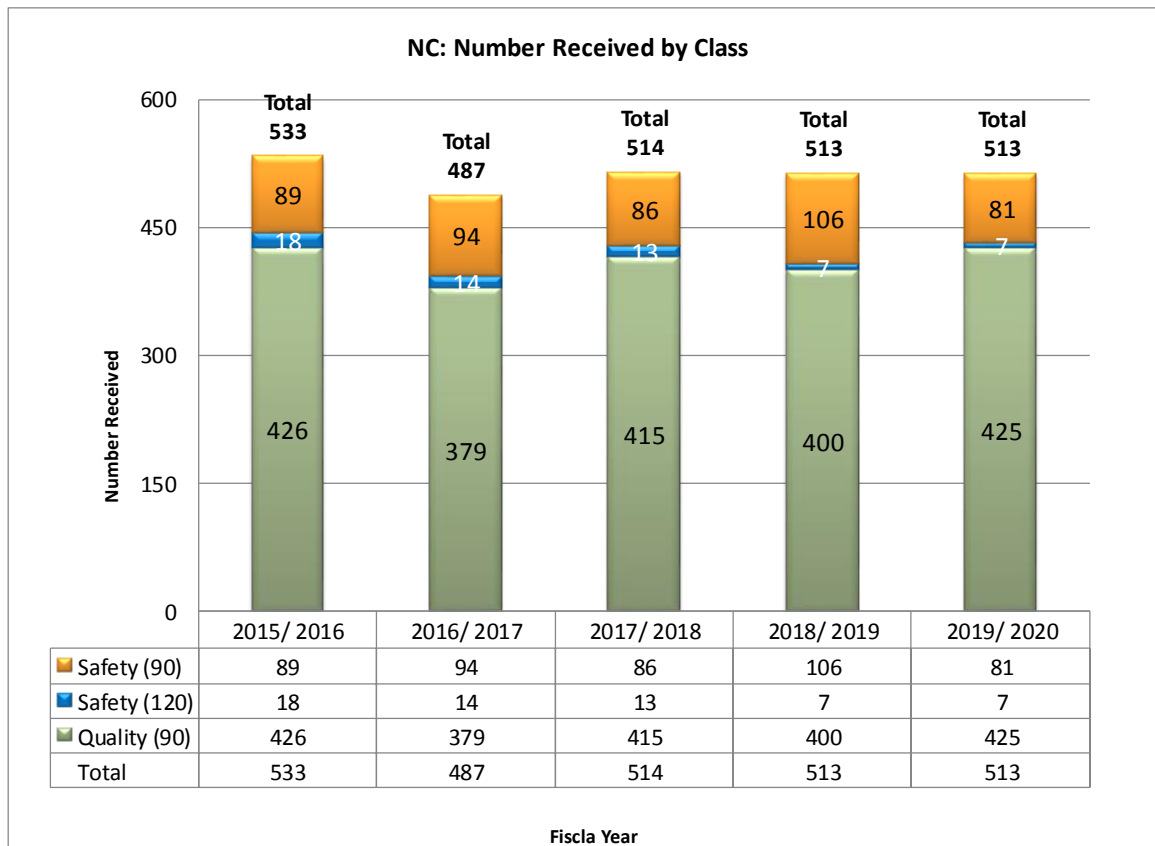
<b>"Priority Review Request" - Requests for Reconsideration of Final Decisions</b>							
Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020	Final Decision in Dispute	Submission Status (as of May 2020)
Total Received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



## **NC: NOTIFIABLE CHANGES**

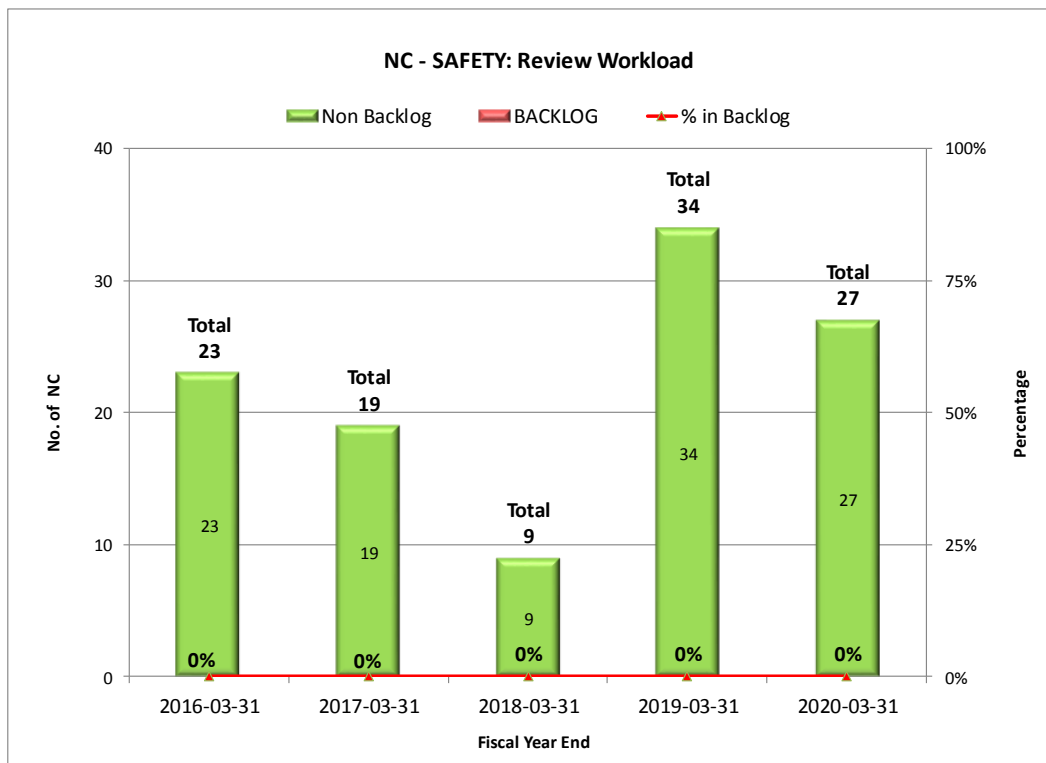
## NC: NOTIFIABLE CHANGE RECEIVED

### NC: Number Received by Class

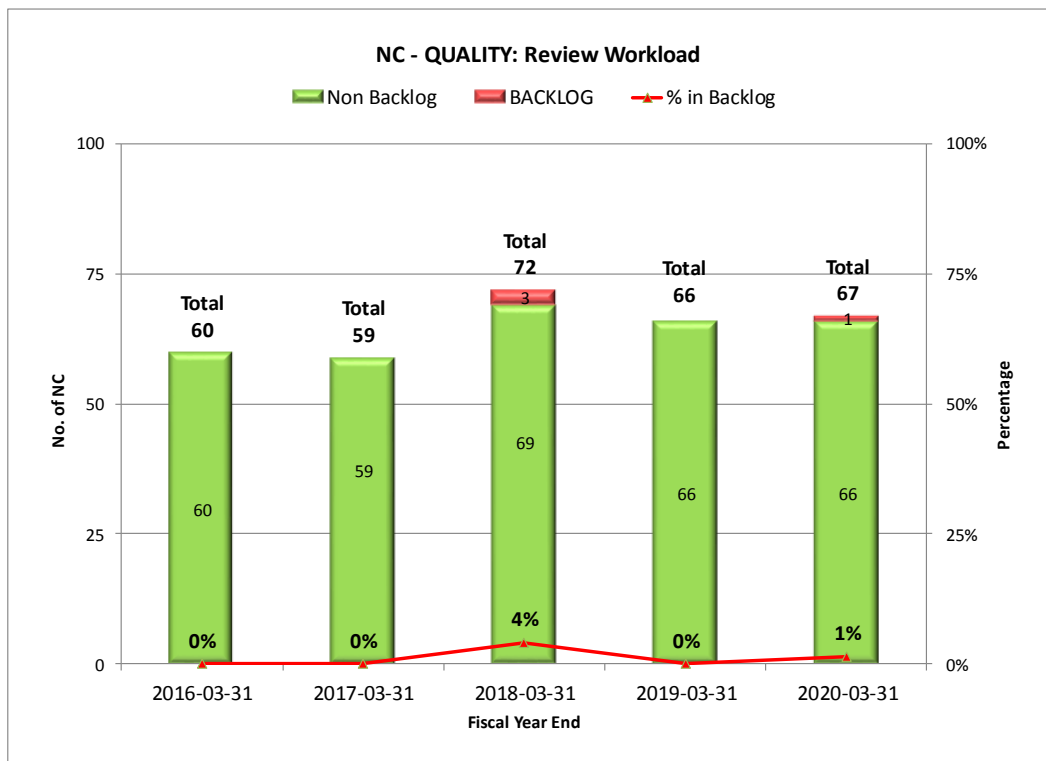


## WORKLOAD

### NC-SAFETY: Review Workload



### NC-QUALITY: Review Workload



**WORKLOAD****NC-SAFETY: Review Workload by Class**

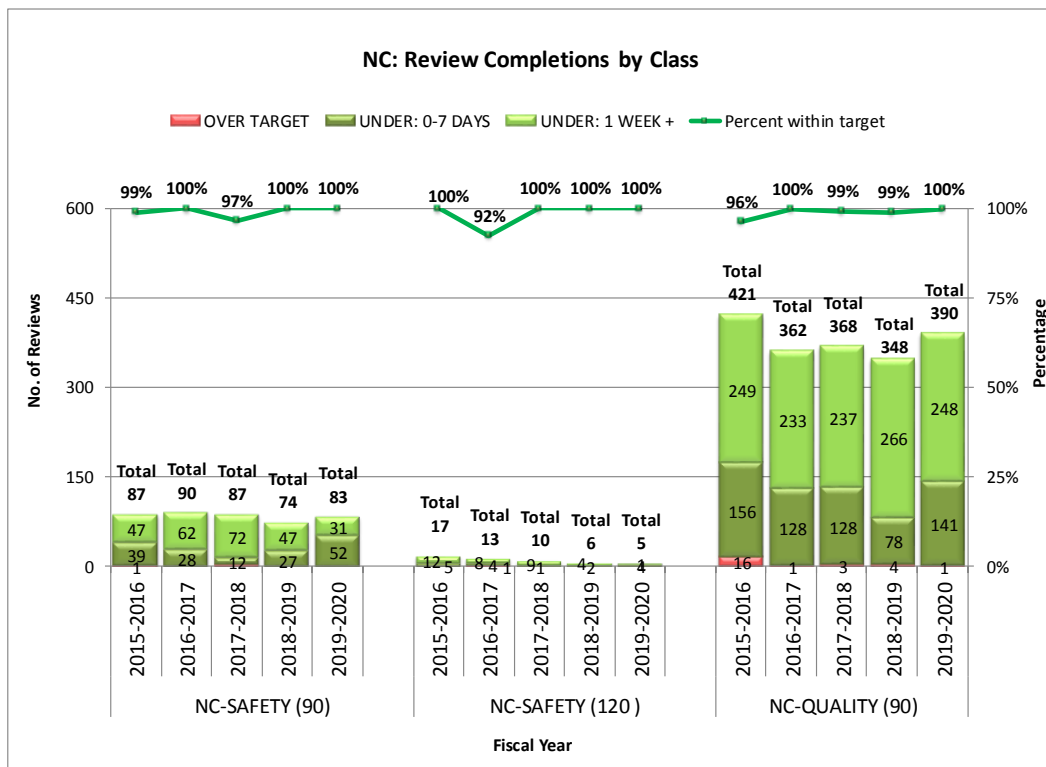
<b>BBRD NC - SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END</b>					
<b>CLASS</b>	<b>2016-03-31</b>	<b>2017-03-31</b>	<b>2018-03-31</b>	<b>2019-03-31</b>	<b>2020-03-31</b>
<b>SAFETY - 90 day</b>	20	15	8	34	24
Backlog	0	0	0	0	0
<b>SAFETY - 120 day</b>	3	4	1	0	3
Backlog	0	0	0	0	0
<b>Total</b>	<b>23</b>	<b>19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

**NC-QUALITY: Review Workload by Class**

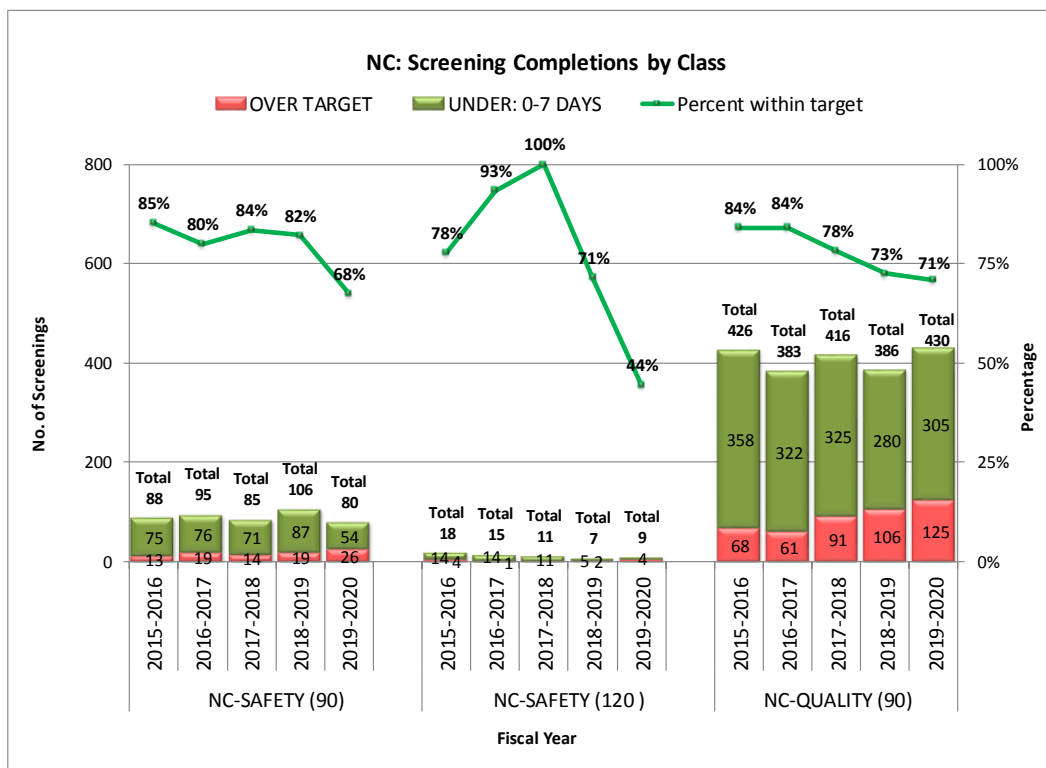
<b>BBRD NC - QUALITY: REVIEW WORKLOAD AT FISCAL YEAR END</b>					
<b>CLASS</b>	<b>2016-03-31</b>	<b>2017-03-31</b>	<b>2018-03-31</b>	<b>2019-03-31</b>	<b>2020-03-31</b>
<b>QUALITY - 90 day</b>	60	59	72	66	67
Backlog	0	0	3	0	1
<b>Total</b>	<b>60</b>	<b>59</b>	<b>72</b>	<b>66</b>	<b>67</b>
<b>Non Backlog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

## PERFORMANCE

### NC: Review Completions by Class



### NC: Screening Completions by Class



**DECISIONS****NC: Decision Documents by Class**

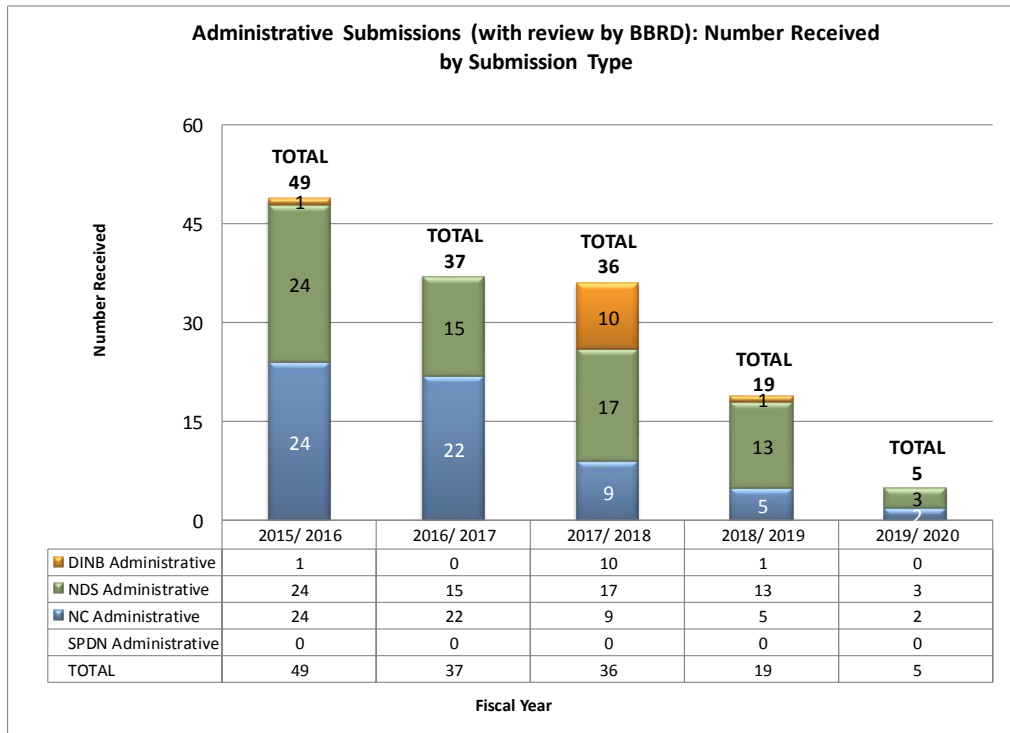
DOCUMENT TYPE	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
<b>NC - QUALITY (90)</b>					
NO OBJECTION LETTER	410	363	381	358	415
NOT SATISFACTORY NOTICE	3	1	0	0	0
REJECTION LETTER (SCR)	33	7	12	16	1
CANCELLED BY COMPANY	6	13	8	16	15
SCREENING DEFICIENCY NOTICE	7	5	2	0	0
NC - HOLD (PATENT)	0	0	0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

**REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS****Requests for Reconsideration of Final Decisions- NC**

<b>NC - Requests for Reconsideration of Final Decisions</b>					
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

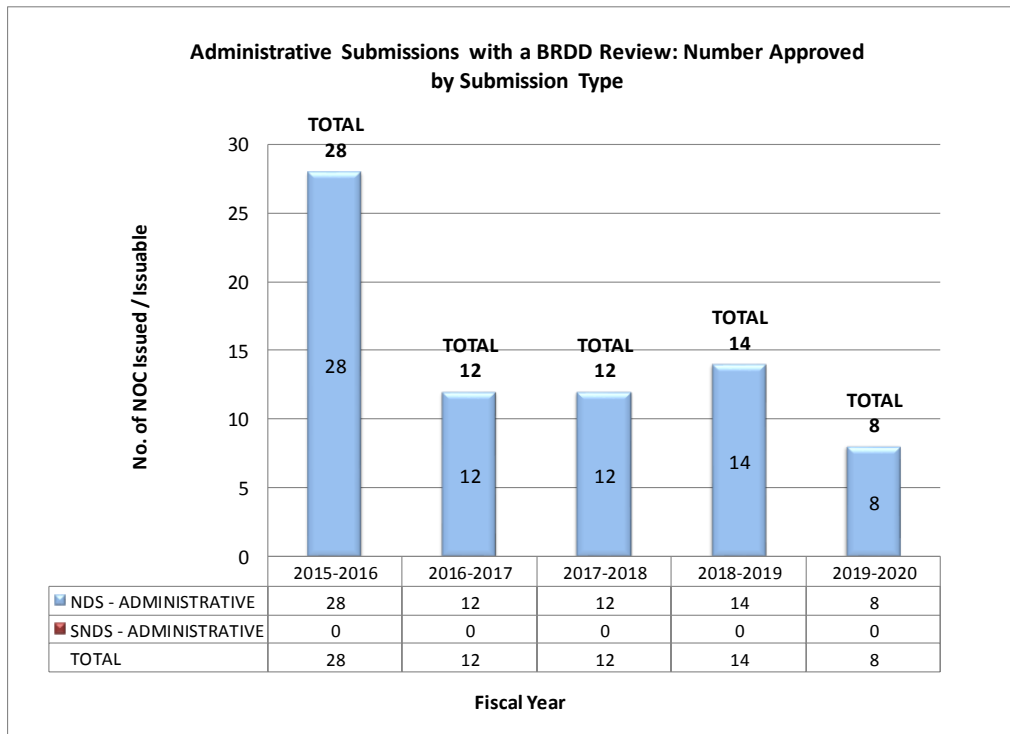
## ADMINISTRATIVE SUBMISSIONS (processed by BRDD) RECEIVED

### Administrative Submissions: Number Received



## APPROVALS

### Administrative Submission: Number Approved



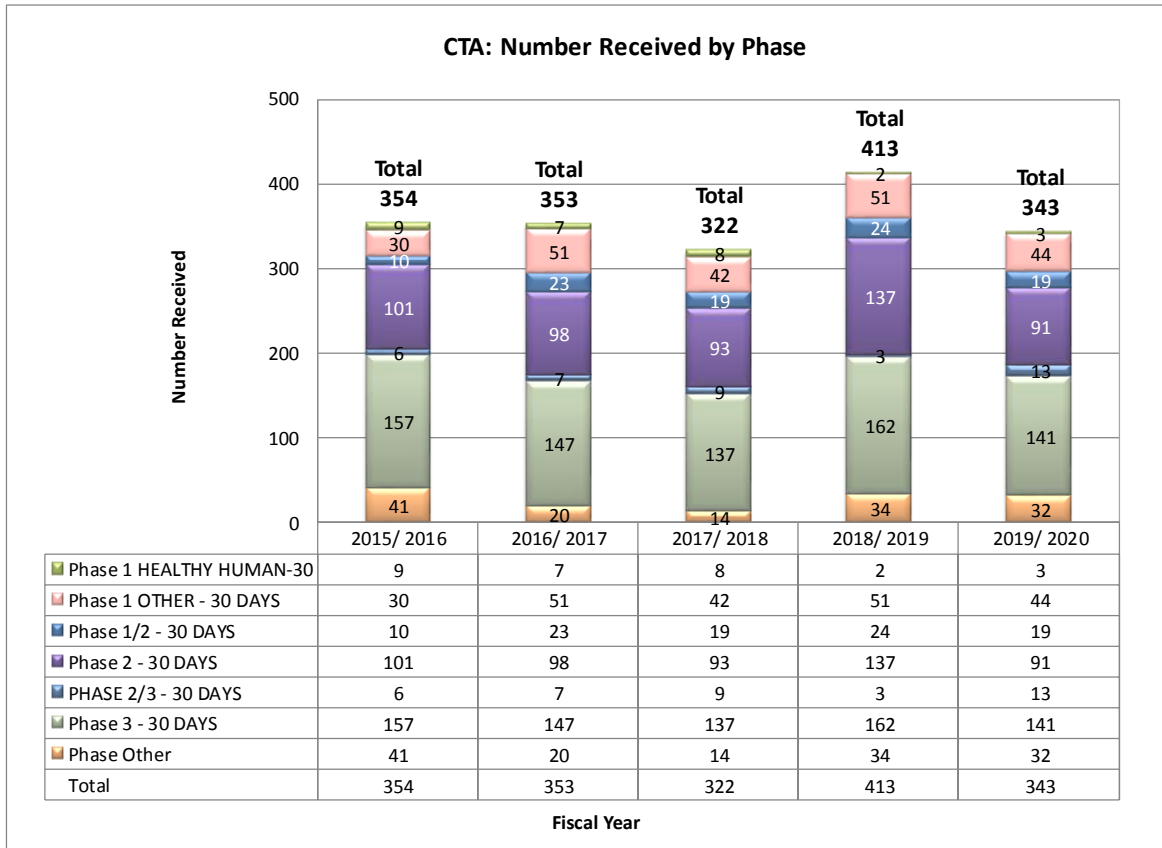
# **CLINICAL TRIAL APPLICATIONS AND AMENDMENTS**

## **(CTA & CTA-A)**



## CTA: CLINICAL TRIAL APPLICATIONS RECEIVED

### CTA: Number Received by Phase



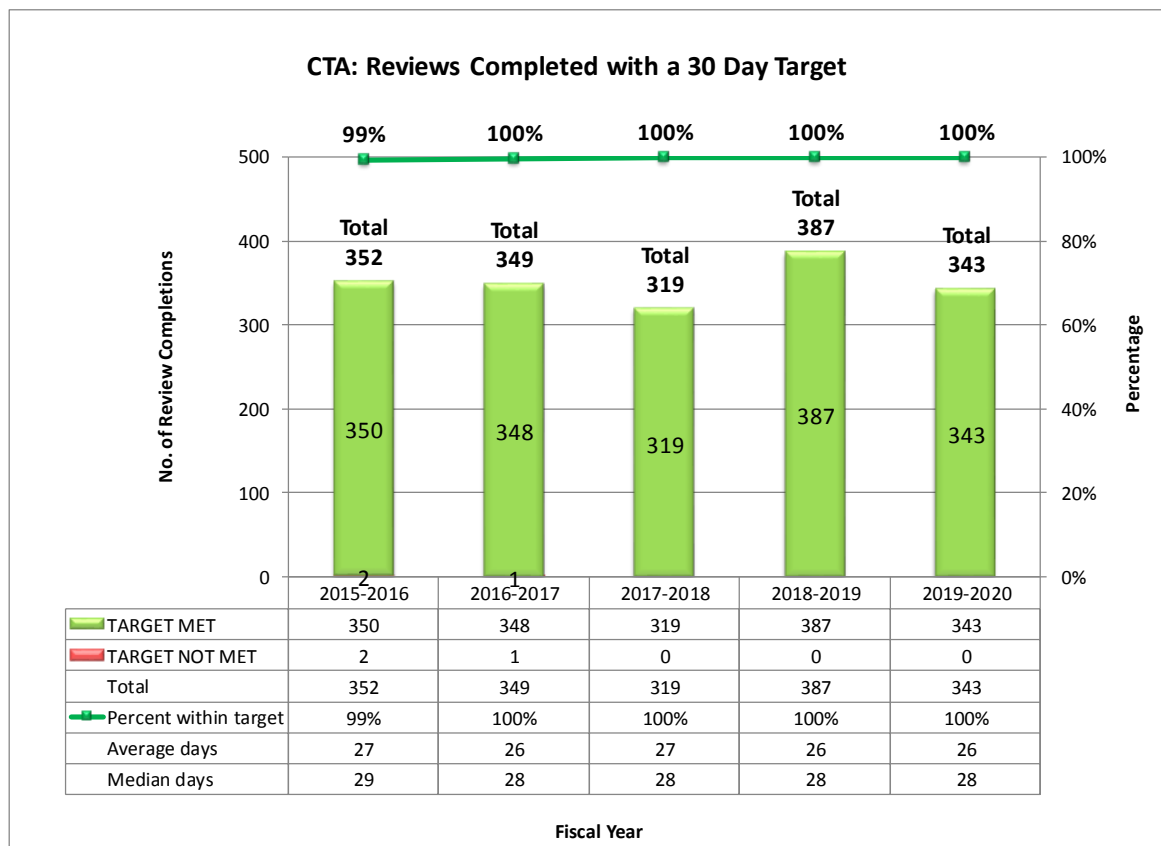
## DECISIONS

### 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

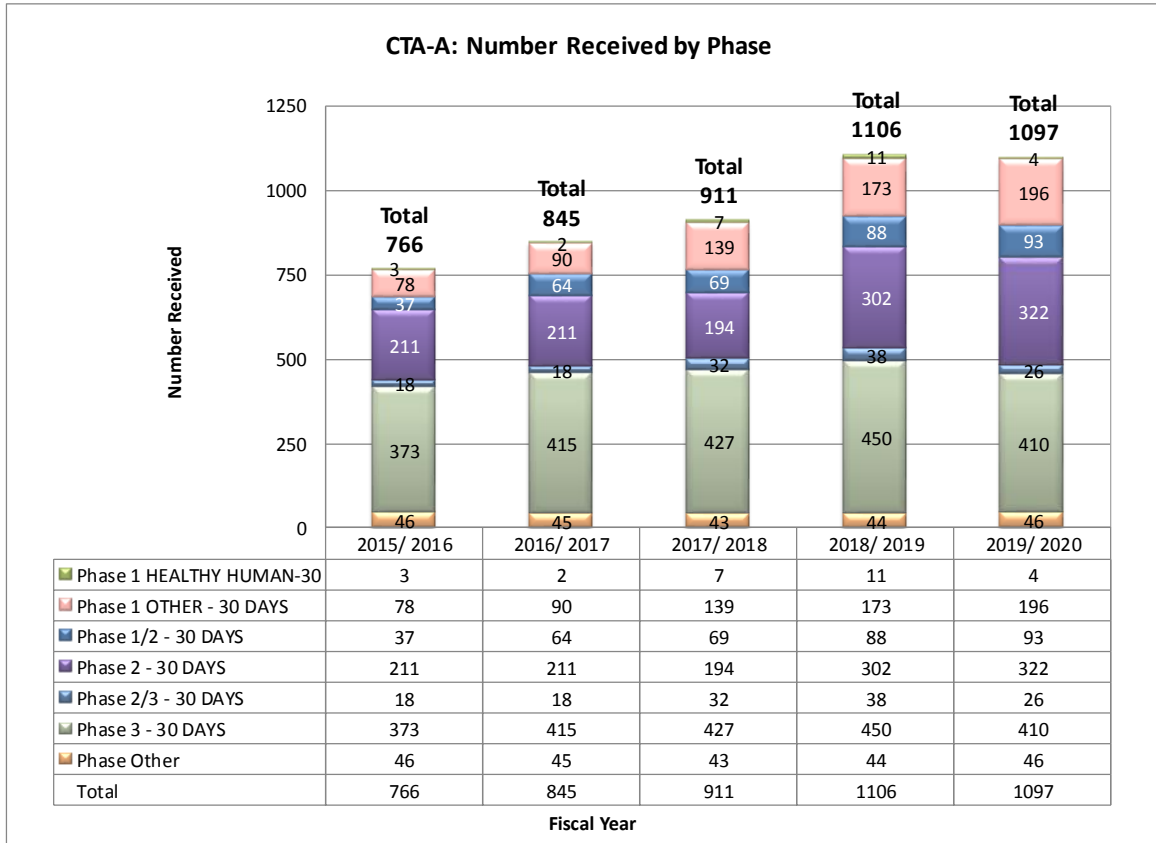
## PERFORMANCE

### CTA: Reviews Completed with a 30 Day Target



## CTA-A: CLINICAL TRIAL APPLICATION-AMENDMENTS RECEIVED

### CTA-A: Number Received by Phase



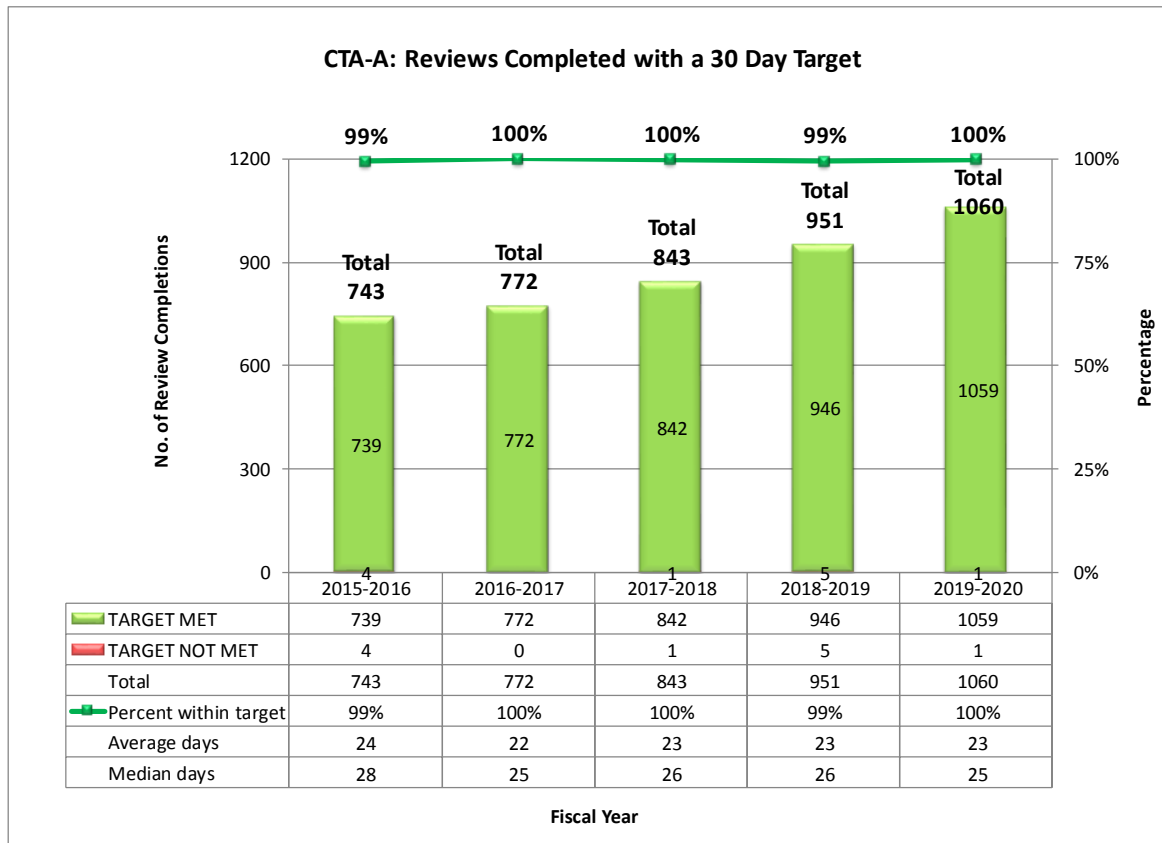
## DECISIONS

### 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



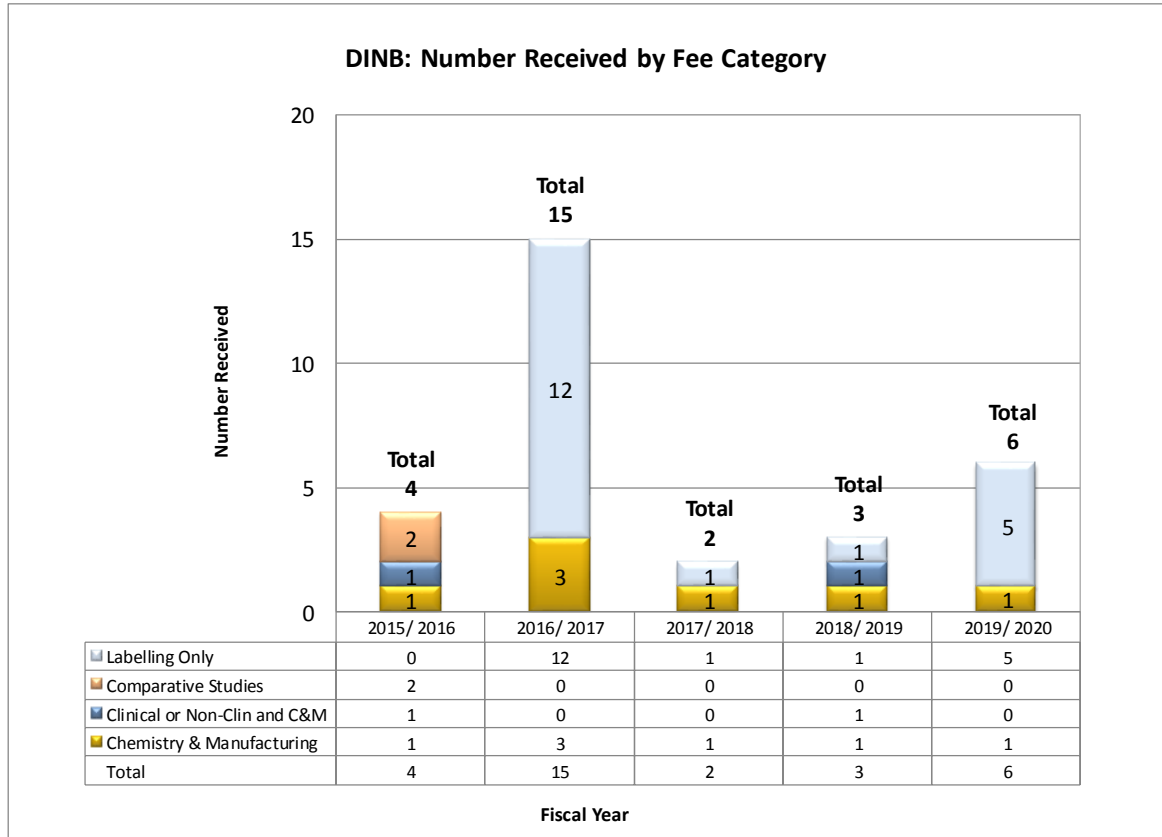
# **DINB**

## **Application for a Drug Identification Number**

### **Biological Products**

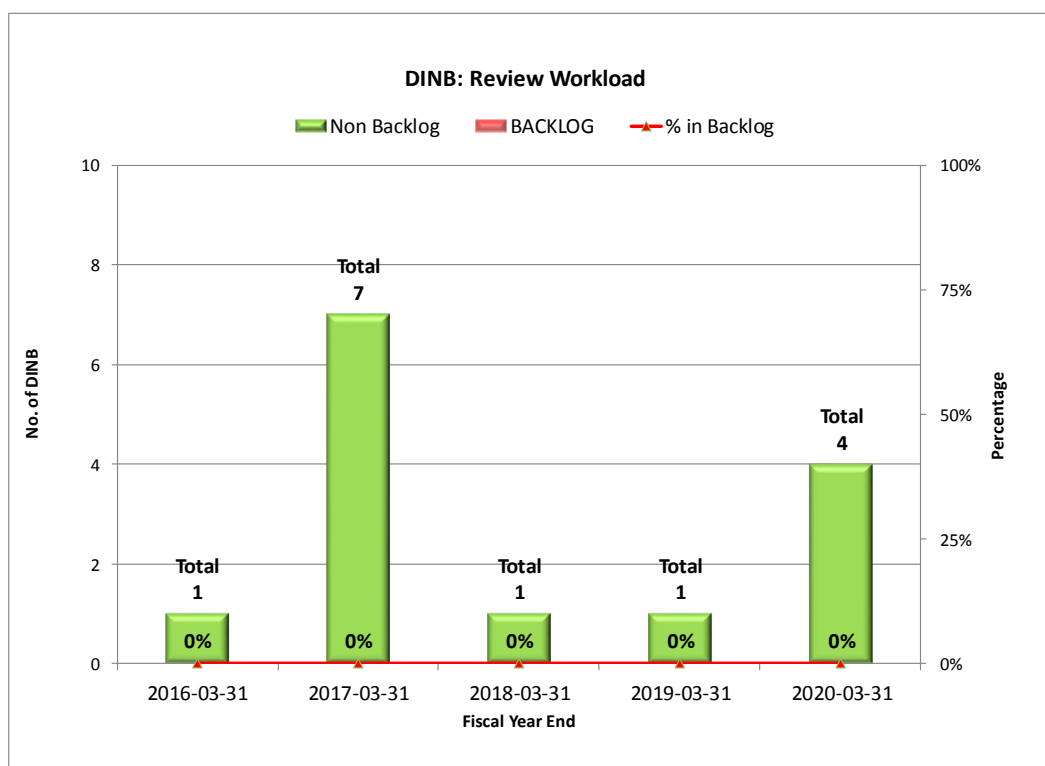
## DINB: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - BIOLOGICAL PRODUCT RECEIVED

### DINB: Number Received by Fee Category



## REVIEW WORKLOAD

### DINB: Review Workload

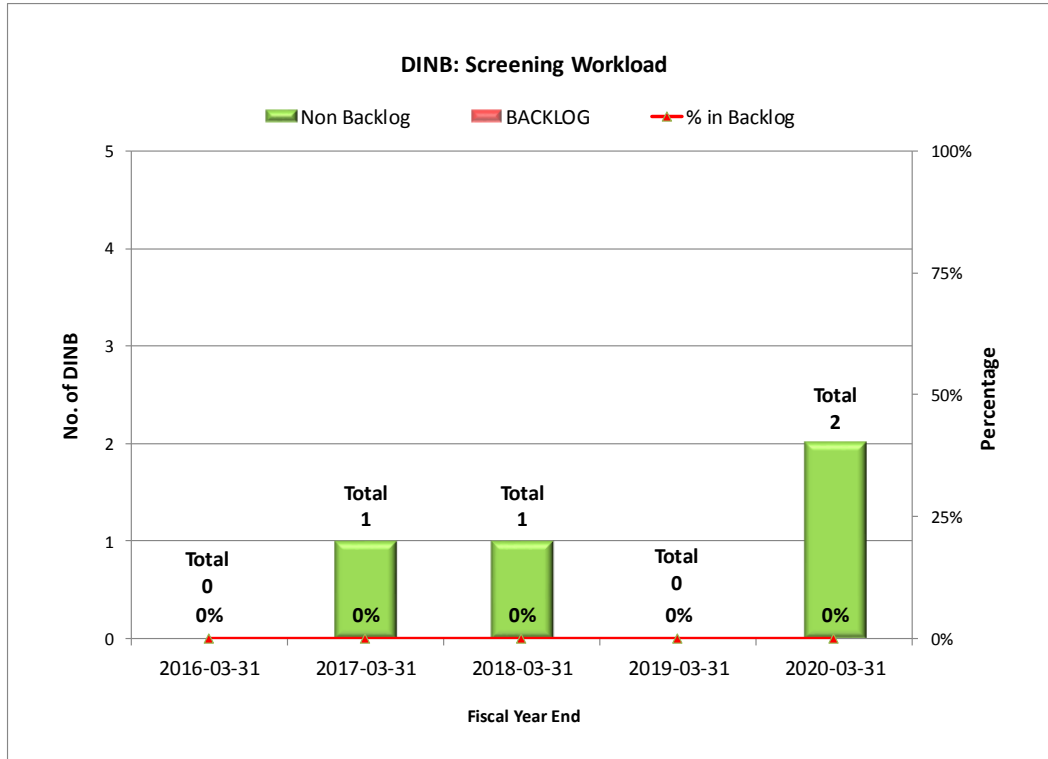


### DINB: Review Workload by Fee Category

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
<i>Backlog</i>	0	0	0	0	0
Chemistry & Manufacturing	1	1	0	1	1
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	1	7	1	1	4
Non Backlog	1	7	1	1	4
<b>BACKLOG</b>	0	0	0	0	0
<b>% in Backlog</b>	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
<i>Backlog</i>	0	0	0	0	0
Chemistry & Manufacturing	0	1	1	0	0
<i>Backlog</i>	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
<b>DINB - LABELLING ONLY</b>					
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
<b>DINB - CHEMISTRY &amp; MANUFACTURING</b>					
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
<b>DINB - CLIN/C&amp;M</b>					
NO OBJECTION LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	1	0	0	0	0
<b>DINB - ADMINISTRATIVE</b>					
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
CANCELLED BY COMPANY	0	0	1	0	0
<b>DINB - COMPARATIVE STUDIES</b>					
REJECTION LETTER (SCREENING)	1	0	0	0	0
SCREENING DEFICIENCY NOTICE	1	0	0	0	0

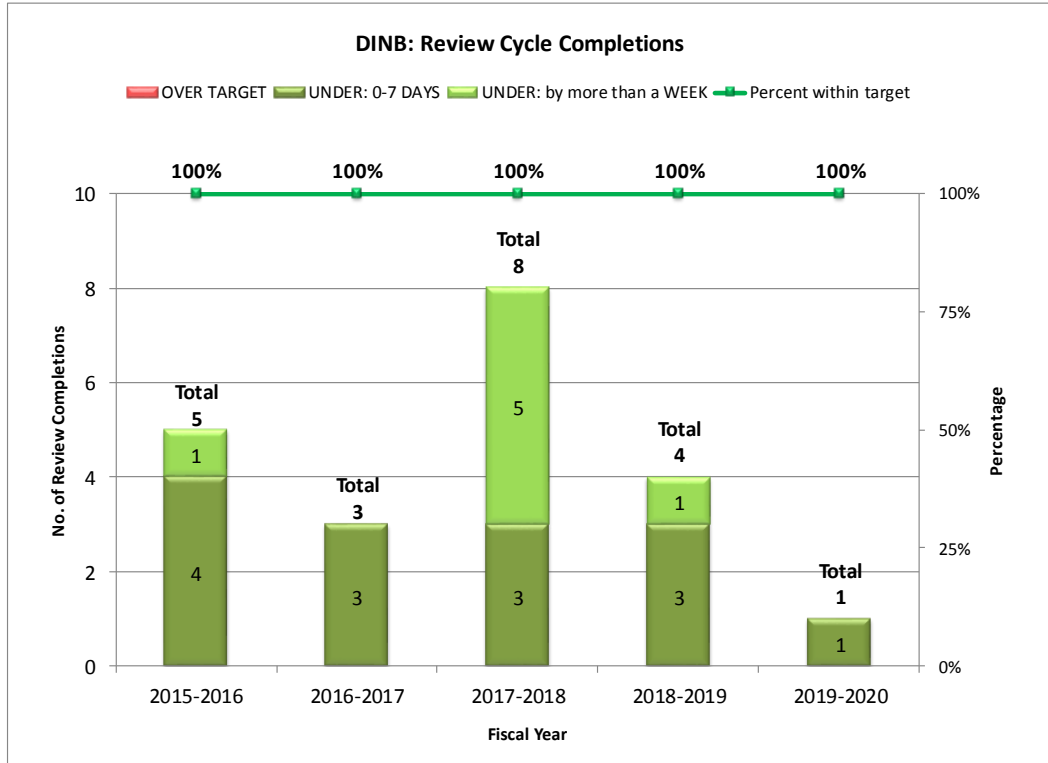
## REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

### DINB: Requests for Reconsideration of Final Decisions

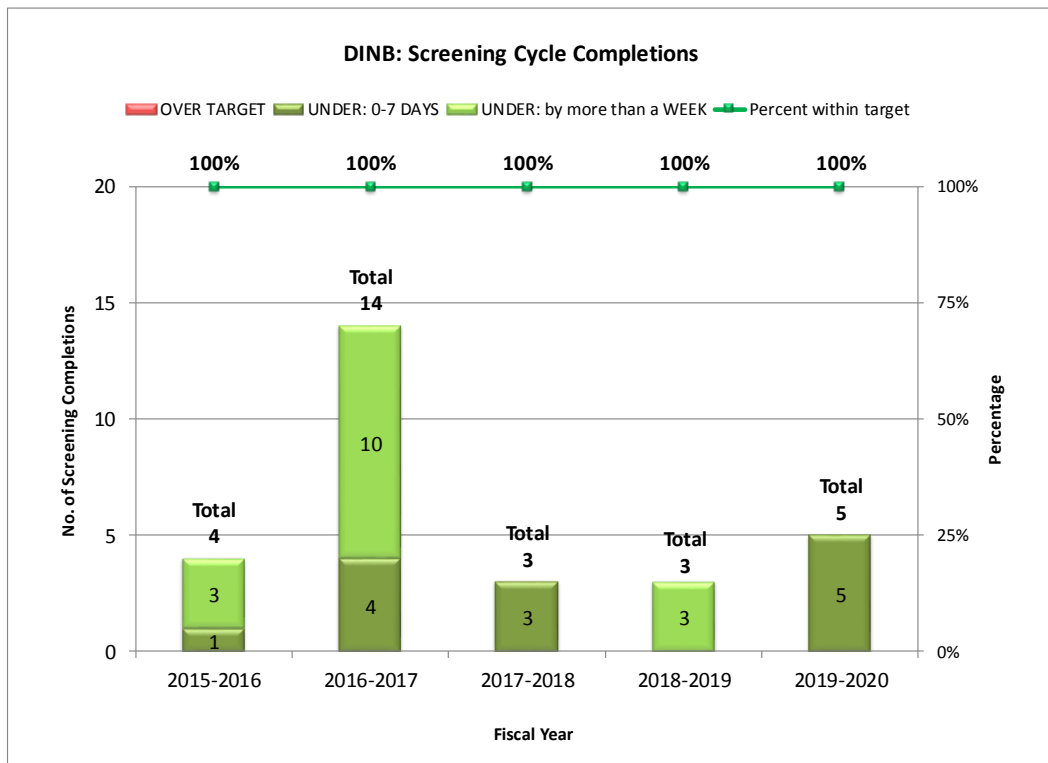
DINB - Requests for Reconsideration of Final Decisions					
Fiscal Year of Request (April 1 - March 31)					
	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
Total	0	0	0	0	0

## PERFORMANCE

### DINB: Review Cycle Completions

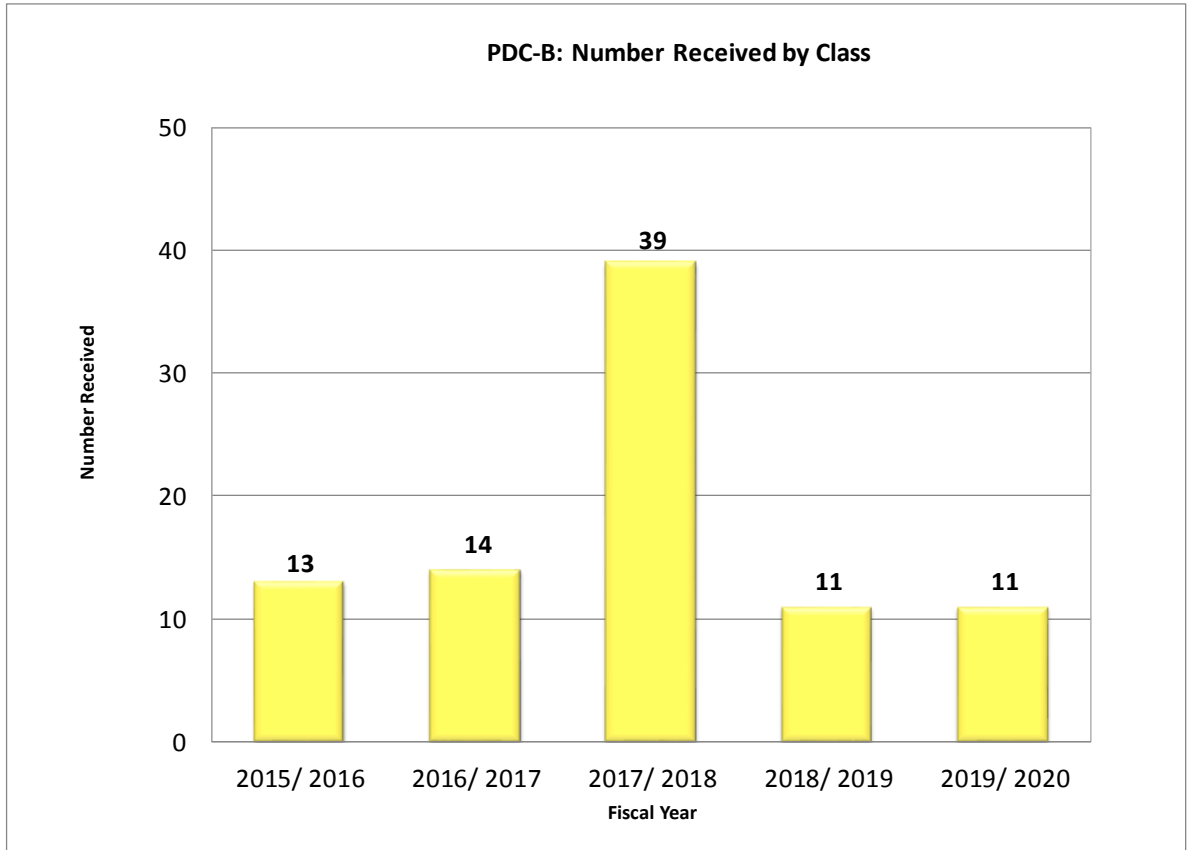


### DINB: Screening Cycle Completions



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

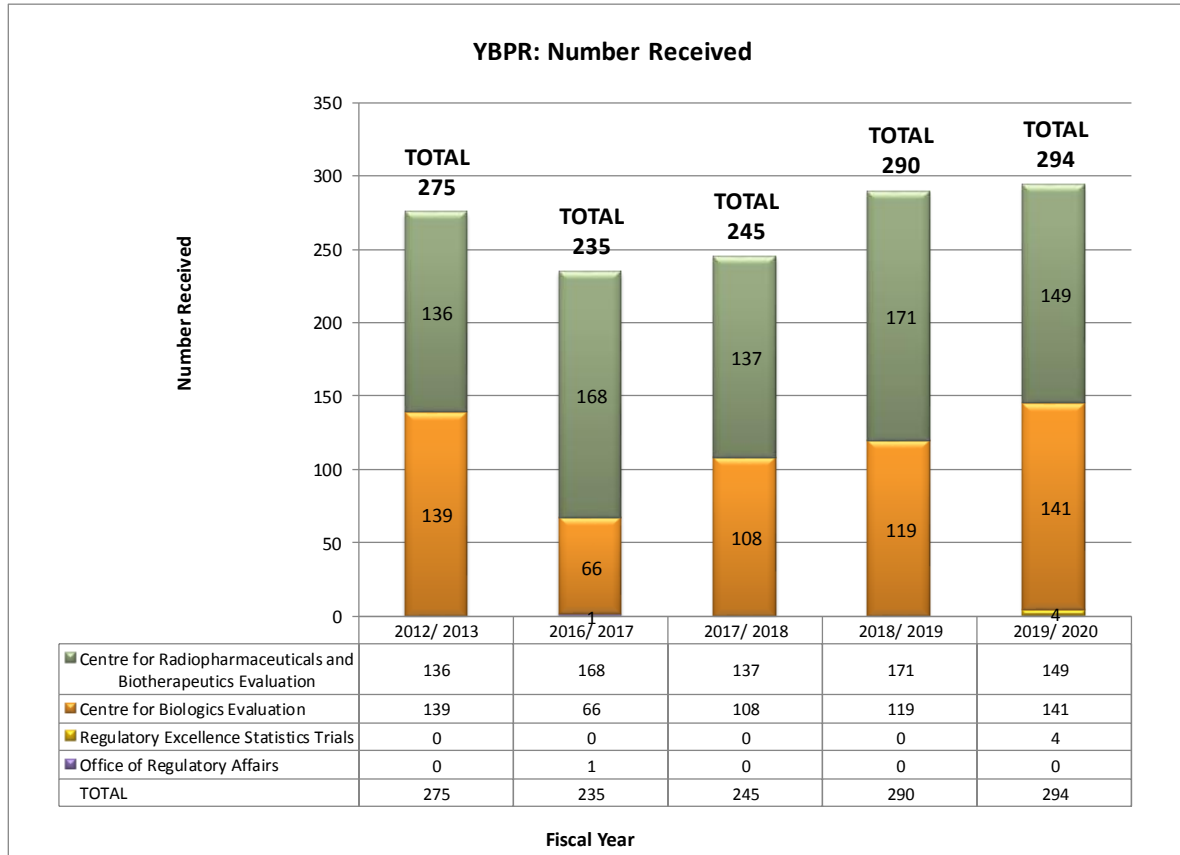
## PDC-B: Number Received



## YBPR: YEARLY BIOLOGIC PRODUCT REPORTS <sup>12</sup>

### RECEIVED

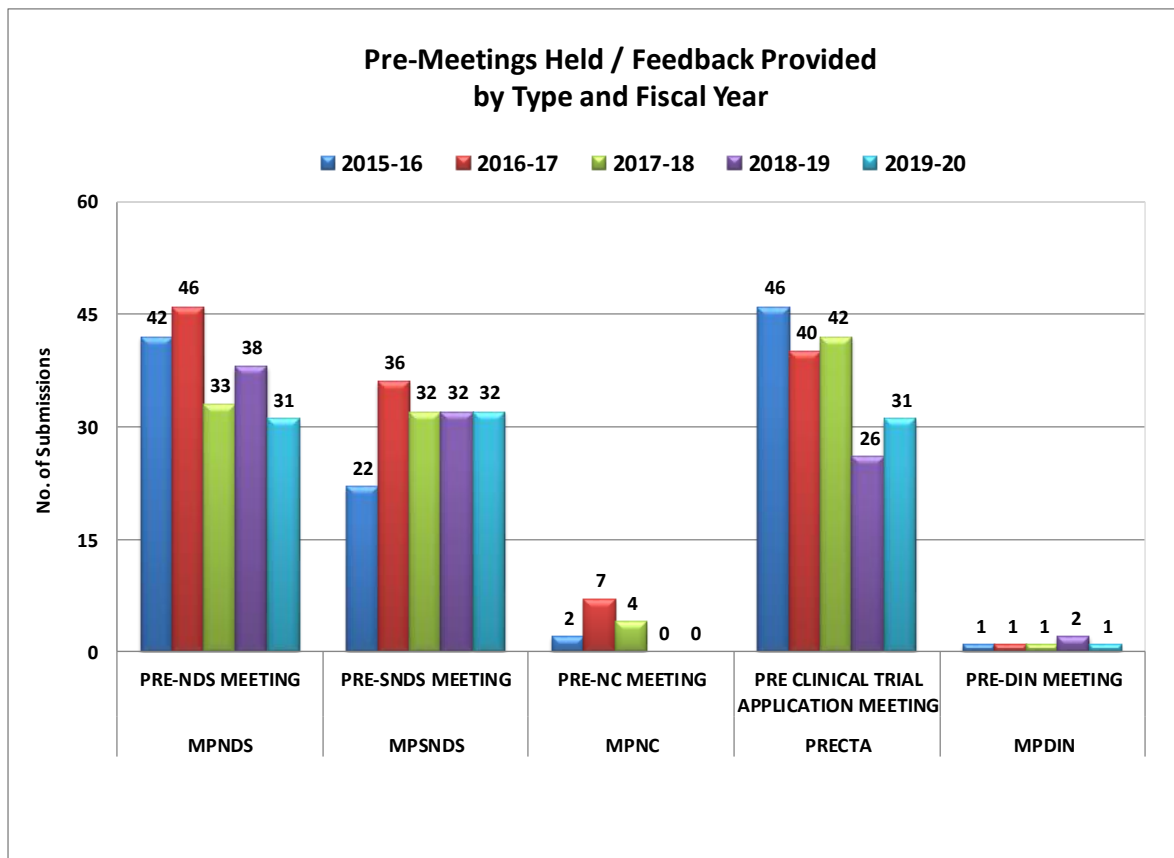
#### YBPR: Number Received



<sup>12</sup> 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 <sup>13</sup>

### Pre-Submission Meetings Held / Feedback Provided



<sup>13</sup> 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](#)

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