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Biologic and Radiopharmaceutical Drugs Directorate

Drug Submission Performance Quarterly
Report

April - June

2021



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.

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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: publications-publications@hc-sc.gc.ca

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Table of Contents

| | |
|--|-----------|
| OVERVIEW | 7 |
| ACRONYMS | 11 |
| Submission Types | 11 |
| Documents | 13 |
| FEE CATEGORIES | 14 |
| NDS AND SNDS | 16 |
| SUBMISSIONS RECEIVED | 17 |
| NDS: Received by Fee Category | 17 |
| SNDS: Received by Fee Category | 17 |
| WORKLOAD | 18 |
| NDS: Review Workload | 18 |
| SNDS: Review Workload | 18 |
| NDS: Review Workload by Fee Category | 19 |
| SNDS: Review Workload by Fee Category | 19 |
| APPROVALS | 20 |
| NDS: Number Approved by Fee Category and NOC Type | 20 |
| SNDS: Number Approved by Fee Category and NOC Type | 20 |
| BIOSIMILARS: NDS & SNDS Market Authorizations | 21 |
| Biosimilars: Number of Market Authorization for NDS & SNDS by Quarter | 21 |
| Biosimilars: NDS Market Authorizations during FY 2021-22 (Apr 1 2021 - Mar 31 2022) | 22 |
| Biosimilars: SNDS Market Authorizations during FY 2021-22 (Apr 1 2021 - Mar 31 2022) | 23 |
| REVIEW PERFORMANCE | 24 |
| NDS: Review Decisions by Type | 24 |
| NDS: Review Cycle Completions | 24 |
| SNDS: Review Decisions by Type | 25 |
| SNDS: Review Cycle Completions | 25 |
| SCREENING PERFORMANCE | 26 |
| NDS: Screening Decisions by Type | 26 |
| NDS: Screening Cycle Completions | 26 |
| SNDS: Screening Decisions by Type | 27 |
| SNDS: Screening Cycle Completions | 27 |

| | |
|--|-----------|
| REQUEST FOR PRIORITY REVIEW STATUS (NDS & SNDS) | 28 |
| Request for Priority Review Status: Number Received | 28 |
| Request for Priority Review Status: Decisions Rendered | 29 |
| Request for Priority Review Status: Performance | 29 |
| COV19 & COV19A | 30 |
| RECEIVED | 31 |
| COV19 & COV19A: Number Received | 31 |
| WORKLOAD | 31 |
| COV19: Review Workload | 31 |
| AUTHORIZATIONS | 32 |
| COV19 & COV19A: Number Authorized | 32 |
| NEW DRUG SUBMISSIONS FOR DESIGNATED COVID-19 DRUGS | 33 |
| RECEIVED | 34 |
| NDS-CV: Number Received | 34 |
| WORKLOAD | 34 |
| NDS-CV: Review Workload | 34 |
| AUTHORIZATIONS | 35 |
| NDS-CV: Number Authorized | 35 |
| NC: NOTIFIABLE CHANGE | 36 |
| NC: Number Received by Class | 37 |
| WORKLOAD | 38 |
| NC-SAFETY: Review Workload | 38 |
| NC-QUALITY: Review Workload | 38 |
| NC-SAFETY: Review Workload by Class | 39 |
| NC-QUALITY: Review Workload by Class | 39 |
| PERFORMANCE | 40 |
| NC: Review Completions by Class | 40 |
| NC: Screening Completions by Class | 40 |
| NC: Decision Documents by Class | 41 |

| | |
|--|-----------|
| ADMINISTRATIVE SUBMISSIONS | 42 |
| ADMINISTRATIVE SUBMISSIONS (Processed by BRDD) | 42 |
| Administrative Submissions (with BRDD Review): Number Received | 42 |
| Administrative Submissions (with BRDD Review): Number Approved | 42 |
| CLINICAL TRIAL APPLICATIONS (CTA) | 44 |
| CTA: Number Received by Phase | 44 |
| CTA: Number of Decisions by Document Type | 45 |
| CTA: Review Completed with a 30 Day Target..... | 45 |
| CLINICAL TRIAL APPLICATION- AMENDMENTS (CTA-A) | 46 |
| CTA-A: Number Received by Phase..... | 46 |
| CTA-A: Decisions by Type | 47 |
| CTA-A: Reviews Completed with a 30 Day Target | 47 |
| CTA & CTA-A RECEIVED UNDER THE INTERIM ORDER COVID-19..... | 48 |
| CTA: Number Received under the Interim Order Covid-19 by phase | 48 |
| CTA-A: Number Received under the Interim Order Covid-19 by phase | 48 |
| DINB: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - BIOLOGICAL PRODUCT | 49 |
| DINB: Number Received by Fee Category | 49 |
| REVIEW WORKLOAD..... | 50 |
| DINB: Review Workload | 50 |
| DINB: Review Workload by Fee Category | 50 |
| SCREENING WORKLOAD..... | 51 |
| DINB: Screening Workload | 51 |
| DINB: Screening Workload by Fee Category | 51 |
| DECISIONS | 52 |
| DINB: Number of Decisions by Fee Category | 52 |
| PERFORMANCE | 53 |
| DINB: Review Cycle Completions..... | 53 |
| DINB: Screening Cycle Completions | 53 |

| | |
|--|-----------|
| POST-AUTHORIZATION DIVISION 1 CHANGE FOR A BIOLOGIC DRUG PRODUCT (PDC-B)..... | 54 |
| PDC-B: Number Received..... | 54 |
| YEARLY BIOLOGIC PRODUCT REPORTS (YBPR) | 55 |
| YBPR: Number Received | 55 |
| APPENDIX A: PRE-SUBMISSION MEETINGS | 56 |
| Pre-submission Meetings Held / Feedback Provided..... | 56 |

OVERVIEW

The Biologic and Radiopharmaceutical Drugs Directorate (BRDD) Quarterly Drug Submission Performance Report reflects biologic and radiopharmaceutical drug submission review activity over five consecutive quarters: from April - June 2020 to April - June 2021. Statistics are provided by Submission Type and show the number received, the number in workload, the number of decisions and the number of approvals.

Several significant events occurred during the spring of 2020 including the COVID-19 Pandemic and the implementation of revised fees in accordance with the *Fees in Respect of Drugs and Medical Devices Order (SOR/2019-124)*.

- Health Canada employees shifted from working in their offices to working remotely from home. Fortunately in 2019, HPFB had implemented [new forms to take advantage of the gateway for transmission of regulatory transactions in electronic format](#).¹ This method is more efficient than sending transactions on physical media by courier and is mandatory as of October 1, 2020.
- The publication of the Quarterly Drug Submission Performance Report was cancelled for two quarters (there were no reports published for Q4 Jan-Mar 2020 and Q1 Apr-June 2020), however figures for the past three quarters are provided in this report.
- An [Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19](#) was approved and on August 13, 2020 the Minister of Health approved the [Order respecting certain time limits under the Food and Drug Regulations](#) temporarily extending the default period to review clinical trial applications and amendments from 30 days to 45 days to allow Health Canada to expedite the influx of COVID-19 related clinical trial applications. The order extending the default period expired on November 16, 2020. [The number of CTA and CTA-As received under orders](#) are included in this report.
- The [Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19](#) (ISAD Interim Order) was approved by the Governor in Council on September 25, 2020. This interim order was introduced, in part, to create a new authorization pathway to help expedite the authorization of drugs and vaccines for COVID-19. The number of applications and amendments filed, the number of applications and amendments in review, and the number of authorizations issued under the ISAD Interim Order are included in this report.

¹ [The Regulatory Enrolment Process \(REP\) and the Common Electronic Submissions Gateway \(CESG\)](#)

- There was a significant increase in the volume of Drug Identification Number Applications for Disinfectant products (DIND) received (see the Quarterly Drug Submission Performance Report for the Natural and Non-Prescription Health Products Directorate (NNHPD)).
- On April 1, 2020, revised fees were implemented in accordance with the *Fees in Respect of Drugs and Medical Devices Order (SOR/2019-124)*. In addition, submissions based only on clinical or non-clinical data, in support of safety updates to the labelling materials for a new drug are now submitted as an SNDS or SANDS (and not as an [NC](#)).
- Decisions made in 2020-2021 included submissions filed under both the pre-2020 and post-2020 cost recovery framework.
- The *Food and Drug Regulations* have been amended to allow for modified requirements that facilitate the regulatory process for new COVID-19 drugs to receive an NOC through a new drug submission (NDS). The amendments maintain some of the mechanisms introduced through the Interim order respecting the importation, sale and advertising of drugs for use in relation to COVID-19 (ISAD IO), thus continuing to provide Canadians with quick access to safe and effective COVID-19 drugs. The “NDS CV” submission type has been created for NDSs that use any of the provisions in subsections C.08.002(2.1), C.08.002(2.2) or C.08.002(2.3) of the *Regulations*. Additional information can be found at <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/updated-requirements-drug-authorization-notice.html>

General Information

There are several steps involved in the drug submission review² 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.

Approvals³ 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.

Authorization means an authorization issued under section 5 of the ISAD Interim Order.

A **review cycle completion**⁴ 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 to complete a cycle (excluding any pause days⁵) is compared to a set [performance standard](#) which is based on the type of submission, class and cycle (status).

[Performance for all submissions or applications filed after April 1, 2020 is tracked individually.](#)

² For further clarification, refer to the [Guidance for Industry: Management of Drug Submissions](#).

³ Final results from confirmatory trials submitted in the form of an SNDS-C are 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 \(NOC/c\)](#).

⁴ Review cycles include all types e.g. Review 1, Review 2, Review QN, Review Post JR. 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.

⁵ In the event that the review clock has been paused, the duration of the pause will be deducted from the total review time when calculating performance. That is, the days during which the clock is paused will not count when measuring performance (effective date: April 1, 2020).

"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"⁶ submissions.

Biosimilar is 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: osip-bppi@hc-sc.gc.ca

⁶ For further clarification refer to the [Guidance for Industry: Management of Drug Submissions](#).

ACRONYMS

Submission Types

| | |
|---------|--|
| ANDS | - Abbreviated New Drug Submission |
| COV19 | - Application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 |
| COV19A | - Application for an amendment to an application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 |
| 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 |
| IO_NOA | | Notice of Authorization |
| IO_NOA_TC | | Notice of Authorization with Terms and 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 | Description |
|---|---|
| New active substance | Submissions in support of a drug, other than a disinfectant, that contains a medicinal ingredient not previously approved in a drug in Canada and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph |
| 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 new active substance |
| Clinical or nonclinical data only | Submissions based only on clinical or non-clinical data for a drug that does not include a new active substance |
| Comparative studies | Submissions based on comparative studies (e.g., clinical or non-clinical data, bioavailability data and data on the pharmacokinetics and pharmacodynamics of the drug) with or without chemistry and manufacturing data for a drug that does not include a new active substance |
| Chemistry and manufacturing data only | Submissions based only on chemistry and manufacturing data for a drug that does not include a new active substance |
| Clinical or nonclinical data only, in support of safety updates to the labelling | Submissions based only on clinical or non-clinical data, in support of safety updates to the labelling materials for a new drug that does not include a new active substance |
| Switch status from prescription drug to non-prescription drug | Submissions based only on data that support the modification or removing of a medicinal ingredient listed in Schedule F of the Food and Drug Regulations (i.e. identical claim for existing drug) - Category discontinued |
| Labelling only | Submissions, other than those described in item 9, 12 or 13, of labelling material, that include data in support of the following: brand name assessment, standardized or published test methods, in vitro or in vivo photostability or applications for a drug identification number in support of changes to brand names of non-prescription drugs (but not including examination of other supporting clinical or non-clinical data, comparative data, or chemistry and manufacturing data) |

| Fee Category | Description |
|---|--|
| Labelling only (generic drugs) | Submissions in support of a change to the labelling to be consistent with the Canadian reference product that do not include any additional labelling updates requiring a labelling assessment |
| Administrative submission | Submissions in support of a change in the manufacturer's name or brand name, including the following: changes in ownership of the drug, request for an additional brand name or changes resulting from a licensing agreement being entered into by two manufacturers that do not require an assessment of labelling material or brand name (e.g., post-authorization label changes filed by licensees to remain identical to licensor's drug and post-authorization chemistry and manufacturing updates for drugs listed in Schedule C or D of the Food and Drugs Act) |
| Disinfectant – full review | Submissions, other than those described in item 12, that include data in support of a disinfectant |
| Labelling only (disinfectants) | Submissions in support of changes to the labelling of disinfectants that do not require supporting data, submissions in support of safety updates for disinfectants that are new drugs or submissions in support of a change in the manufacture's name or brand name that requires a review of labelling material due to deviations from the previously authorized labelling or drug |
| Drug identification number application - labelling standards | Applications, including those that pertain to changes to brand names for non-prescription drugs, that include an attestation of compliance with a labelling standard or Category IV Monograph for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data |
| Published data only | Submissions based only on published clinical or non-clinical data for a drug that does not include a new active substance - Category discontinued |

For further information please consult the [Guidance Document: Fees for the Review of Human and Disinfectant Drug Submissions and Applications](#).

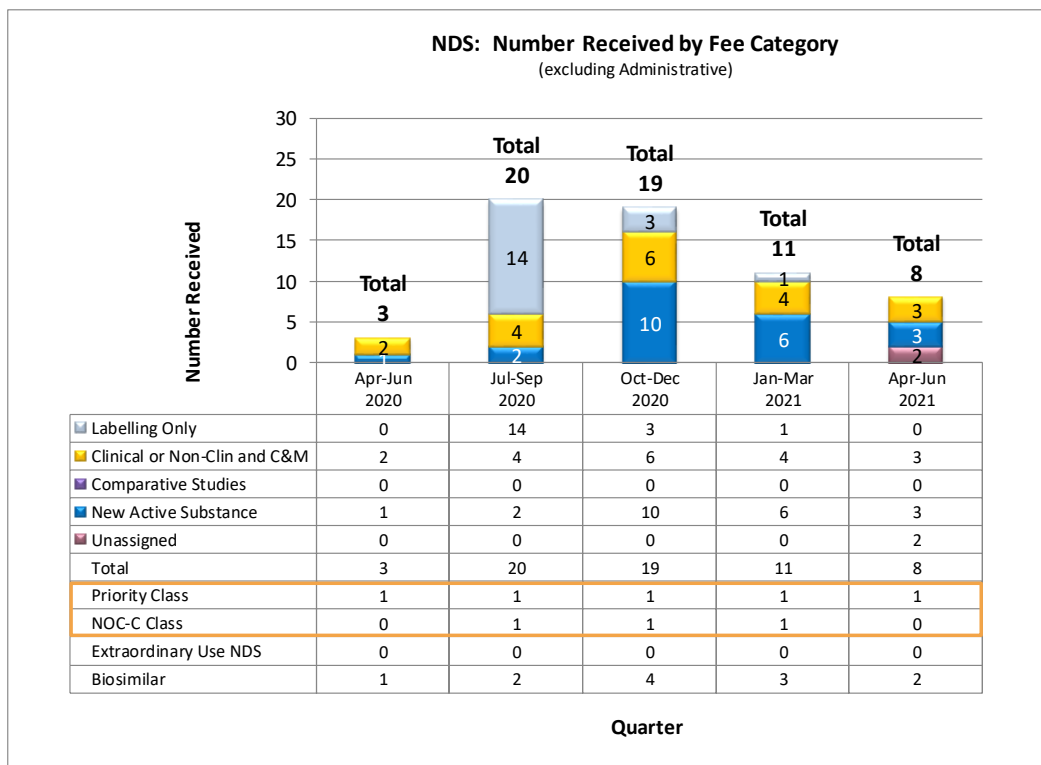
**New Drug Submissions
(NDS)**

&

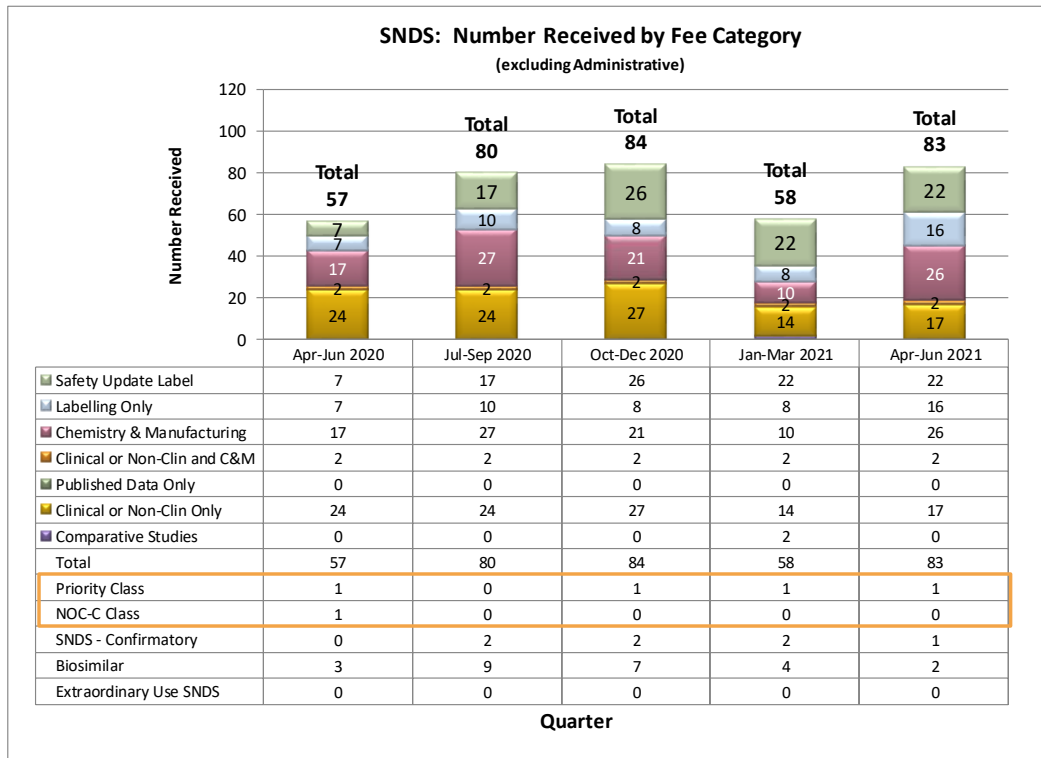
**Supplemental New Drug Submissions
(SNDS)**

SUBMISSIONS RECEIVED ⁷

NDS: Received by Fee Category



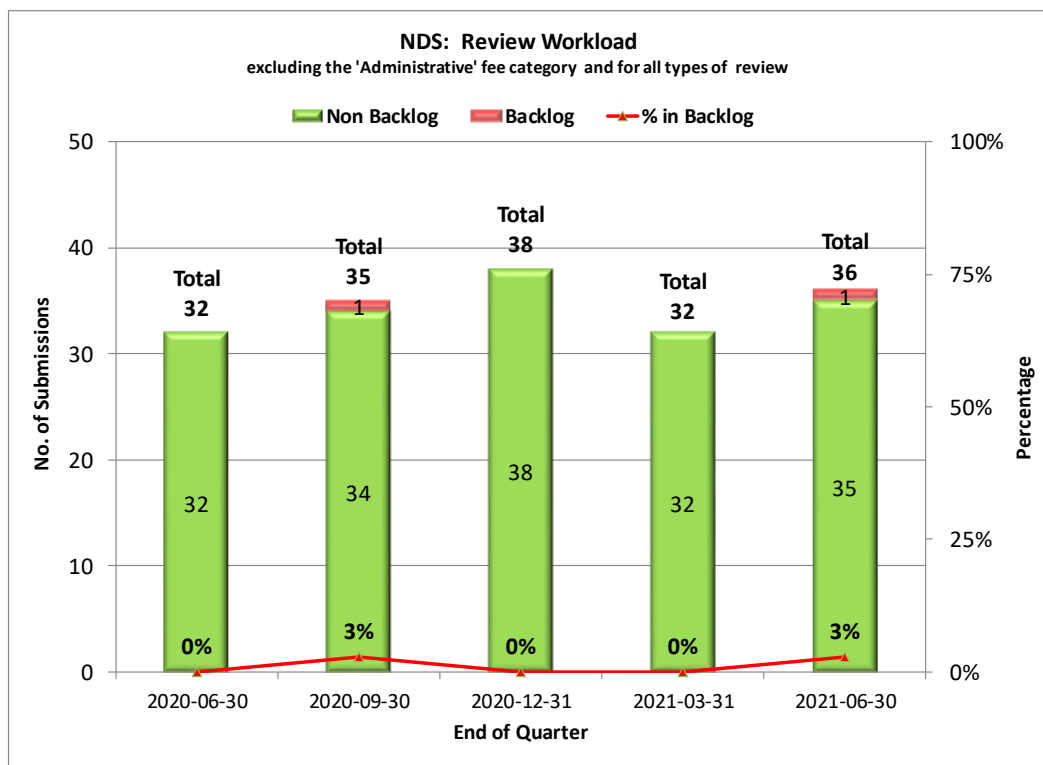
SNDS: Received by Fee Category



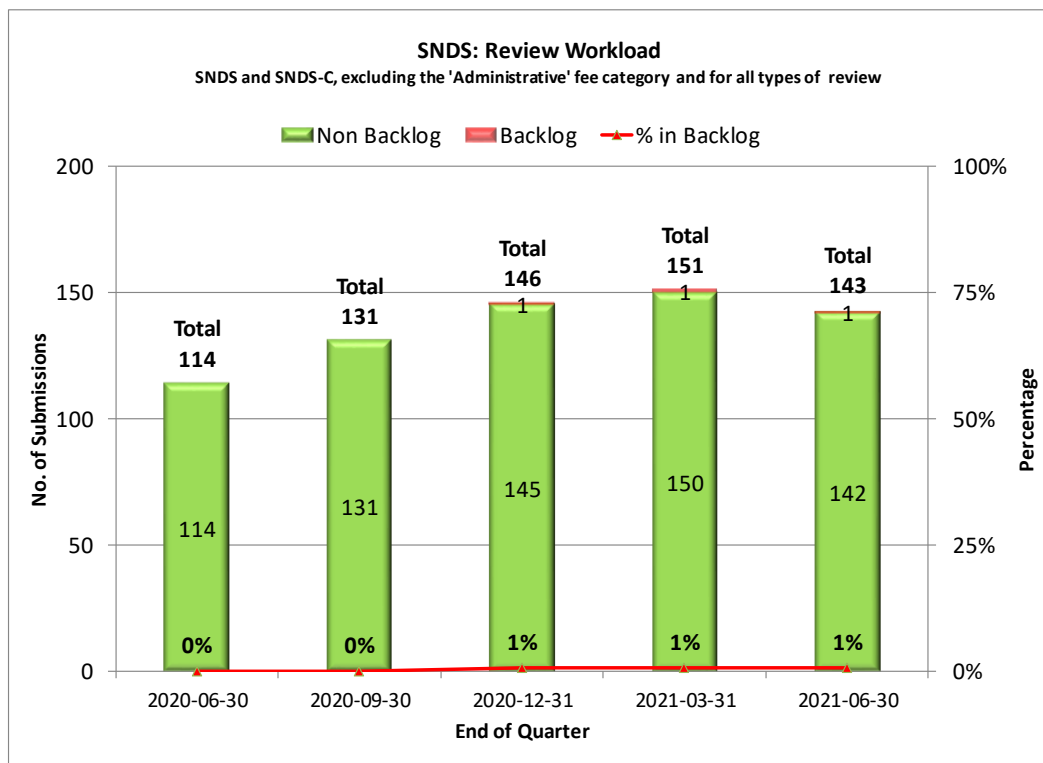
⁷ Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the [Priority Review of Drug Submissions Policy](#), the [Notice of Compliance with conditions \(NOC/c\) Guidance](#) and the [Management of Drug Submissions Guidance](#).

WORKLOAD

NDS: Review Workload



SNDS: Review Workload



WORKLOAD

NDS: Review Workload by Fee Category

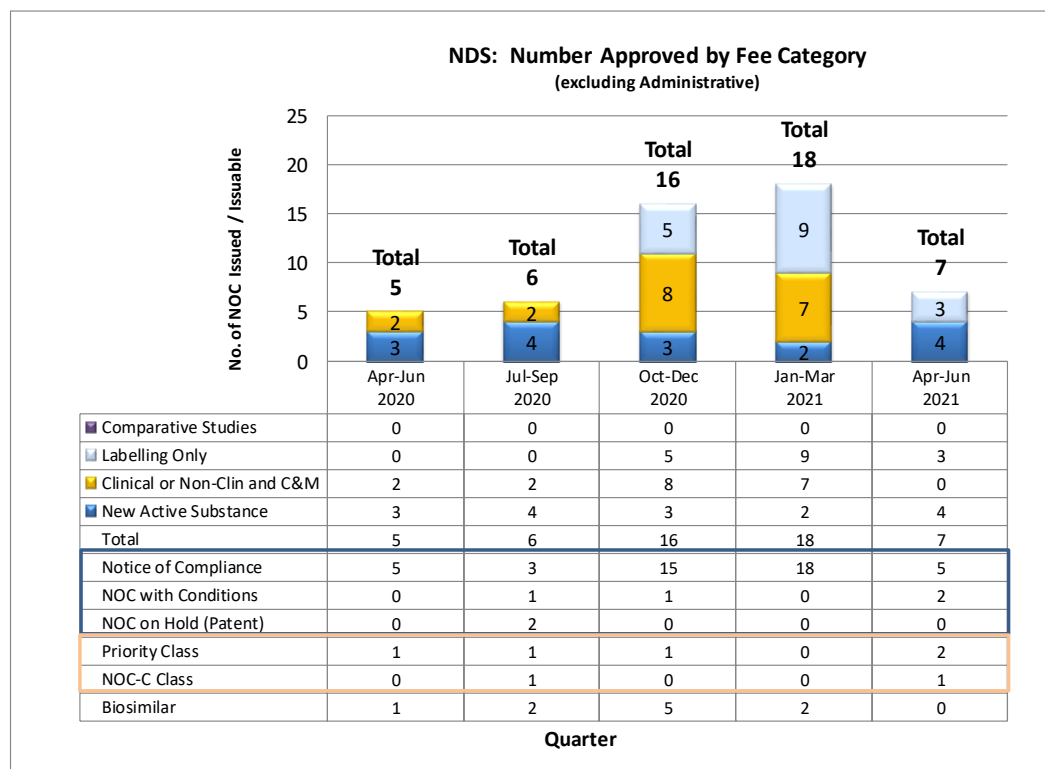
| NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter | | | | | |
|---|------------|------------|------------|------------|------------|
| FEE Category | 2020-06-30 | 2020-09-30 | 2020-12-31 | 2021-03-31 | 2021-06-30 |
| Clinical or Non-Clin and C&M | 22 | 19 | 14 | 14 | 17 |
| Backlog | 0 | 1 | 0 | 0 | 0 |
| New Active Substance | 10 | 9 | 13 | 14 | 18 |
| Backlog | 0 | 0 | 0 | 0 | 1 |
| Labelling Only | 0 | 7 | 11 | 4 | 1 |
| Backlog | 0 | 0 | 0 | 0 | 0 |
| Total | 32 | 35 | 38 | 32 | 36 |
| Non Backlog | 32 | 34 | 38 | 32 | 35 |
| Backlog | 0 | 1 | 0 | 0 | 1 |
| % in Backlog | 0% | 3% | 0% | 0% | 3% |
| Priority (subset) | 2 | 1 | 2 | 3 | 2 |
| Backlog | 0 | 0 | 0 | 0 | 0 |

SNDS: Review Workload by Fee Category

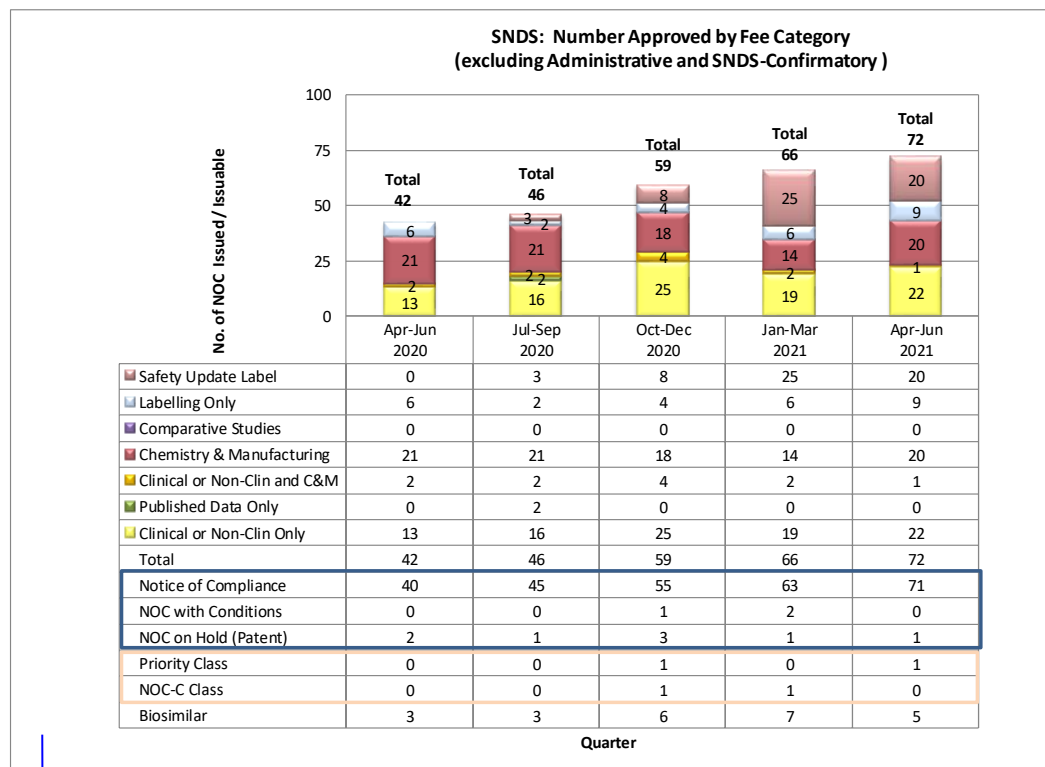
| SNDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter | | | | | |
|--|------------|------------|------------|------------|------------|
| FEE Category | 2020-06-30 | 2020-09-30 | 2020-12-31 | 2021-03-31 | 2021-06-30 |
| Comparative Studies | 0 | 0 | 0 | 2 | 2 |
| Backlog | 0 | 0 | 0 | 0 | 0 |
| Chemistry & Manufacturing | 28 | 26 | 26 | 31 | 30 |
| Backlog | 0 | 0 | 0 | 0 | 0 |
| Clinical or Non-Clin Only | 70 | 75 | 78 | 75 | 65 |
| Backlog | 0 | 0 | 0 | 0 | 0 |
| Clinical or Non-Clin and C&M | 8 | 8 | 6 | 5 | 7 |
| Backlog | 0 | 0 | 0 | 0 | 0 |
| Published Data | 2 | 0 | 0 | 0 | 0 |
| Backlog | 0 | 0 | 0 | 0 | 0 |
| Labelling Only | 2 | 5 | 8 | 13 | 12 |
| Backlog | 0 | 0 | 0 | 0 | 0 |
| Safety Update Label | 4 | 17 | 28 | 25 | 27 |
| Backlog | 0 | 0 | 1 | 1 | 1 |
| Total | 114 | 131 | 146 | 151 | 143 |
| Non Backlog | 114 | 131 | 145 | 150 | 142 |
| Backlog | 0 | 0 | 1 | 1 | 1 |
| % in Backlog | 0% | 0% | 1% | 1% | 1% |
| Priority (subset) | 1 | 1 | 1 | 2 | 1 |
| Backlog | 0 | 0 | 0 | 0 | 0 |
| SNDS-C (Confirmatory) | 4 | 4 | 5 | 5 | 7 |
| Backlog | 0 | 0 | 0 | 0 | 0 |

APPROVALS ⁸

NDS: Number Approved by Fee Category and NOC Type



SNDS: Number Approved by Fee Category and NOC Type



⁸ 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](#).

BIOSIMILARS: NDS & SNDS Market Authorizations

Biosimilars: Number of Market Authorization for NDS & SNDS by Quarter

| Submission Type | Class | Apr-Jun 2020 | Jul-Sep 2020 | Oct-Dec 2020 | Jan-Mar 2021 | Apr-Jun 2021 |
|-------------------|---------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| NDS | CLIN/C&M | 4 | 0 | 9 | 3 | 0 |
| NDS Total | | 4 | 0 | 9 | 3 | 0 |
| SNDS | C&M ONLY | 1 | 0 | 3 | 4 | 2 |
| | C&M/LABELLING | 0 | 1 | 2 | 0 | 0 |
| | CLIN ONLY | 2 | 1 | 3 | 1 | 4 |
| | CLIN/C&M | 0 | 0 | 0 | 1 | 0 |
| | COMP/C&M | 0 | 0 | 0 | 0 | 0 |
| | LABELLING ONLY | 0 | 0 | 1 | 0 | 0 |
| | SAFETY UPDATE LABEL | 0 | 0 | 1 | 1 | 1 |
| SNDS Total | | 3 | 2 | 10 | 7 | 7 |

Biosimilars: NDS Market Authorizations during FY 2021-22 (Apr 1 2021 - Mar 31 2022)

| Brand Name | Class | Company | Active Ingredient(s) | Quarter FY 2021-22 | Notice of Compliance (NOC) Date |
|---------------------------|-------|---------|----------------------|--------------------------|---------------------------------------|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| New Drug Submission Total | | | | | 0 |

Biosimilars: SNDS Market Authorizations during FY 2021-22 (Apr 1 2021 - Mar 31 2022)

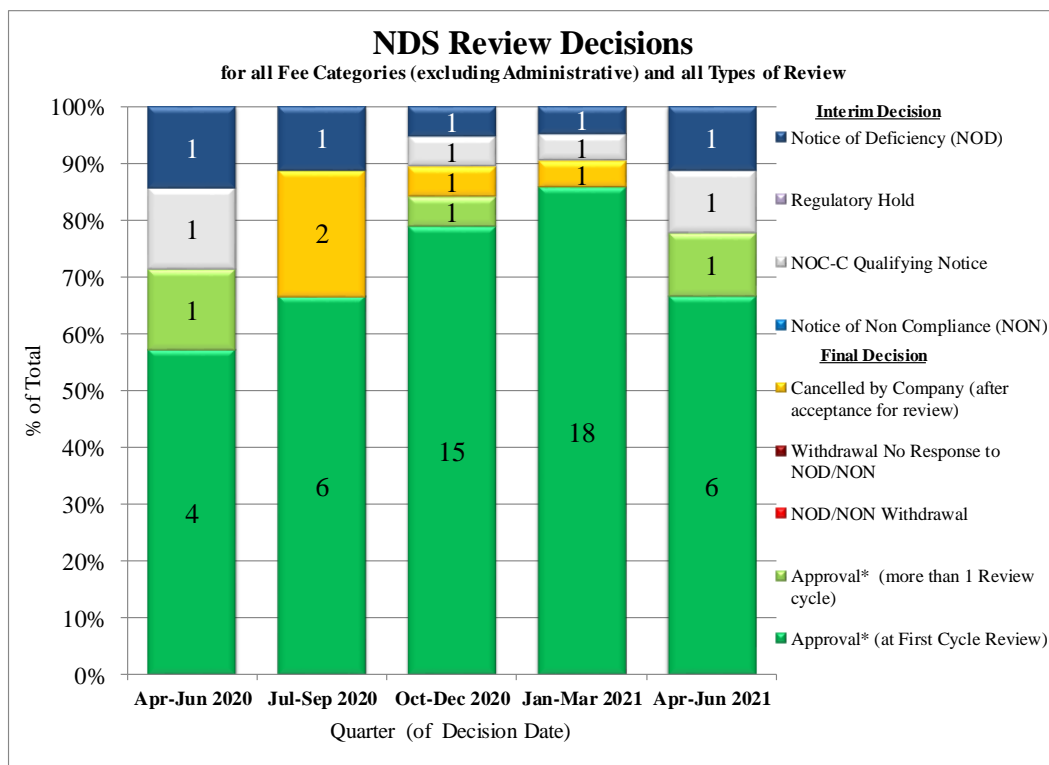
| Brand Name | Class | Company | Active Ingredient(s) | Quarter FY 2021-22 | Notice of Compliance (NOC) Date |
|--|---------------------|--------------------------------|----------------------|--------------------------|---------------------------------------|
| ERELZI | C&M ONLY | SANDOZ CANADA INCORPORATED | ETANERCEPT | Q1 | 2021-Jun-24 |
| HERZUMA | CLIN ONLY | CELLTRION HEALTHCARE CO LTD | TRASTUZUMAB | Q1 | 2021-Apr-16 |
| HULIO | C&M ONLY | BGP PHARMA ULC | ADALIMUMAB | Q1 | 2021-May-14 |
| KANJINTI | CLIN ONLY | AMGEN CANADA INC | TRASTUZUMAB | Q1 | 2021-Apr-14 |
| RITUXIMAB | CLIN ONLY | SANDOZ CANADA INCORPORATED | RITUXIMAB | Q1 | 2021-Jun-30 |
| TRAZIMERA | CLIN ONLY | PFIZER CANADA ULC | TRASTUZUMAB | Q1 | 2021-Apr-14 |
| TRAZIMERA | SAFETY UPDATE LABEL | PFIZER CANADA ULC | TRASTUZUMAB | Q1 | 2021-Jun-18 |
| Supplemental New Drug Submission Total | | | | | 7 |

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

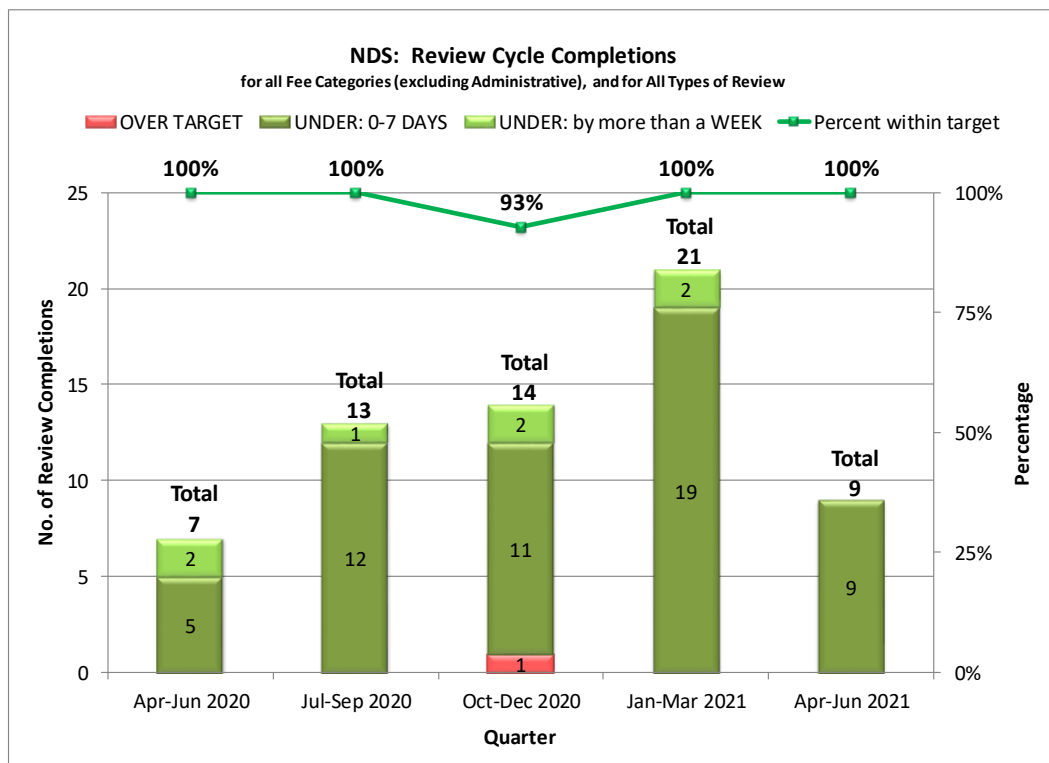
Biosimilar: A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity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

REVIEW PERFORMANCE

NDS: Review Decisions by Type

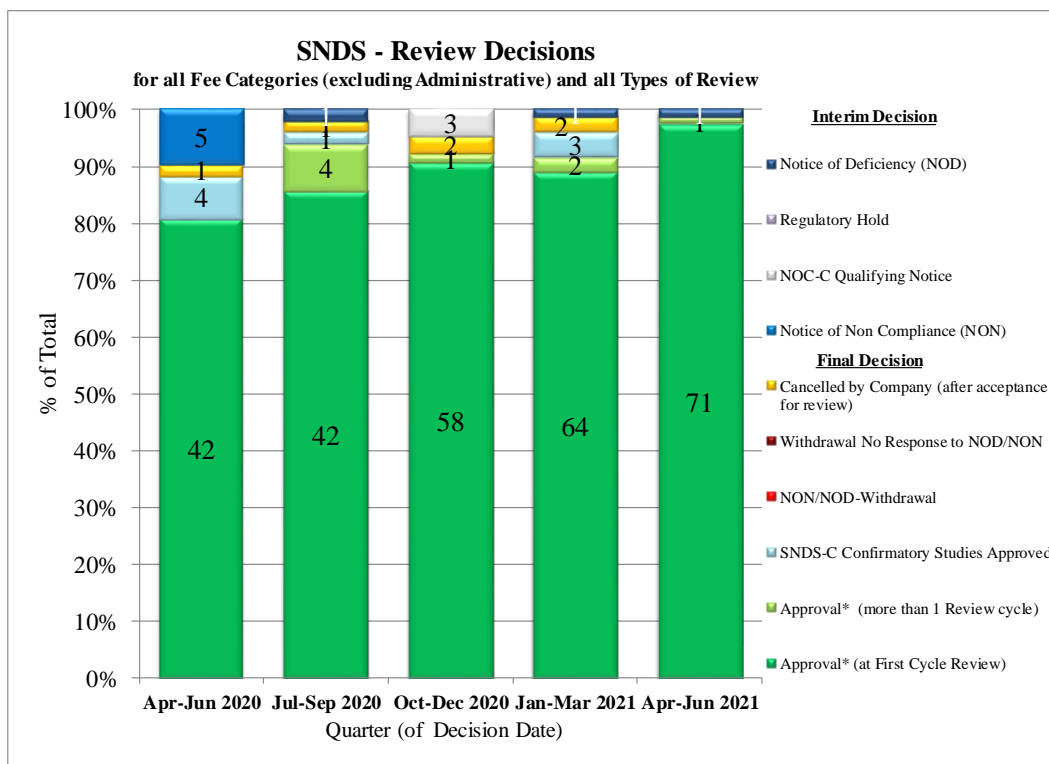


NDS: Review Cycle Completions

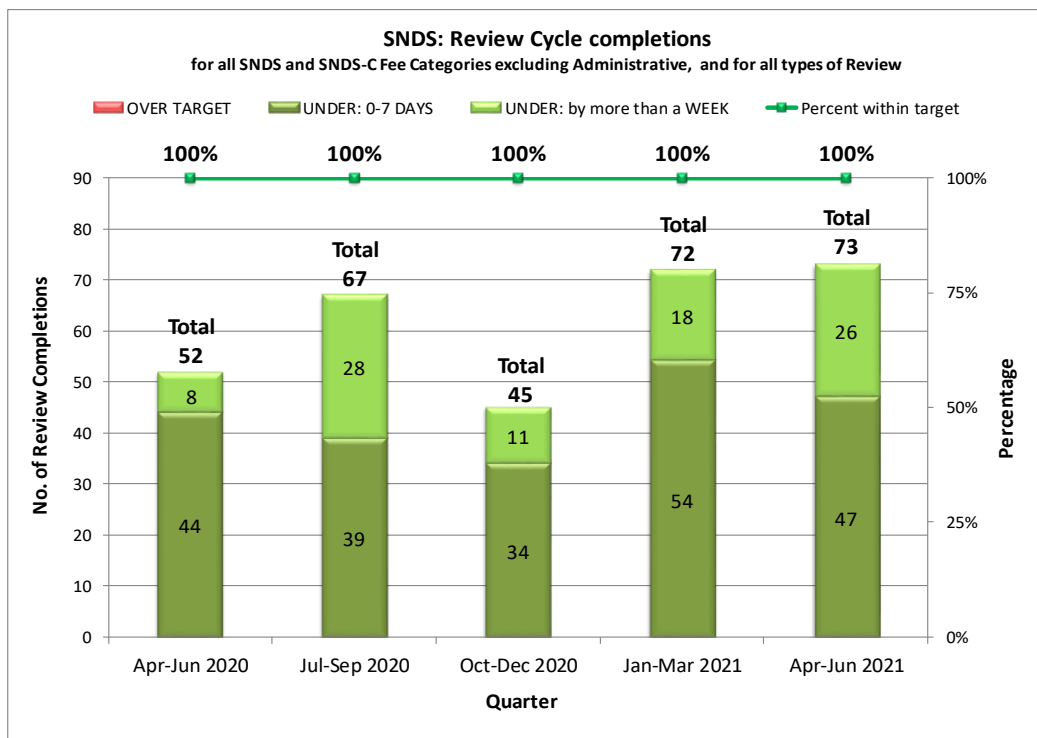


REVIEW PERFORMANCE

SNDS: Review Decisions by Type

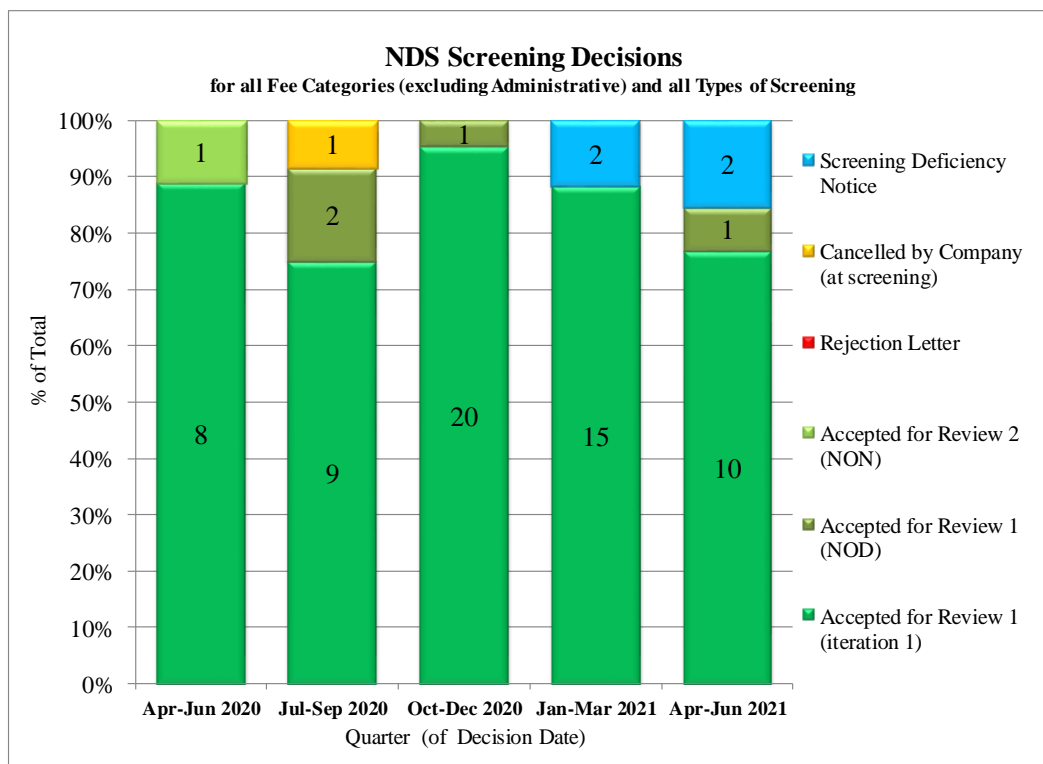


SNDS: Review Cycle Completions

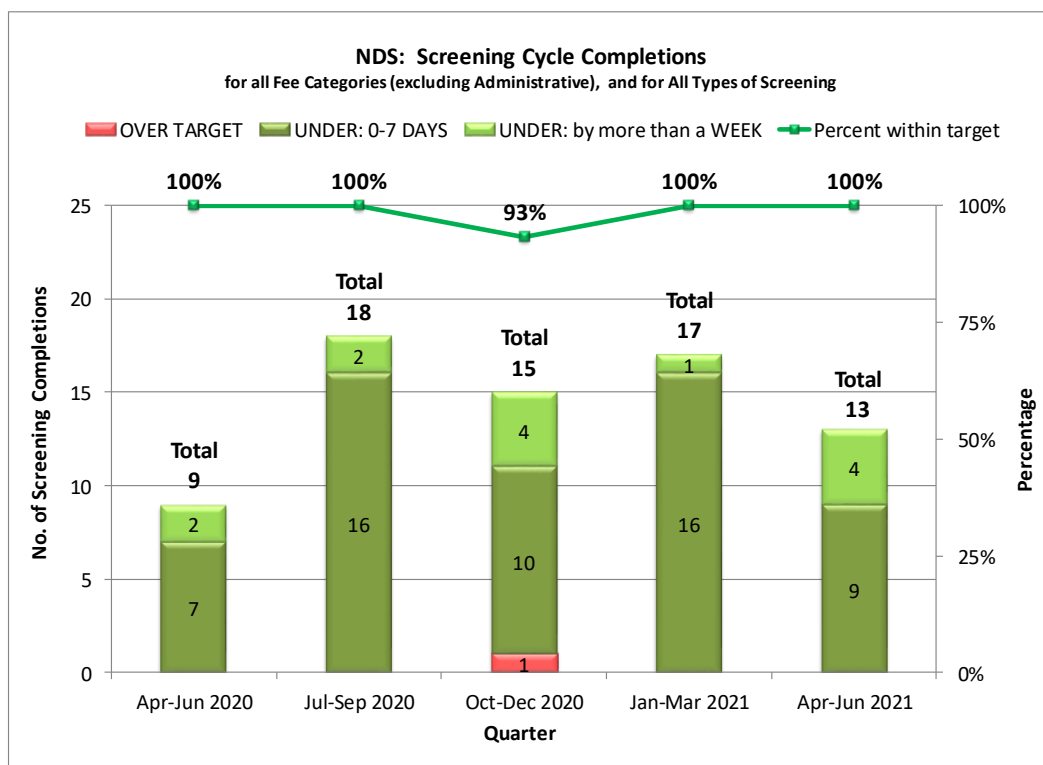


SCREENING PERFORMANCE

NDS: Screening Decisions by Type

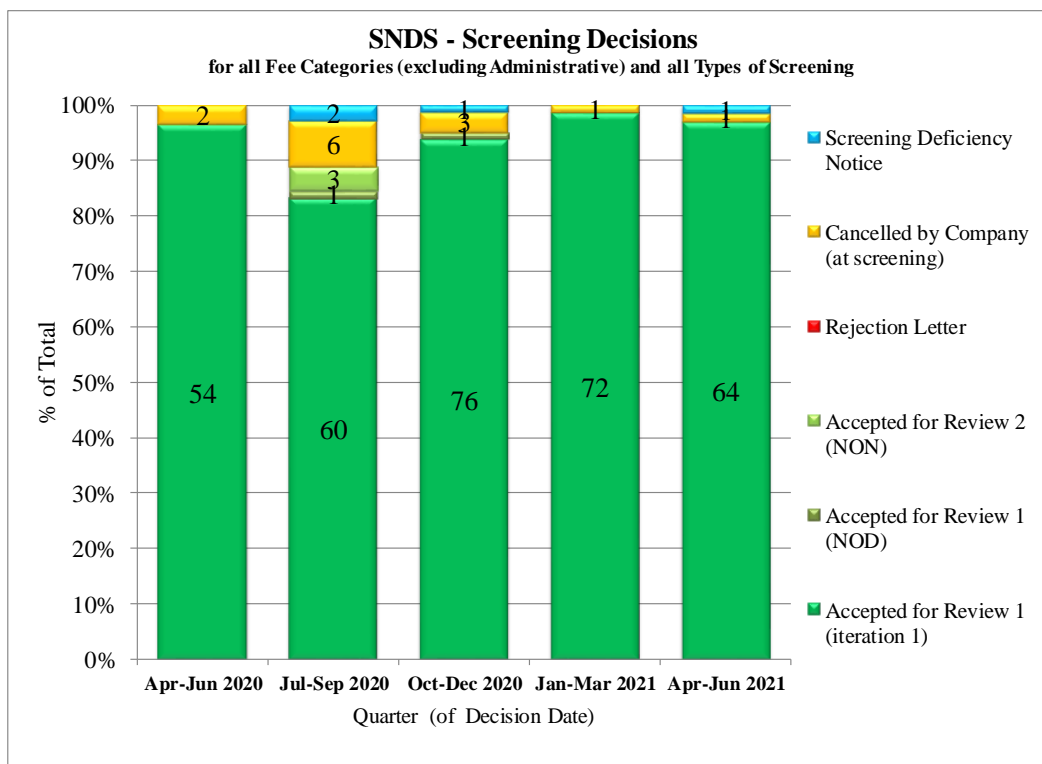


NDS: Screening Cycle Completions

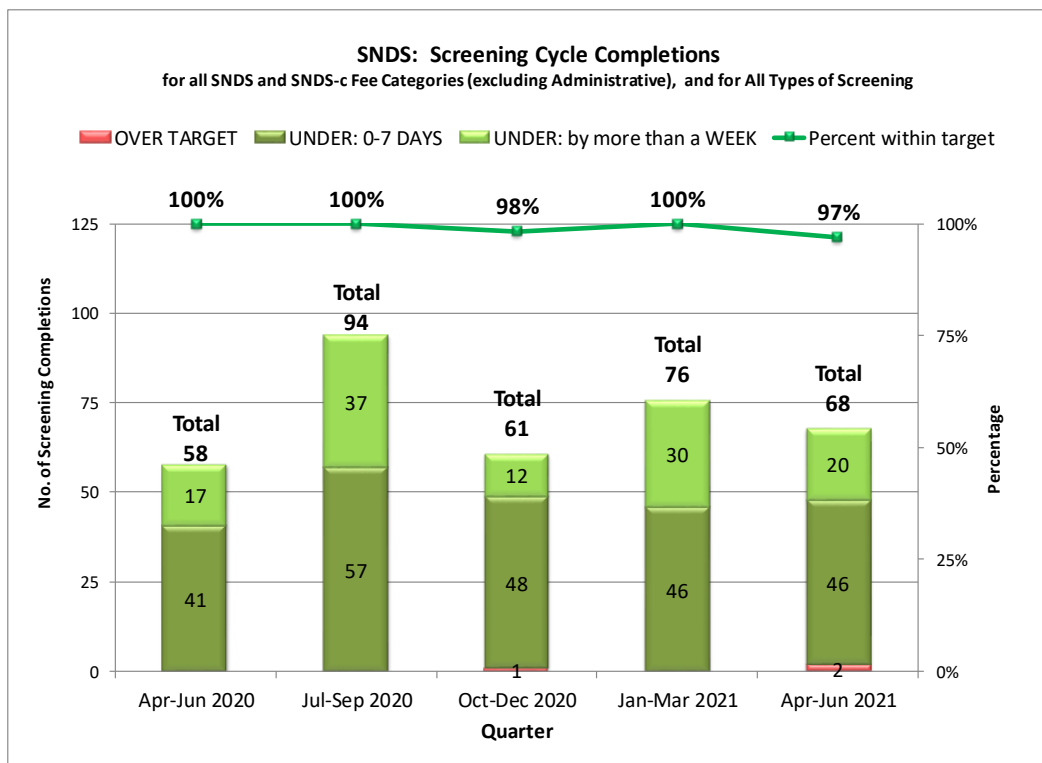


SCREENING PERFORMANCE

SNDS: Screening Decisions by Type

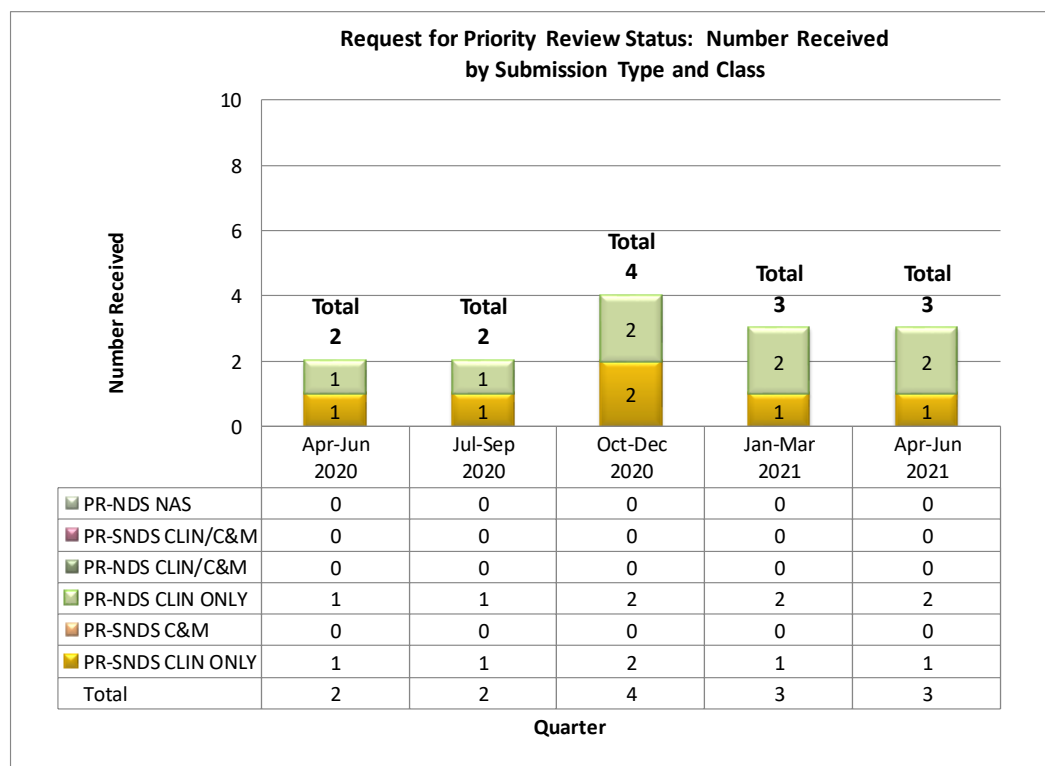


SNDS: Screening Cycle Completions

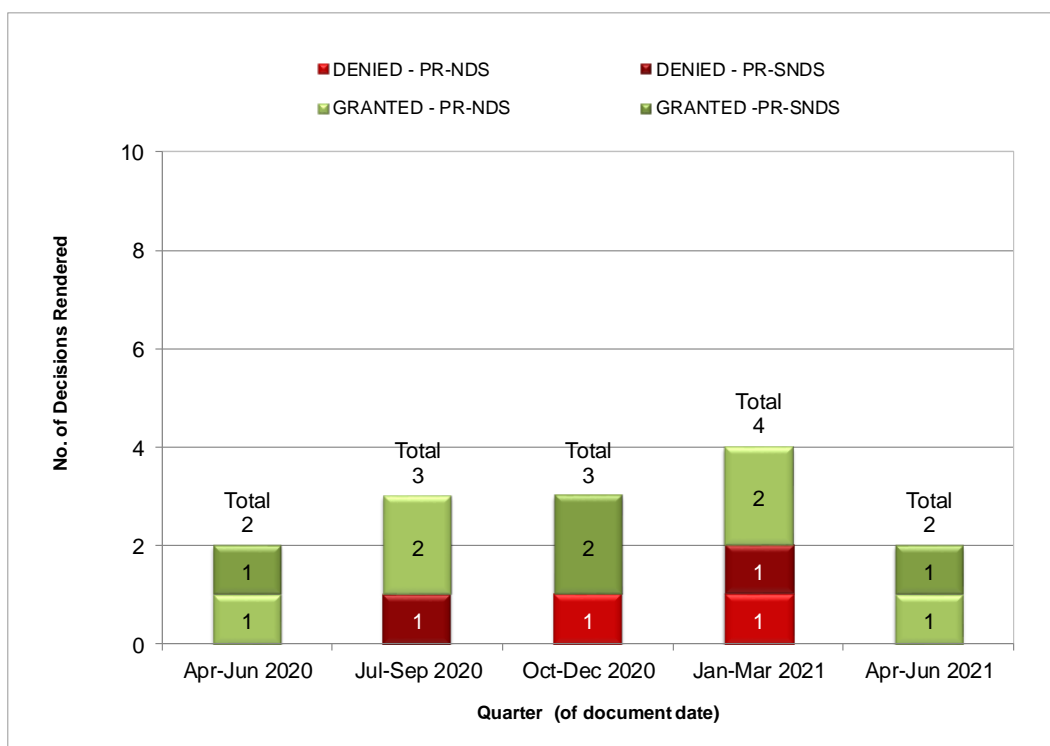


REQUEST FOR PRIORITY REVIEW STATUS (NDS & SNDS)

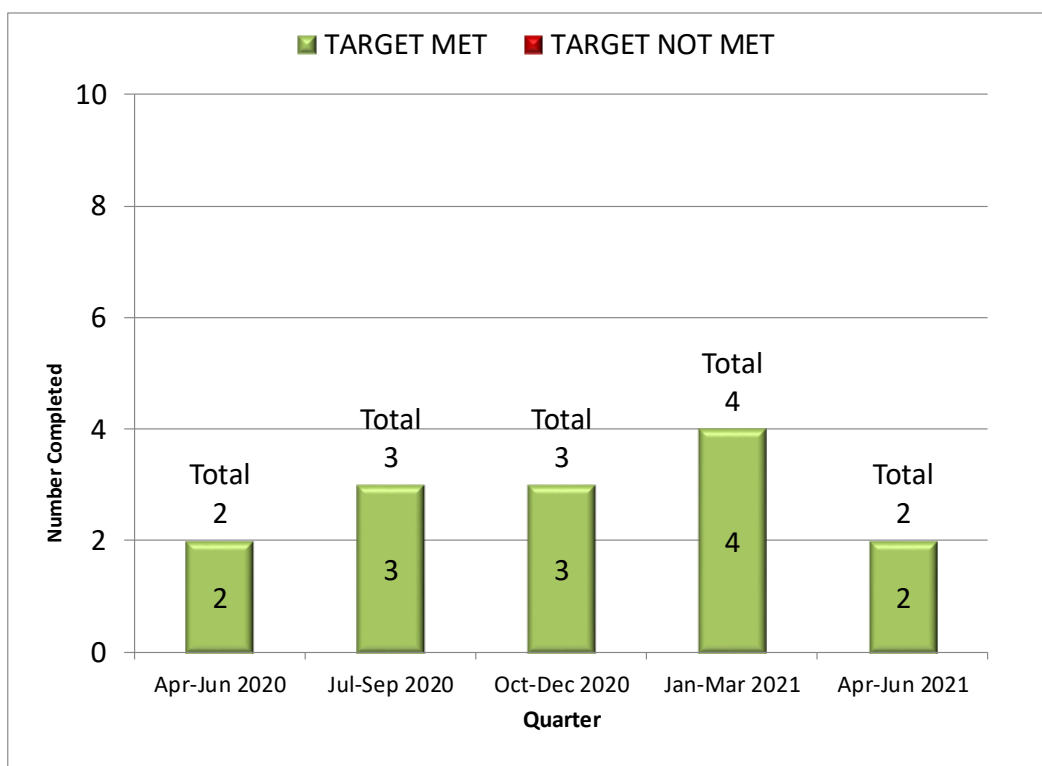
Request for Priority Review Status: Number Received



Request for Priority Review Status: Decisions Rendered



Request for Priority Review Status: Performance



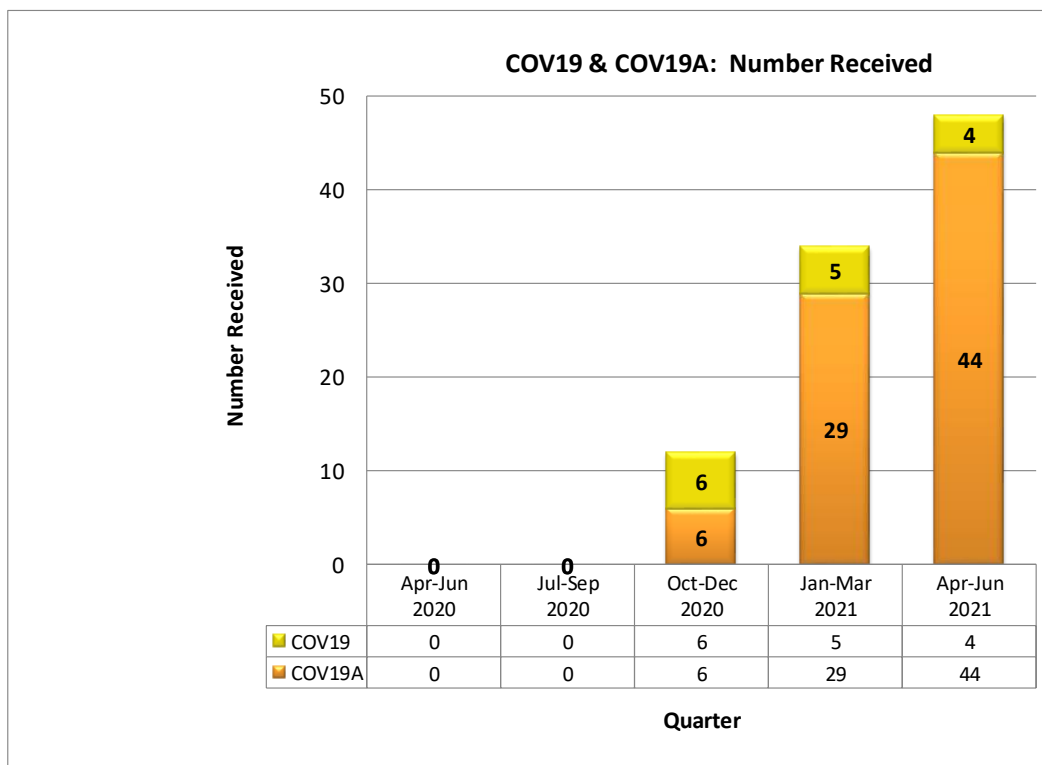
**Application under the Interim Order Respecting the
Importation, Sale and Advertising of Drugs for Use in
Relation to COVID-19
(COV19)**

&

**Application for an amendment to an application under the
Interim Order Respecting the Importation, Sale and
Advertising of Drugs for Use in Relation to COVID-19
(COV19A)**

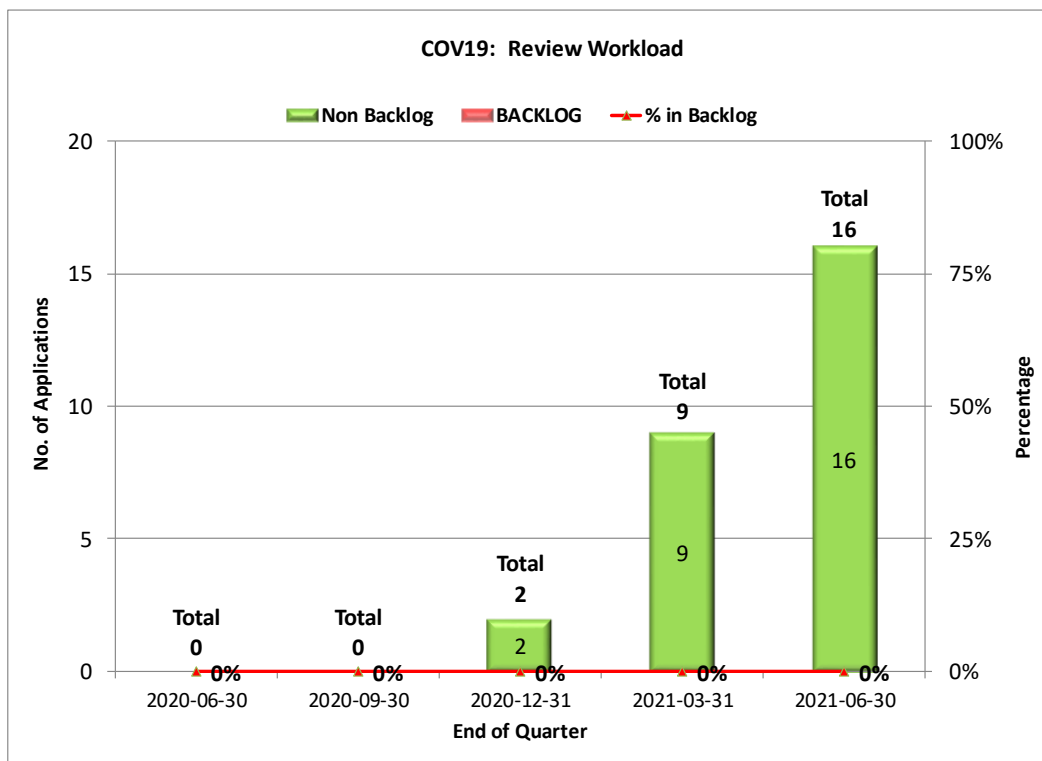
RECEIVED

COV19 & COV19A: Number Received



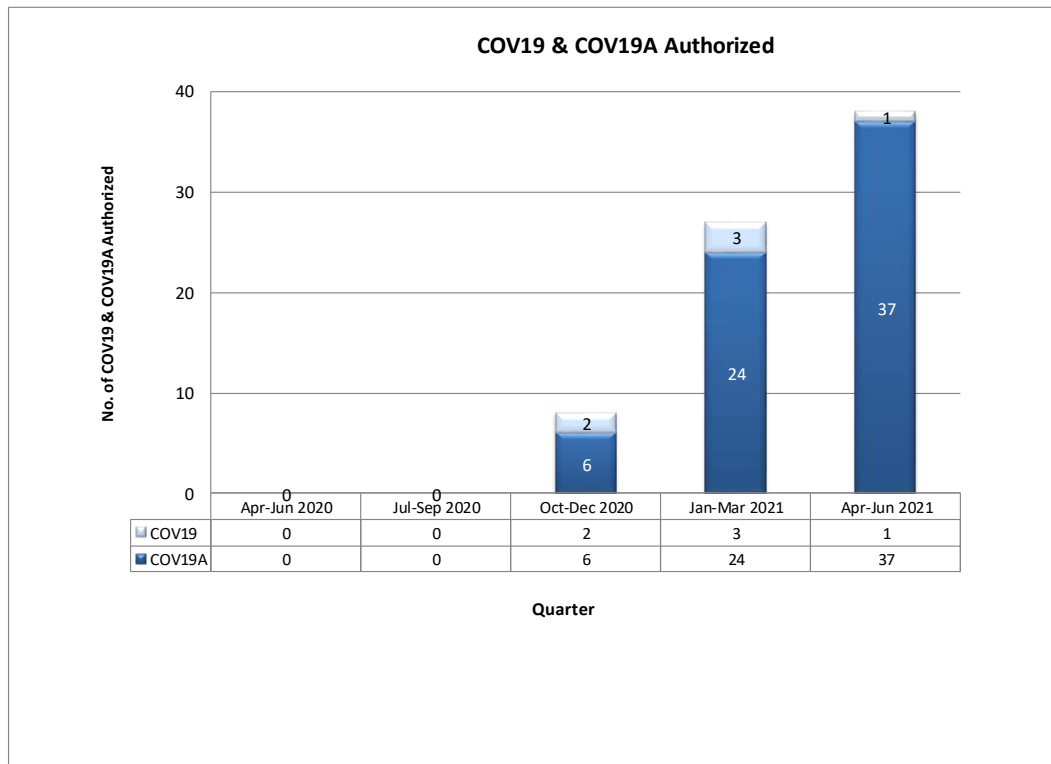
WORKLOAD

COV19: Review Workload



AUTHORIZATIONS

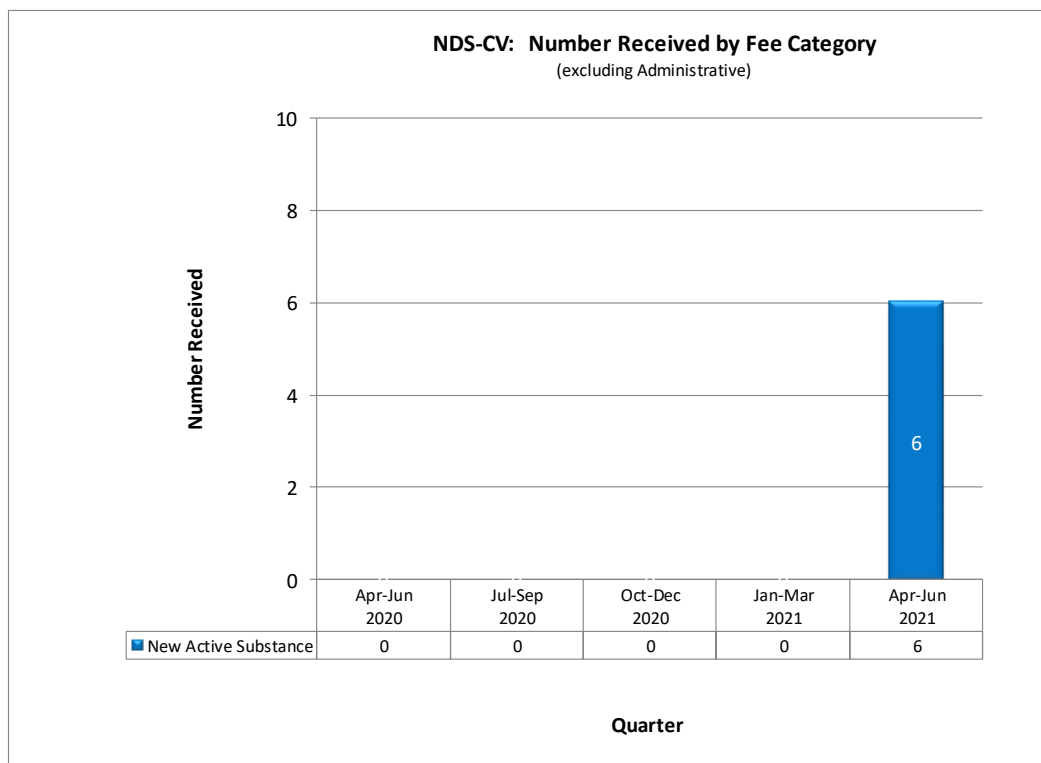
COV19 & COV19A: Number Authorized



New Drug Submissions for Designated COVID-19 Drugs (NDS-CV)

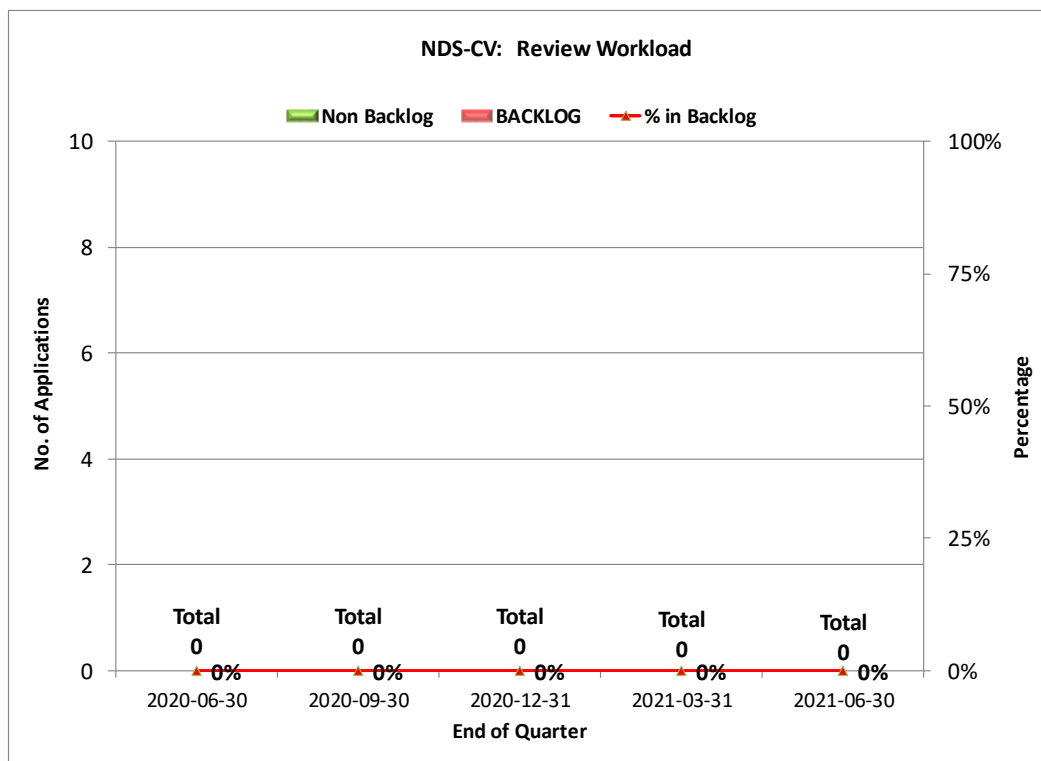
RECEIVED

NDS-CV: Number Received



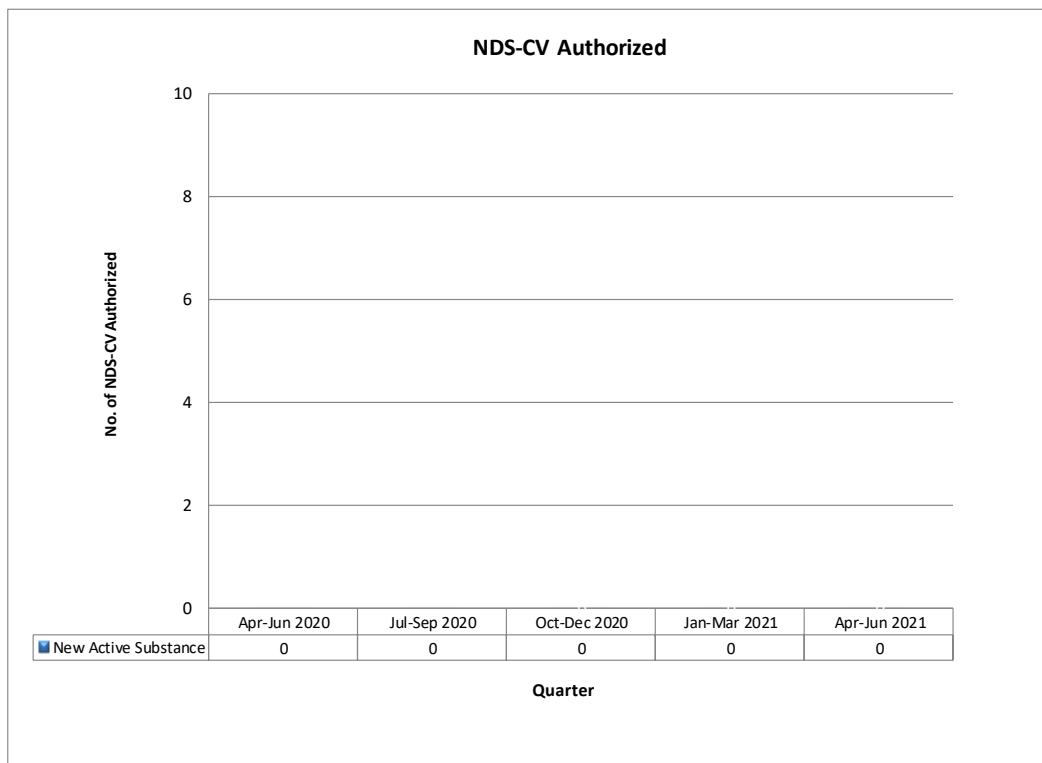
WORKLOAD

NDS-CV: Review Workload



AUTHORIZATIONS

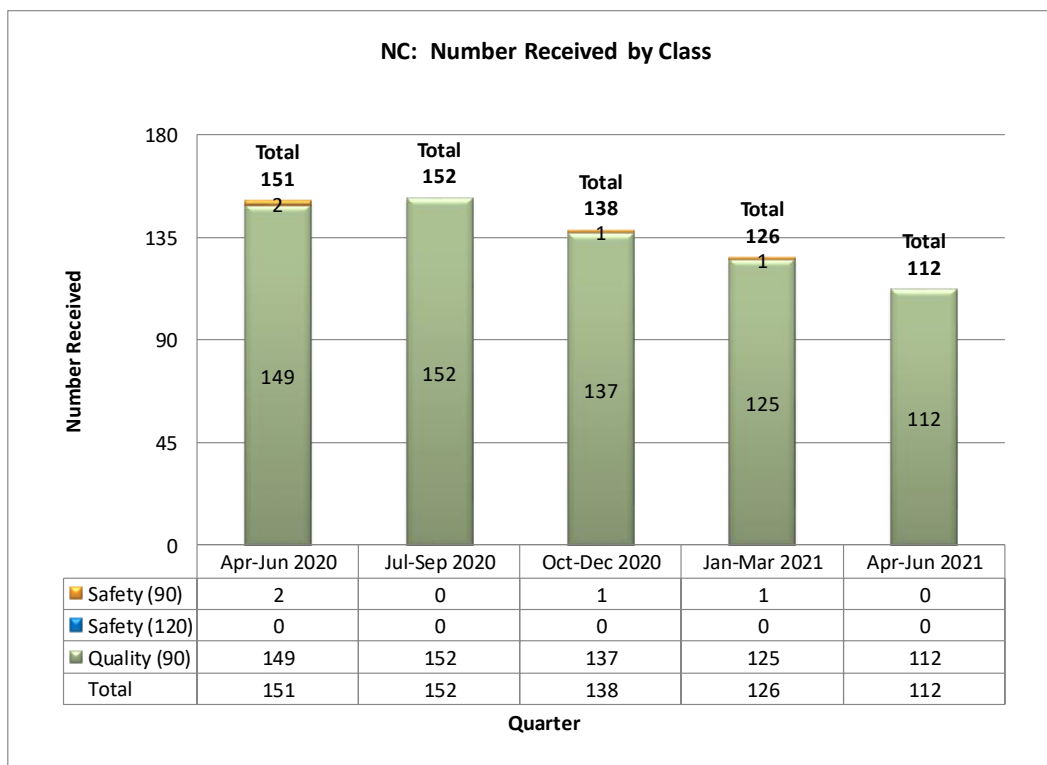
NDS-CV: Number Authorized



NC: NOTIFIABLE CHANGE

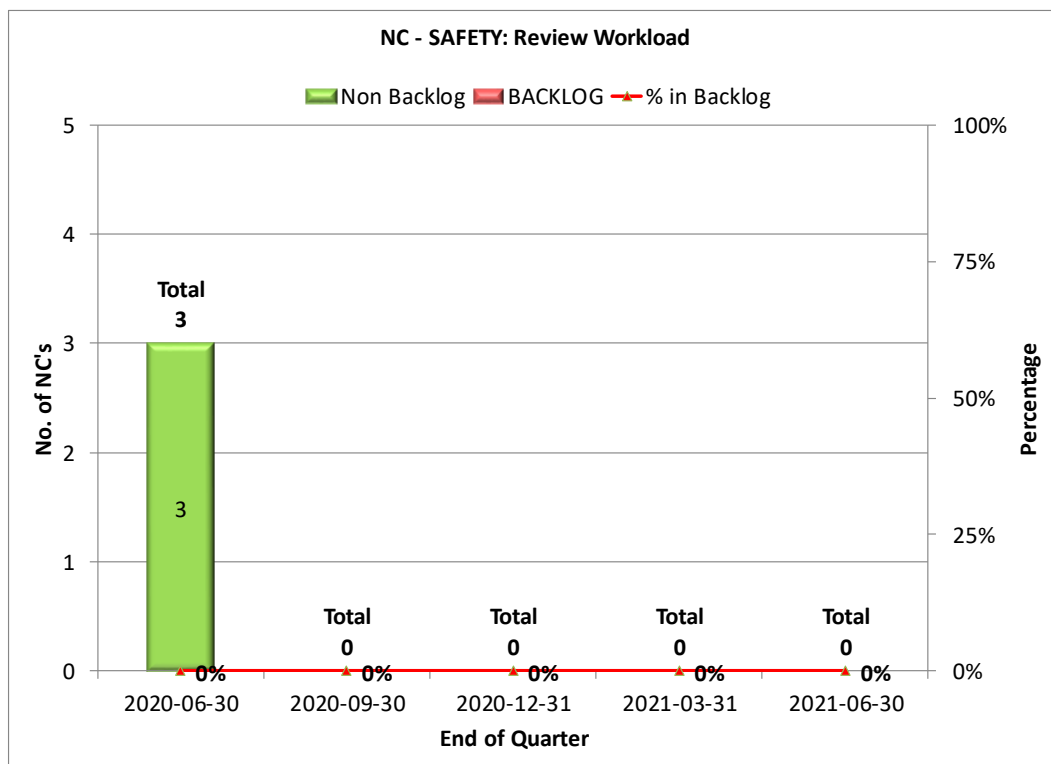
NC: NOTIFIABLE CHANGE

NC: Number Received by Class

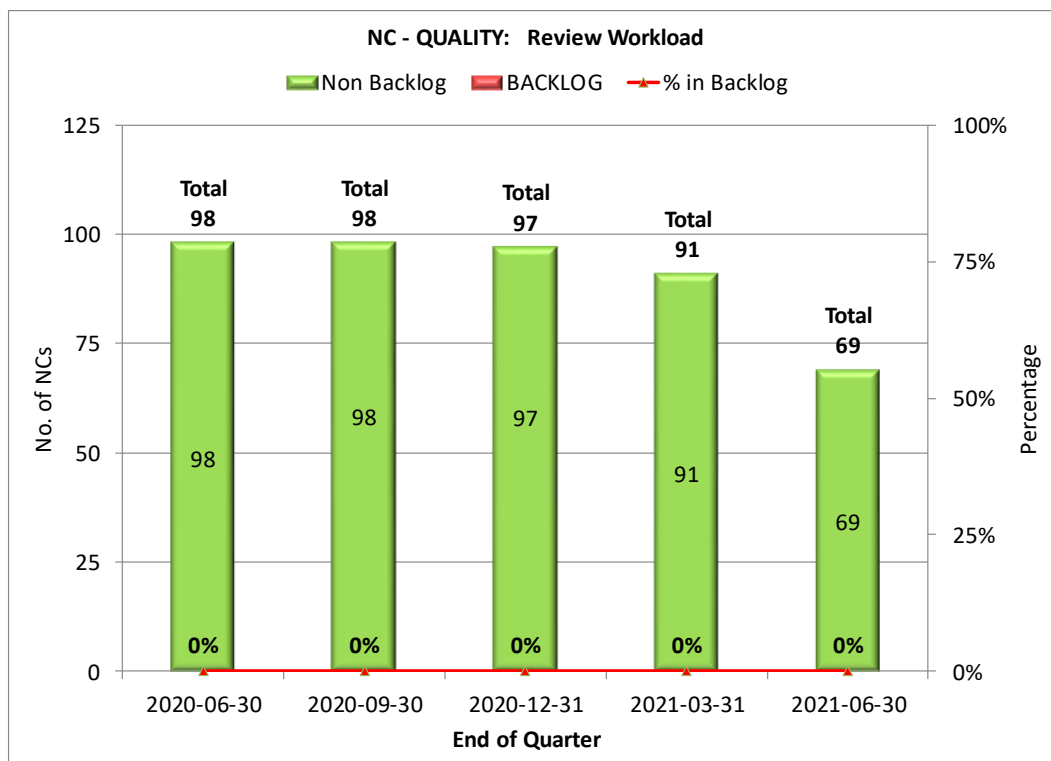


WORKLOAD

NC-SAFETY: Review Workload



NC-QUALITY: Review Workload



WORKLOAD

NC-SAFETY: Review Workload by Class

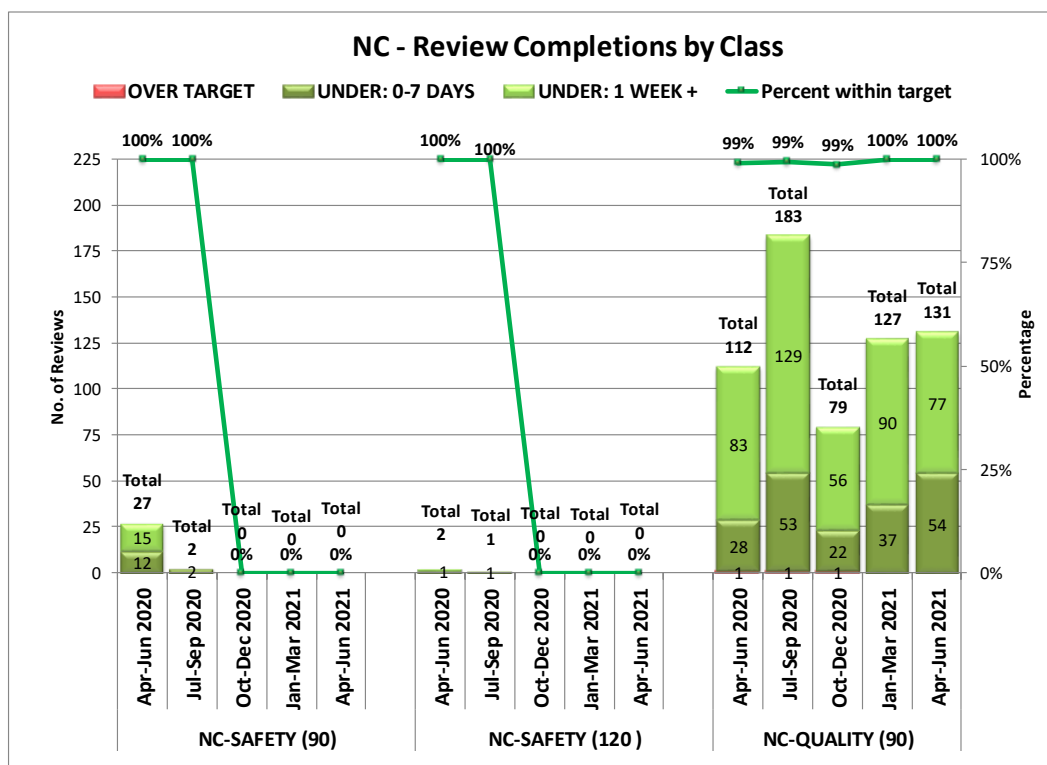
| BRDD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER | | | | | |
|---|------------|------------|------------|------------|------------|
| Class | 2020-06-30 | 2020-09-30 | 2020-12-31 | 2021-03-31 | 2021-06-30 |
| SAFETY - 90 day | 2 | 0 | 0 | 0 | 0 |
| Backlog | 0 | 0 | 0 | 0 | 0 |
| SAFETY - 120 day | 1 | 0 | 0 | 0 | 0 |
| Backlog | 0 | 0 | 0 | 0 | 0 |
| Total | 3 | 0 | 0 | 0 | 0 |
| Non Backlog | 3 | 0 | 0 | 0 | 0 |
| BACKLOG | 0 | 0 | 0 | 0 | 0 |
| % in Backlog | 0% | 0% | 0% | 0% | 0% |

NC-QUALITY: Review Workload by Class

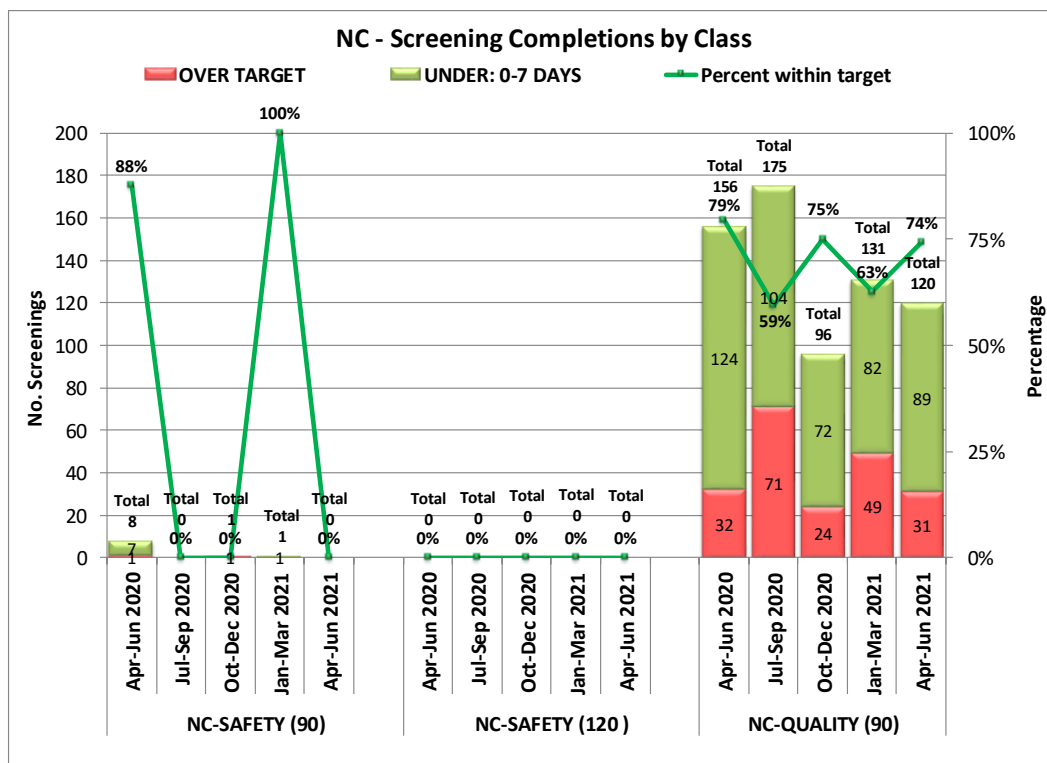
| BRDD NC - QUALITY: REVIEW WORKLOAD AT END OF QUARTER | | | | | |
|--|------------|------------|------------|------------|------------|
| CLASS | 2020-06-30 | 2020-09-30 | 2020-12-31 | 2021-03-31 | 2021-06-30 |
| QUALITY - 90 day | 98 | 98 | 97 | 91 | 69 |
| Backlog | 0 | 0 | 0 | 0 | 0 |
| Total | 98 | 98 | 97 | 91 | 69 |
| Non Backlog | 98 | 98 | 97 | 91 | 69 |
| BACKLOG | 0 | 0 | 0 | 0 | 0 |
| % in Backlog | 0% | 0% | 0% | 0% | 0% |

PERFORMANCE

NC: Review Completions by Class



NC: Screening Completions by Class



NC: Decision Documents by Class

| NC - SAFETY (90) | | | | | |
|-----------------------------|---------------------|---------------------|---------------------|---------------------|---------------------|
| DOCUMENT TYPE | Apr-Jun 2020 | Jul-Sep 2020 | Oct-Dec 2020 | Jan-Mar 2021 | Apr-Jun 2021 |
| NO OBJECTION LETTER | 26 | 2 | 0 | 0 | 0 |
| REJECTION LETTER (SCR) | 2 | 0 | 0 | 0 | 0 |
| CANCELLED BY COMPANY | 2 | 0 | 1 | 1 | 0 |
| SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |
| NOT SATISFACTORY NOTICE | 0 | 0 | 0 | 0 | 0 |
| NC - HOLD (PATENT) | 0 | 0 | 0 | 0 | 0 |

| NC - QUALITY (90) | | | | | |
|-----------------------------|---------------------|---------------------|---------------------|---------------------|---------------------|
| DOCUMENT TYPE | Apr-Jun 2020 | Jul-Sep 2020 | Oct-Dec 2020 | Jan-Mar 2021 | Apr-Jun 2021 |
| NO OBJECTION LETTER | 121 | 129 | 133 | 133 | 136 |
| NOT SATISFACTORY NOTICE | 0 | 0 | 0 | 0 | 0 |
| REJECTION LETTER (SCR) | 0 | 0 | 1 | 0 | 5 |
| SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |
| CANCELLED BY COMPANY | 4 | 3 | 12 | 4 | 1 |
| NC - HOLD (PATENT) | 0 | 0 | 0 | 0 | 0 |

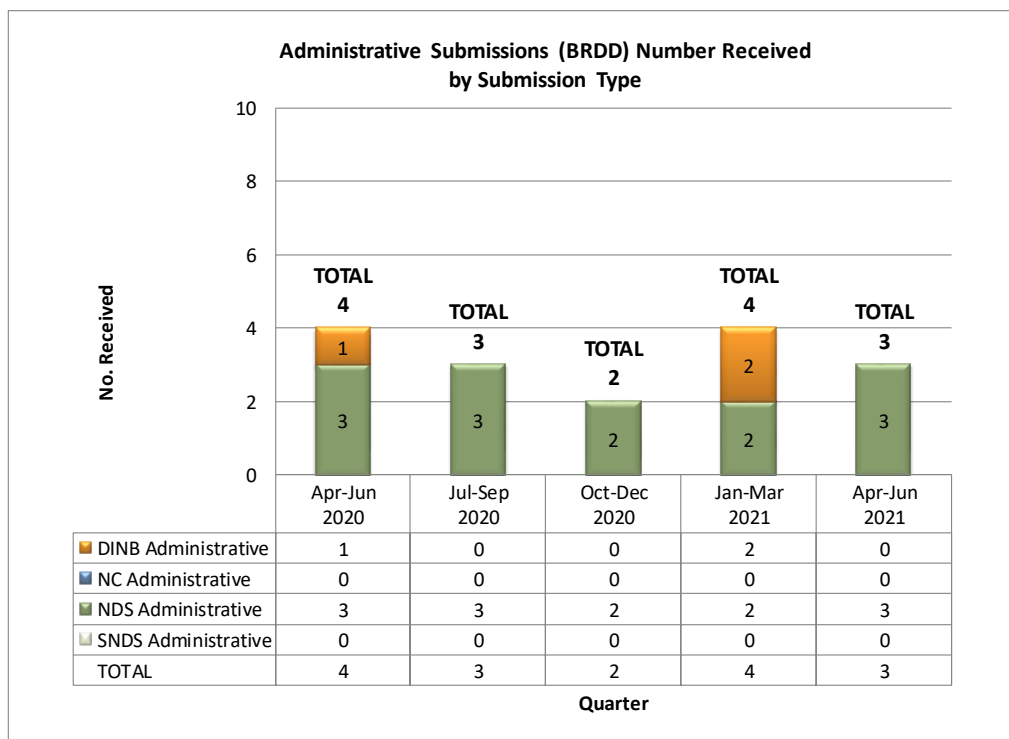
| NC - SAFETY (120) | | | | | |
|-----------------------------|---------------------|---------------------|---------------------|---------------------|---------------------|
| DOCUMENT TYPE | Apr-Jun 2020 | Jul-Sep 2020 | Oct-Dec 2020 | Jan-Mar 2021 | Apr-Jun 2021 |
| NO OBJECTION LETTER | 2 | 1 | 0 | 0 | 0 |
| NOT SATISFACTORY NOTICE | 0 | 0 | 0 | 0 | 0 |
| REJECTION LETTER (SCR) | 0 | 0 | 0 | 0 | 0 |
| SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |
| CANCELLED BY COMPANY | 0 | 0 | 0 | 0 | 0 |

| NC - ADMINISTRATIVE | | | | | |
|----------------------------|---------------------|---------------------|---------------------|---------------------|---------------------|
| DOCUMENT TYPE | Apr-Jun 2020 | Jul-Sep 2020 | Oct-Dec 2020 | Jan-Mar 2021 | Apr-Jun 2021 |
| NO OBJECTION LETTER | 0 | 0 | 0 | 0 | 0 |
| CANCELLED BY COMPANY | 0 | 0 | 0 | 0 | 0 |

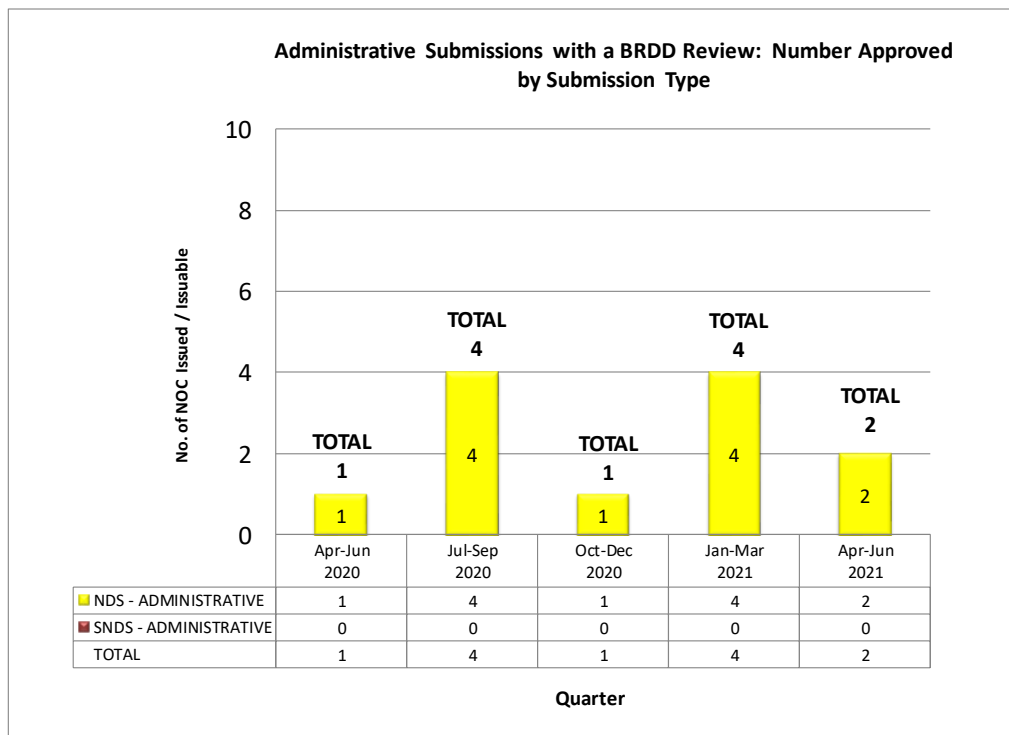
ADMINISTRATIVE SUBMISSIONS (Processed by BRDD)

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

Administrative Submissions (with BRDD Review): Number Received



Administrative Submissions (with BRDD Review): Number Approved

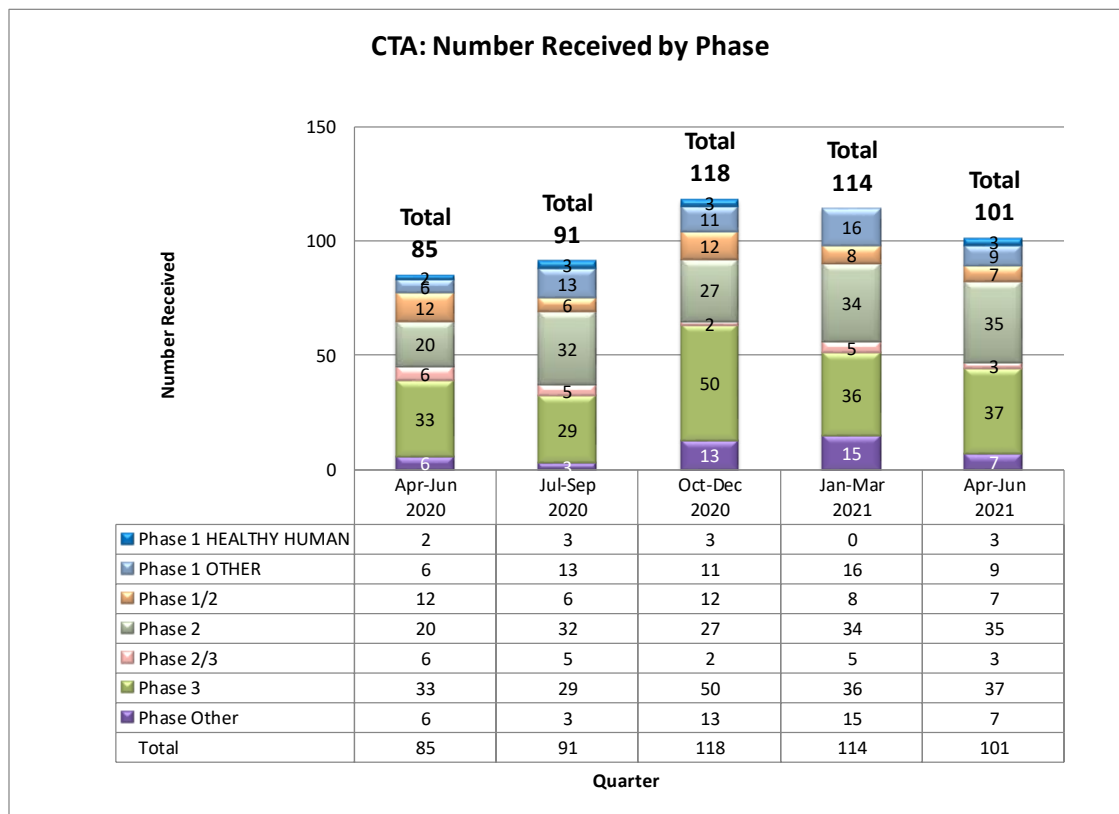


CLINICAL TRIAL APPLICATIONS AND AMENDMENTS

(CTA & CTA-A)

CLINICAL TRIAL APPLICATIONS (CTA)

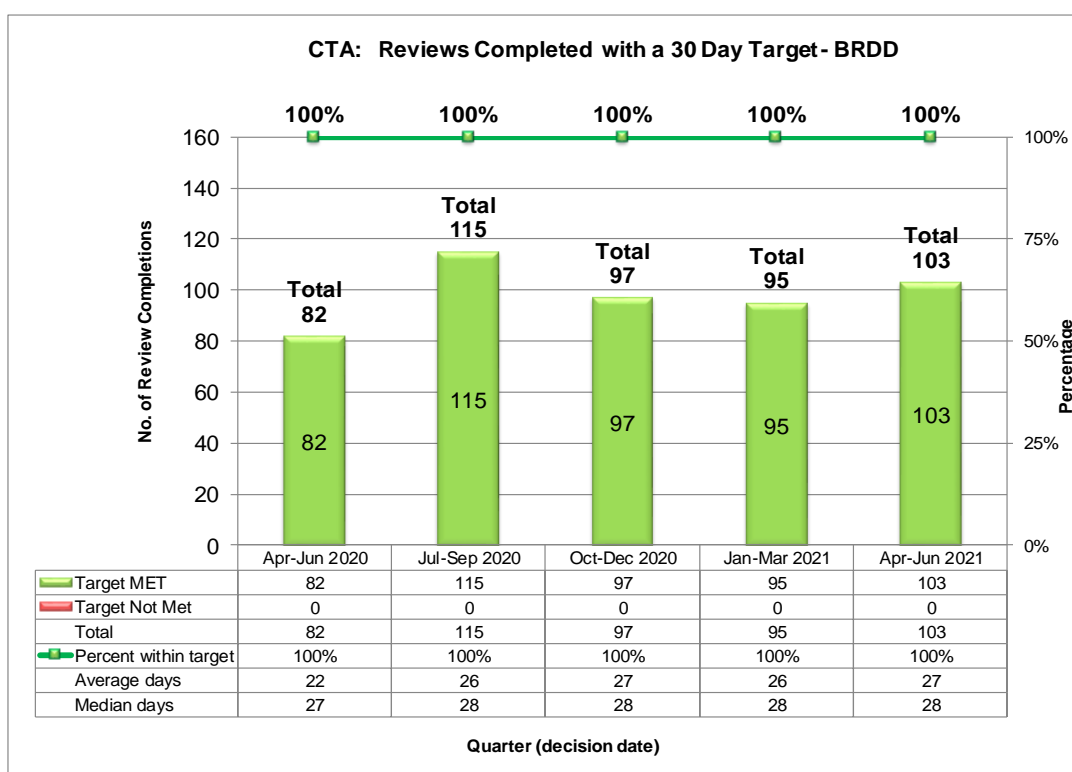
CTA: Number Received by Phase



CTA: Number of Decisions by Document Type

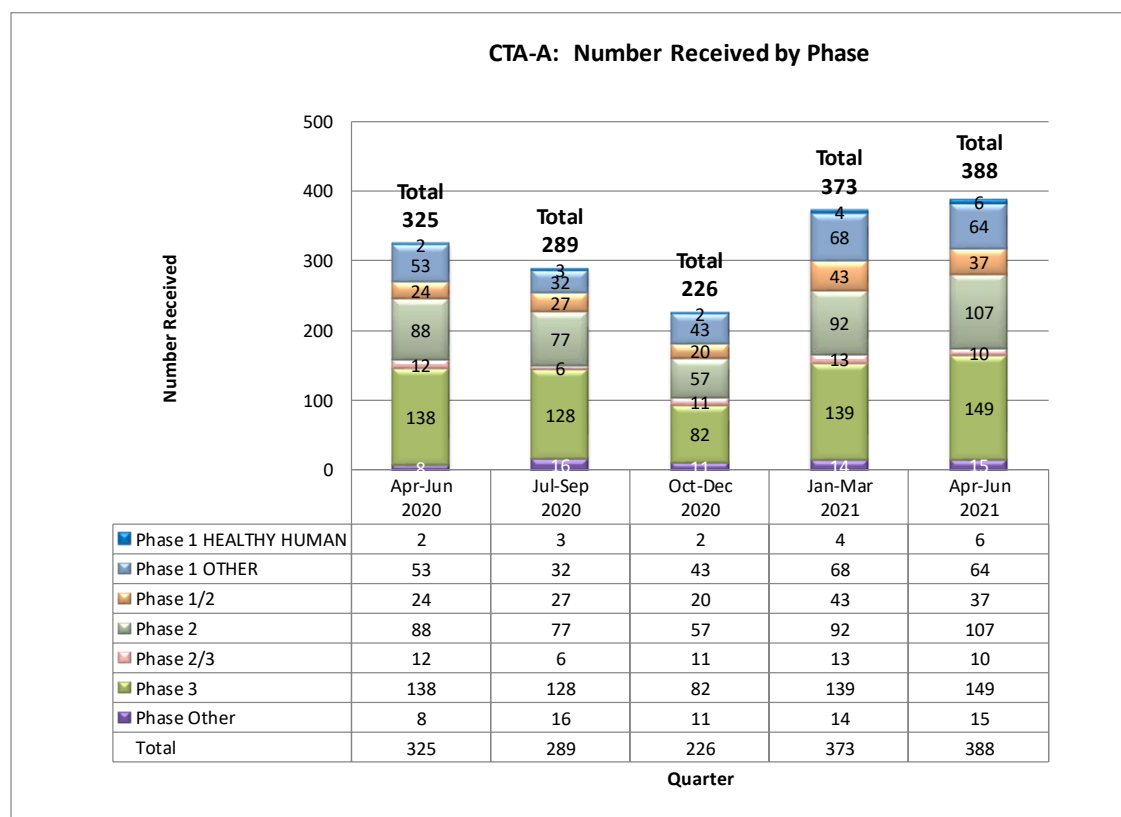
| CTA | | | | | |
|------------------------------------|--------------|--------------|--------------|--------------|--------------|
| DOCUMENT TYPE | Apr-Jun 2020 | Jul-Sep 2020 | Oct-Dec 2020 | Jan-Mar 2021 | Apr-Jun 2021 |
| NO OBJECTION LETTER | 76 | 77 | 115 | 85 | 100 |
| CANCELLED BY COMPANY DURING REVIEW | 4 | 3 | 7 | 7 | 3 |
| CANCELLED BY COMPANY AT PROCESSING | 2 | 0 | 2 | 2 | 1 |
| REJECTION LETTER (SCR) | 0 | 0 | 1 | 0 | 0 |
| NOT SATISFACTORY NOTICE | 0 | 0 | 0 | 0 | 0 |
| NOTICE OF AUTHORIZATION | 2 | 2 | 7 | 3 | 4 |
| NOTICE OF AUTHORIZA/ TC | 0 | 0 | 0 | 0 | 1 |

CTA: Review Completed with a 30 Day Target



CLINICAL TRIAL APPLICATION- AMENDMENTS (CTA-A)

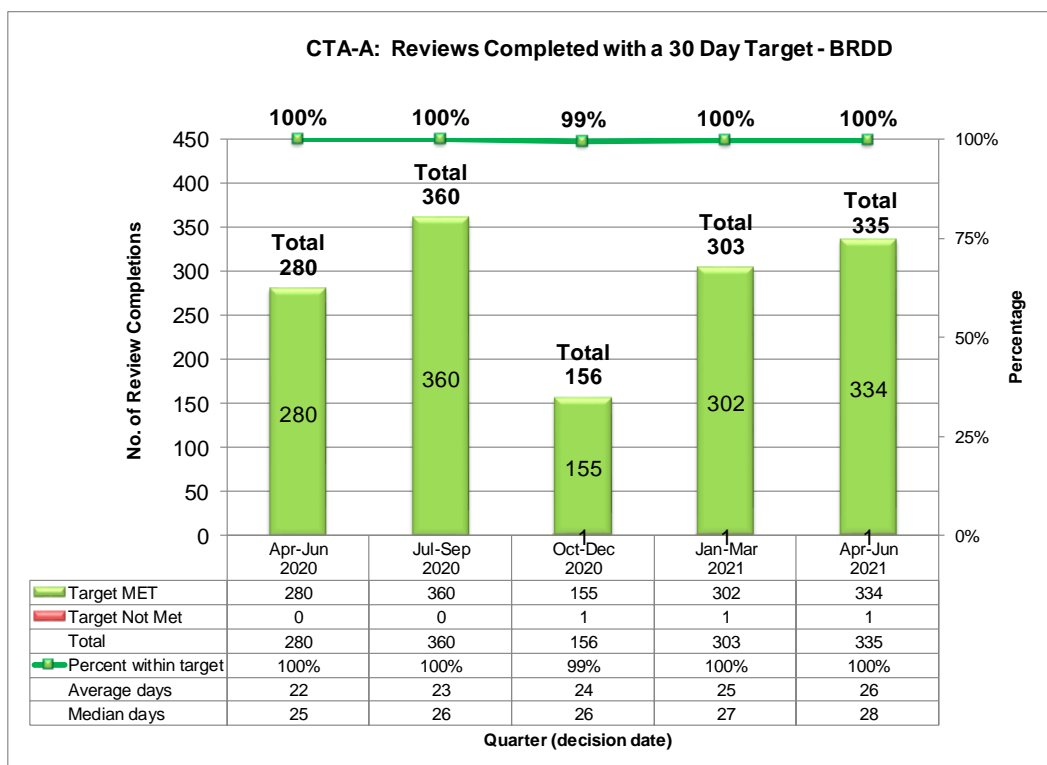
CTA-A: Number Received by Phase



CTA-A: Decisions by Type

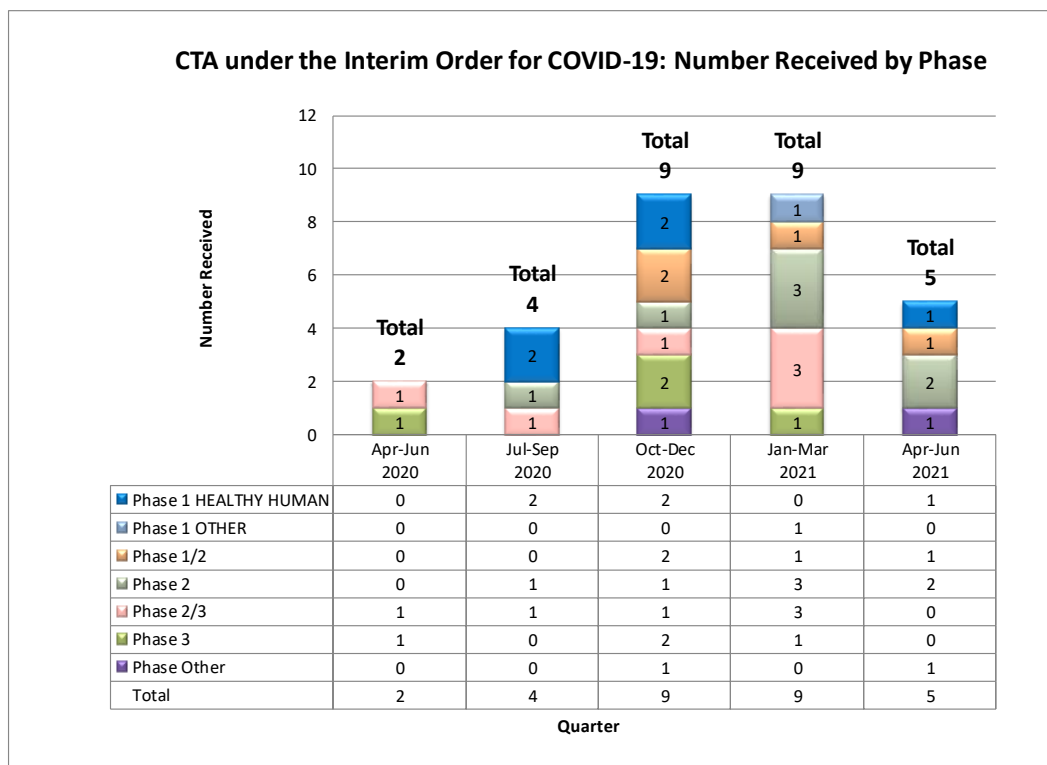
| CTA-A | | | | | |
|------------------------------------|--------------|--------------|--------------|--------------|--------------|
| DOCUMENT TYPE | Apr-Jun 2020 | Jul-Sep 2020 | Oct-Dec 2020 | Jan-Mar 2021 | Apr-Jun 2021 |
| NO OBJECTION LETTER | 310 | 261 | 250 | 294 | 351 |
| REJECTION LETTER (SCR) | 3 | 4 | 5 | 2 | 9 |
| CANCELLED BY COMPANY DURING REVIEW | 1 | 3 | 1 | 7 | 3 |
| CANCELLED BY COMPANY AT PROCESSING | 3 | 1 | 3 | 2 | 0 |
| NOTICE OF AUTHORIZATION | 0 | 0 | 4 | 10 | 14 |

CTA-A: Reviews Completed with a 30 Day Target

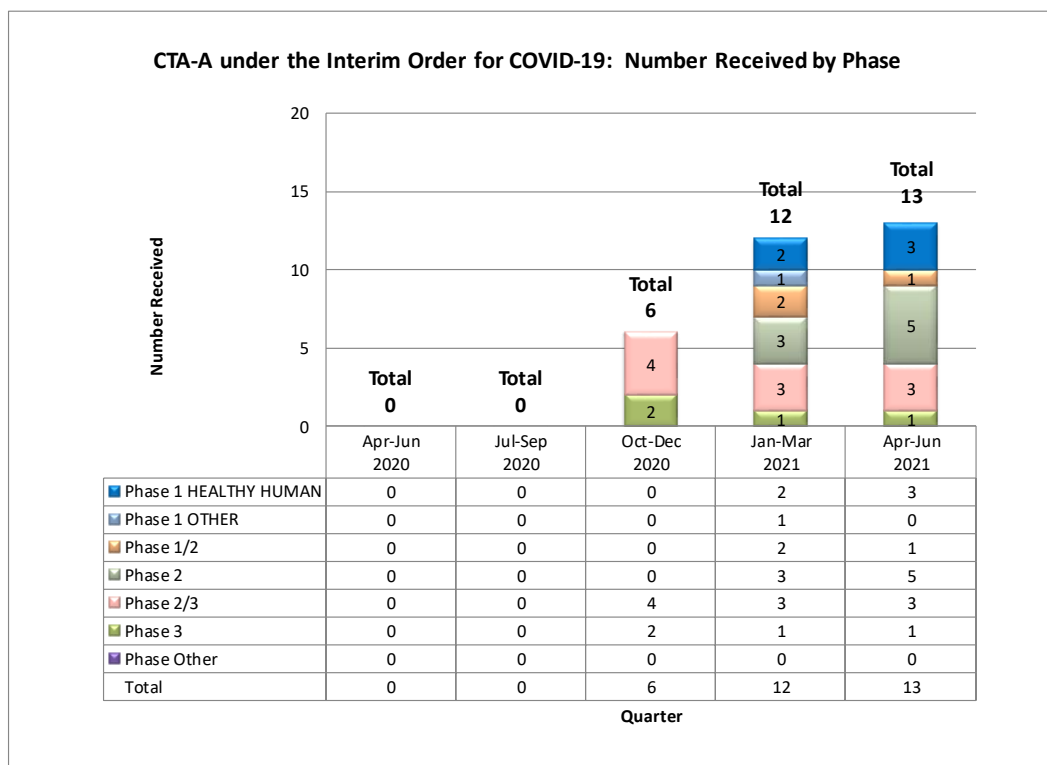


CTA & CTA-A RECEIVED UNDER THE INTERIM ORDER COVID-19

CTA: Number Received under the Interim Order Covid-19 by phase



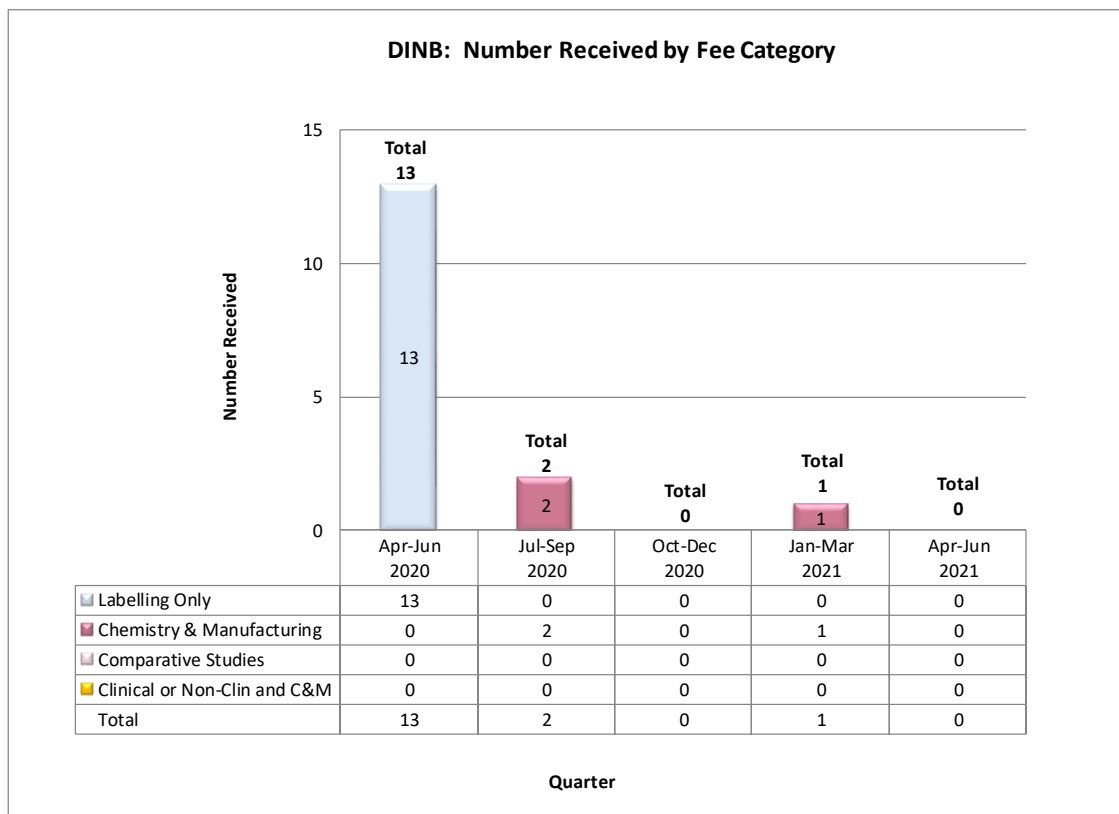
CTA-A: Number Received under the Interim Order Covid-19 by phase



These figures are a subset of the total CTA and CTA-A received.

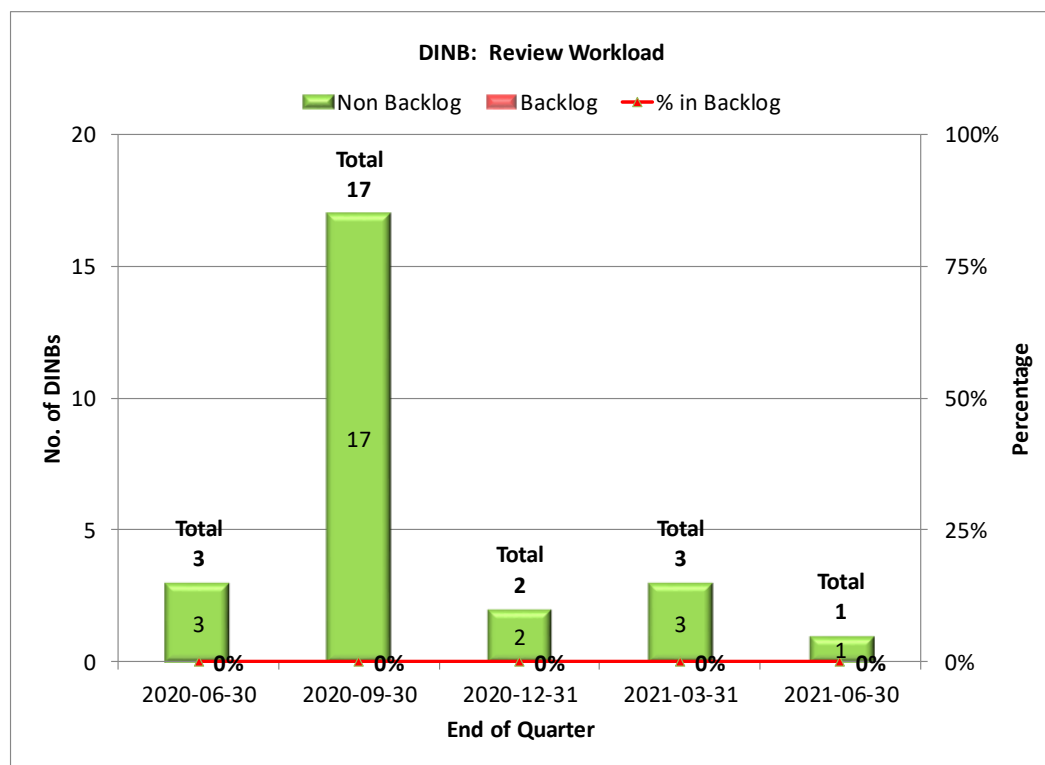
DINB: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - BIOLOGICAL PRODUCT

DINB: Number Received by Fee Category



REVIEW WORKLOAD

DINB: Review Workload

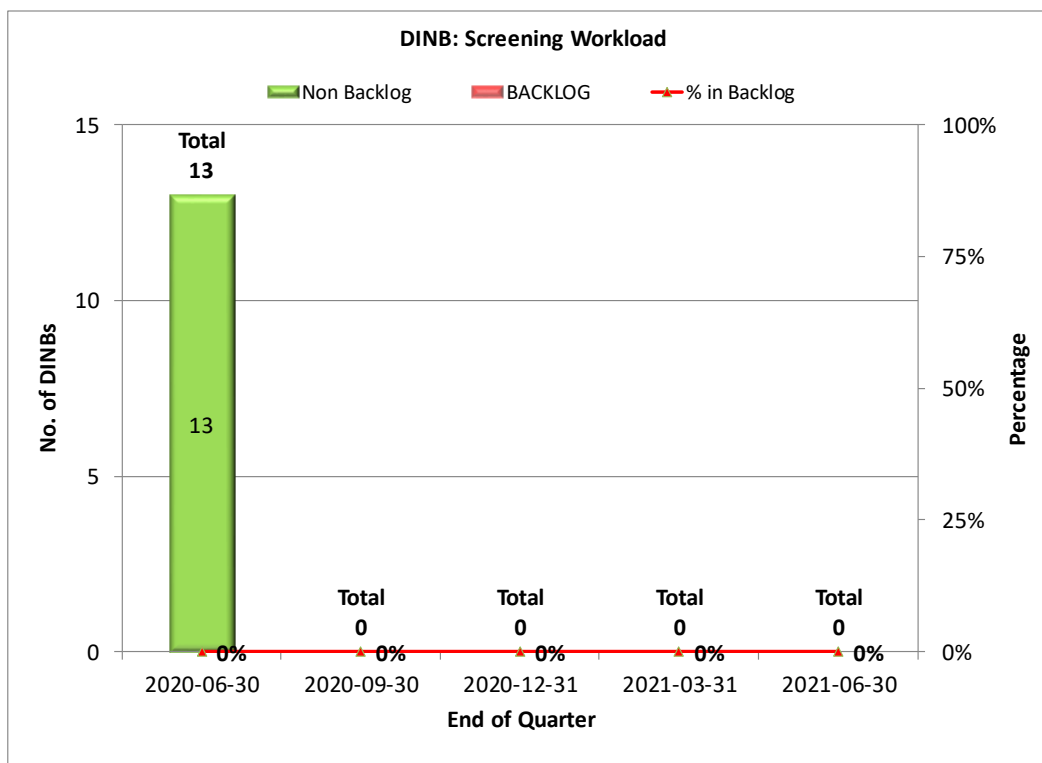


DINB: Review Workload by Fee Category

| DINB: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter | | | | | |
|--|------------|------------|------------|------------|------------|
| FEE Category | 2020-06-30 | 2020-09-30 | 2020-12-31 | 2021-03-31 | 2021-06-30 |
| Labelling Only | 2 | 15 | 0 | 1 | 0 |
| Backlog | 0 | 0 | 0 | 0 | 0 |
| Chemistry & Manufacturing | 1 | 2 | 2 | 2 | 1 |
| Backlog | 0 | 0 | 0 | 0 | 0 |
| Total | 3 | 17 | 2 | 3 | 1 |
| Non Backlog | 3 | 17 | 2 | 3 | 1 |
| 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 End of Quarter | | | | | |
|---|------------|------------|------------|------------|------------|
| FEE Category | 2020-06-30 | 2020-09-30 | 2020-12-31 | 2021-03-31 | 2021-06-30 |
| Labelling Only | 13 | 0 | 0 | 0 | 0 |
| Backlog | 0 | 0 | 0 | 0 | 0 |
| Clinical or Non-Clin and C&M | 0 | 0 | 0 | 0 | 0 |
| Backlog | 0 | 0 | 0 | 0 | 0 |
| Chemistry & Manufacturing | 0 | 0 | 0 | 0 | 0 |
| Backlog | 0 | 0 | 0 | 0 | 0 |
| Total | 13 | 0 | 0 | 0 | 0 |
| Non Backlog | 13 | 0 | 0 | 0 | 0 |
| BACKLOG | 0 | 0 | 0 | 0 | 0 |
| % in Backlog | 0% | 0% | 0% | 0% | 0% |

DECISIONS

DINB: Number of Decisions by Fee Category

| DINB - LABELLING ONLY | | | | | |
|-----------------------------|--------------|--------------|--------------|--------------|--------------|
| DOCUMENT TYPE | Apr-Jun 2020 | Jul-Sep 2020 | Oct-Dec 2020 | Jan-Mar 2021 | Apr-Jun 2021 |
| DINB APPROVAL LETTER | 3 | 0 | 11 | 1 | 2 |
| SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |
| CANCELLED BY COMPANY | 0 | 0 | 2 | 0 | 0 |
| NOTICE OF DEFICIENCY | 0 | 0 | 2 | 0 | 0 |

| DINB - CLINICAL OR NON CLINICAL DATA AND C&M | | | | | |
|--|--------------|--------------|--------------|--------------|--------------|
| DOCUMENT TYPE | Apr-Jun 2020 | Jul-Sep 2020 | Oct-Dec 2020 | Jan-Mar 2021 | Apr-Jun 2021 |
| SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |
| CANCELLED BY COMPANY | 0 | 0 | 0 | 0 | 0 |

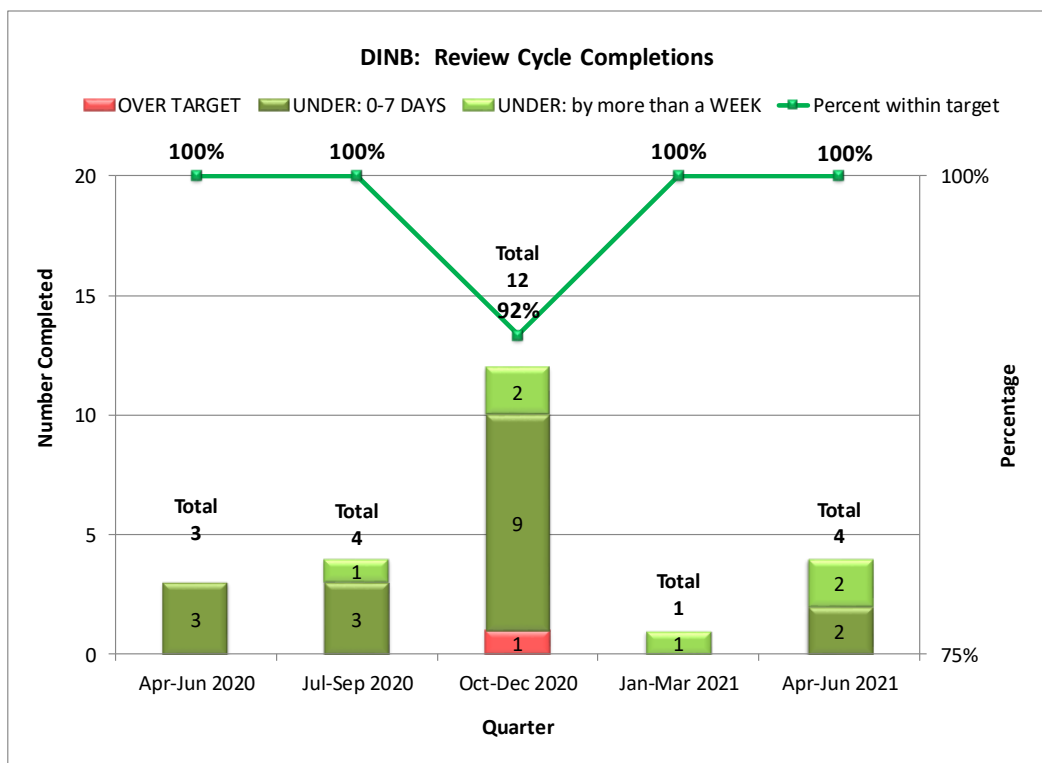
| DINB - CHEMISTRY & MANUFACTURING | | | | | |
|----------------------------------|--------------|--------------|--------------|--------------|--------------|
| DOCUMENT TYPE | Apr-Jun 2020 | Jul-Sep 2020 | Oct-Dec 2020 | Jan-Mar 2021 | Apr-Jun 2021 |
| DINB APPROVAL LETTER | 0 | 1 | 0 | 0 | 2 |
| SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |
| NOTICE OF DEFICIENCY | 0 | 0 | 0 | 0 | 0 |
| NOTIFICATION FORM/DIN ISSUED | 0 | 0 | 0 | 0 | 0 |
| CANCELLED BY COMPANY | 0 | 0 | 0 | 0 | 0 |

| DINB - COMPARATIVE STUDIES | | | | | |
|-----------------------------|--------------|--------------|--------------|--------------|--------------|
| DOCUMENT TYPE | Apr-Jun 2020 | Jul-Sep 2020 | Oct-Dec 2020 | Jan-Mar 2021 | Apr-Jun 2021 |
| SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |
| REJECTION LETTER (SCR) | 0 | 0 | 0 | 0 | 0 |

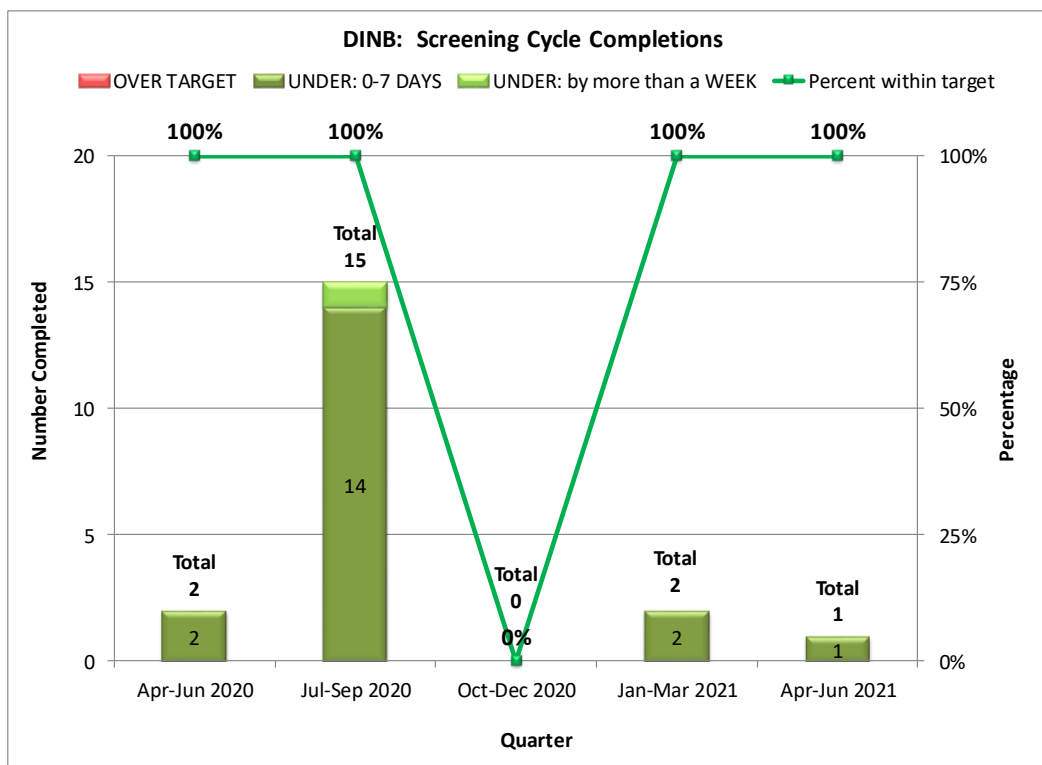
| DINB - Administrative | | | | | |
|-----------------------|--------------|--------------|--------------|--------------|--------------|
| DOCUMENT TYPE | Apr-Jun 2020 | Jul-Sep 2020 | Oct-Dec 2020 | Jan-Mar 2021 | Apr-Jun 2021 |
| DINB APPROVAL LETTER | 0 | 1 | 0 | 2 | 0 |
| CANCELLED BY COMPANY | 0 | 0 | 0 | 0 | 0 |

PERFORMANCE

DINB: Review Cycle Completions

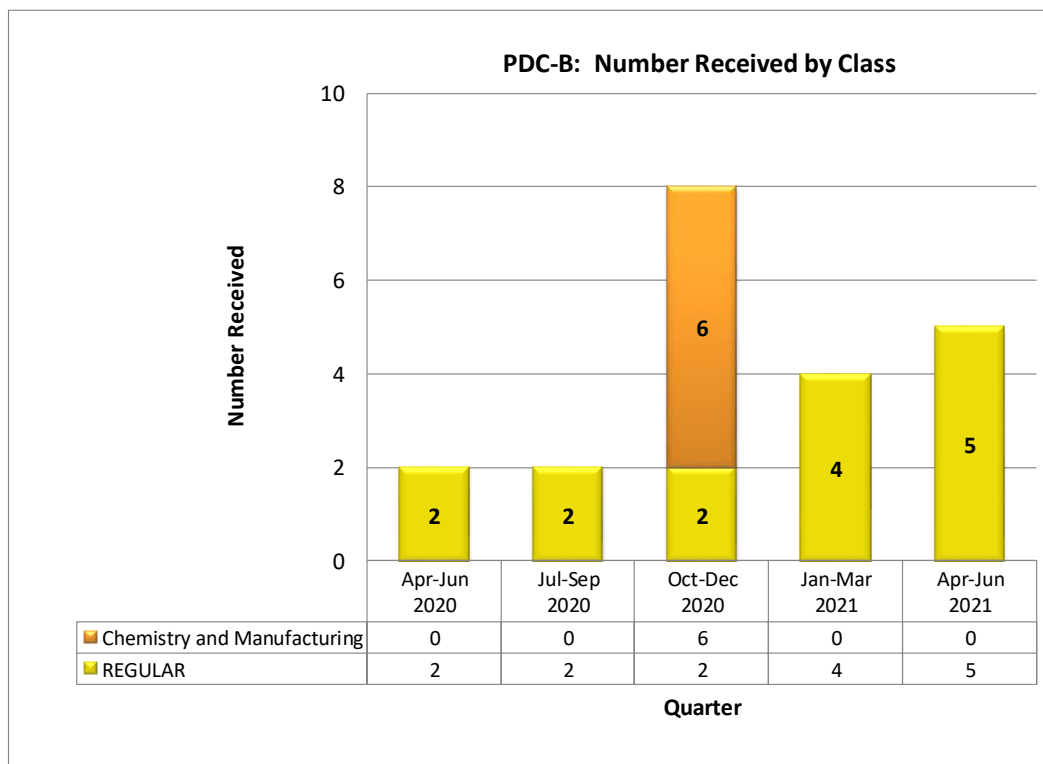


DINB: Screening Cycle Completions



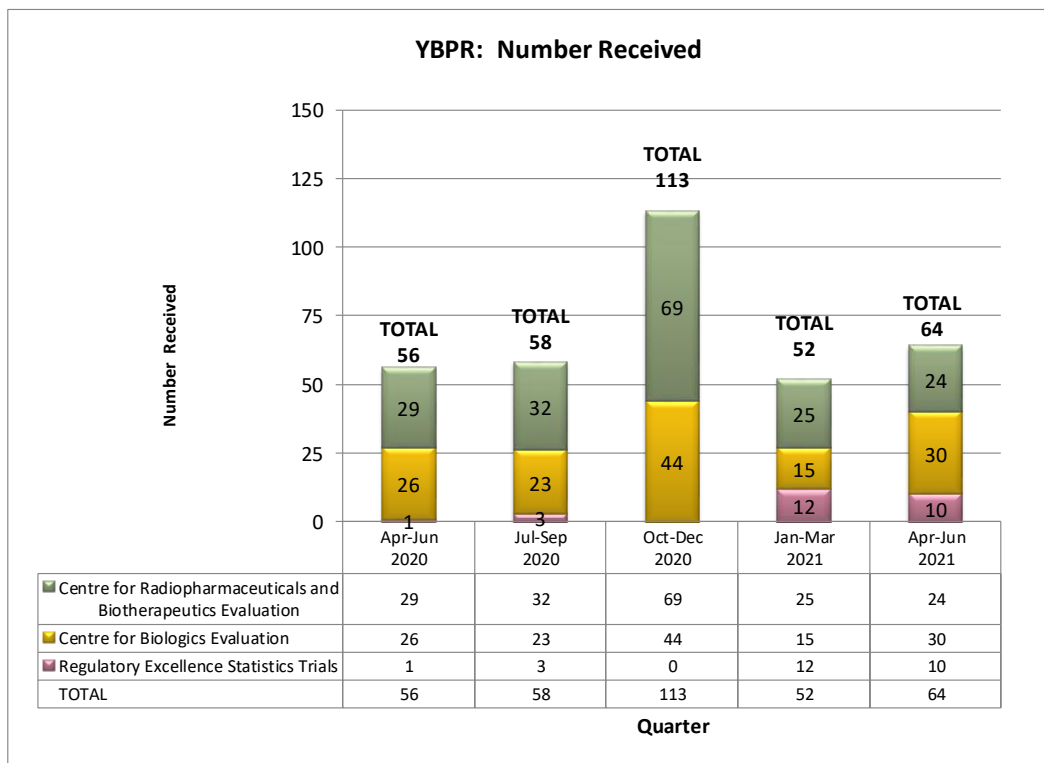
POST-AUTHORIZATION DIVISION 1 CHANGE FOR A BIOLOGIC DRUG PRODUCT (PDC-B)

PDC-B: Number Received



YEARLY BIOLOGIC PRODUCT REPORTS (YBPR) ⁹

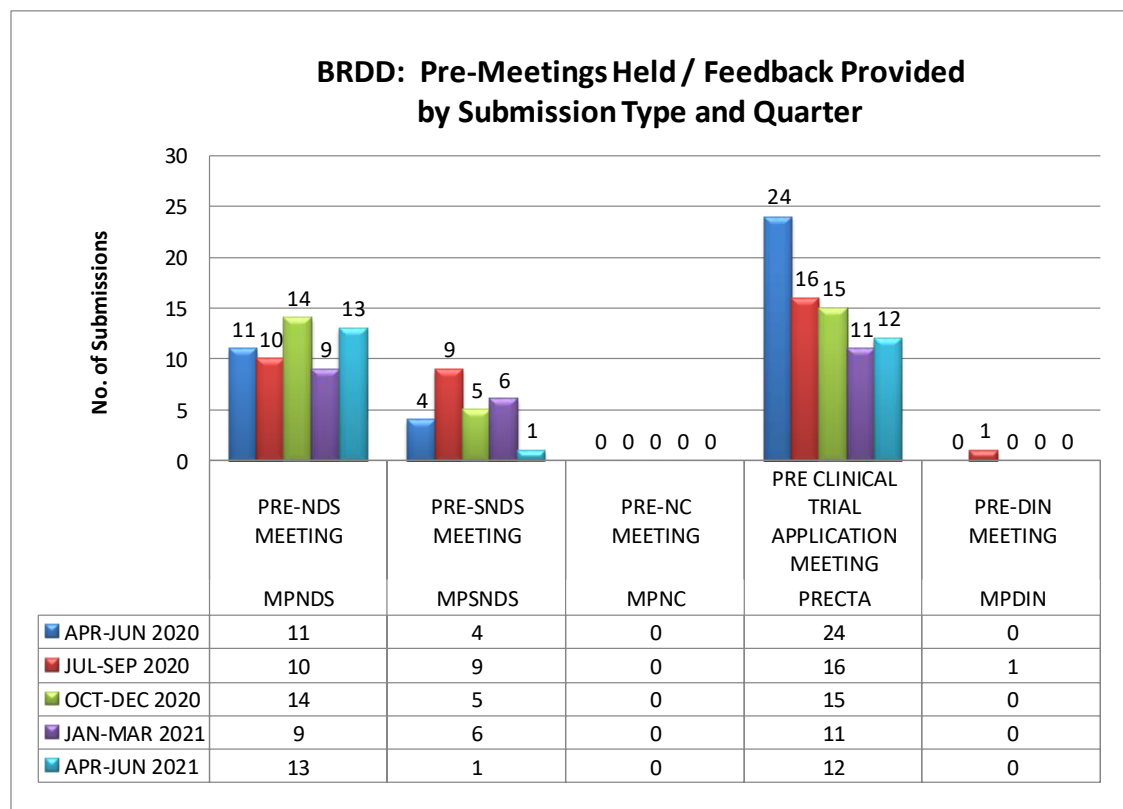
YBPR: Number Received



⁹ 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 ¹⁰

Pre-submission Meetings Held / Feedback Provided



¹⁰ 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](#).