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# Biologic and Radiopharmaceutical Drugs Directorate

Drug Submission Performance Quarterly  
Report

January - March

2022



**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 trimestriel du rendement des présentations de drogue - janvier - mars 2022

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Publication date: June 2022

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Cat H162-5E-PDF  
ISSN 2563-6723  
Pub 220116

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# 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 January - March 2021 to January - March 2022. 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](#).<sup>1</sup> This method is more efficient than sending transactions on physical media by courier and is mandatory as of October 1, 2020.
- The [Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19](#) was repealed and replaced on February 27, 2022 by the [Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations](#) to allow sponsors to continue conducting clinical trials authorized under the interim order and ensure all authorizations, suspensions and exemptions for clinical trials issued under the interim order will remain in effect. The number of CTA and CTA-As received under the interim order and transition regulations 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.

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

- 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, safety updates to the labelling materials for a new drug are now submitted as an SNDS or SANDS (and not as a Notifiable Change) for submissions based only on clinical or non-clinical data.
- 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/drug-products/applications-submissions/guidance-documents/food-drug-regulations-amendments-covid-19.html>.



## General Information

There are several steps involved in the drug submission review<sup>2</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>3</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.

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

A **review cycle completion**<sup>4</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 to complete a cycle (excluding any pause days<sup>5</sup>) 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.](#)

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

<sup>3</sup> 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 \(NOC/c\)](#).

<sup>4</sup> 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.

<sup>5</sup> 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"<sup>6</sup> 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:

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<sup>6</sup> 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-CV	- New Drug Submission - for Designated COVID-19 Drugs
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
<b>New active substance</b>	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
<b>Clinical or non-clinical data and chemistry and manufacturing data</b>	Submissions based on clinical or non-clinical data and chemistry and manufacturing data for a drug that does not include a new active substance
<b>Clinical or nonclinical data only</b>	Submissions based only on clinical or non-clinical data for a drug that does not include a new active substance
<b>Comparative studies</b>	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
<b>Chemistry and manufacturing data only</b>	Submissions based only on chemistry and manufacturing data for a drug that does not include a new active substance
<b>Clinical or nonclinical data only, in support of safety updates to the labelling</b>	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
<b>Switch status from prescription drug to non-prescription drug</b>	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
<b>Labelling only</b>	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
<b>Labelling only (generic drugs)</b>	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
<b>Administrative submission</b>	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)
<b>Disinfectant – full review</b>	Submissions, other than those described in item 12, that include data in support of a disinfectant
<b>Labelling only (disinfectants)</b>	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
<b>Drug identification number application - labelling standards</b>	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
<b>Published data only</b>	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)**

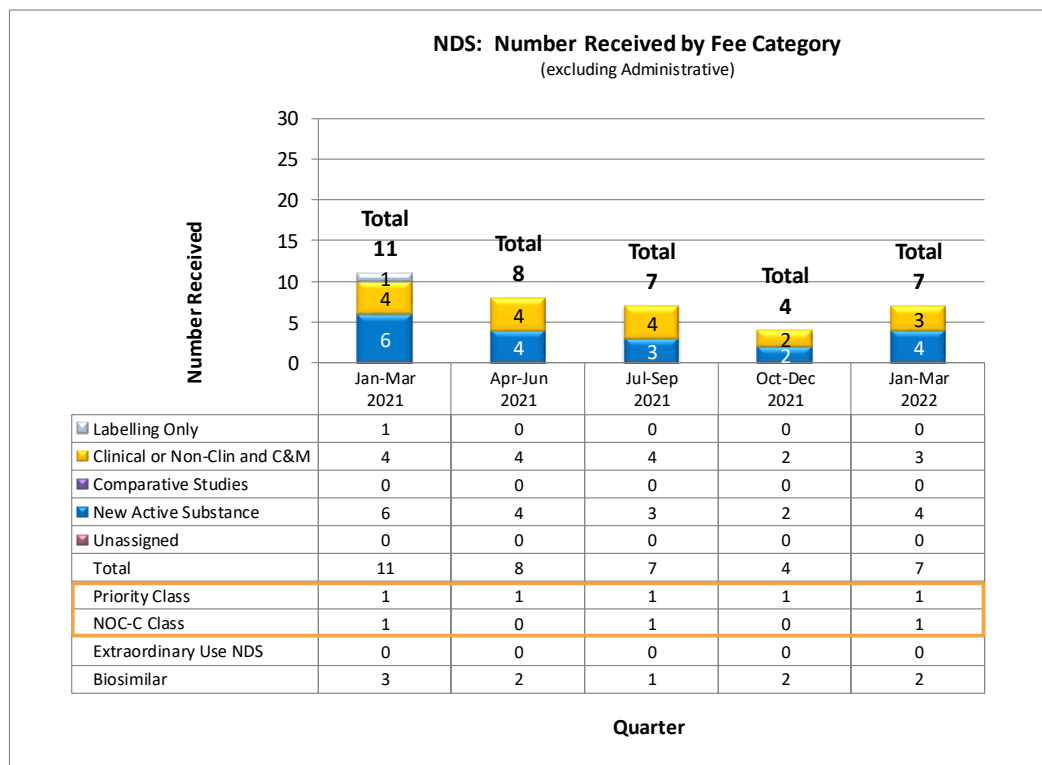
**&**

**Supplemental New Drug Submissions  
(SNDS)**

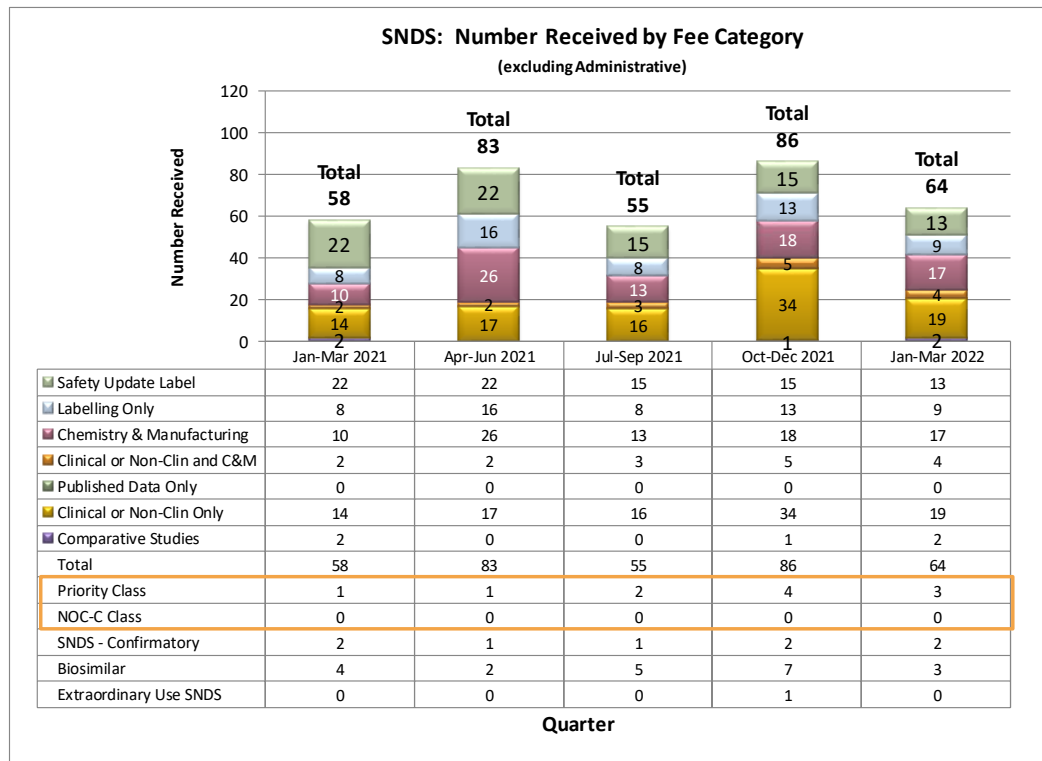


## SUBMISSIONS RECEIVED <sup>7</sup>

### NDS: Received by Fee Category



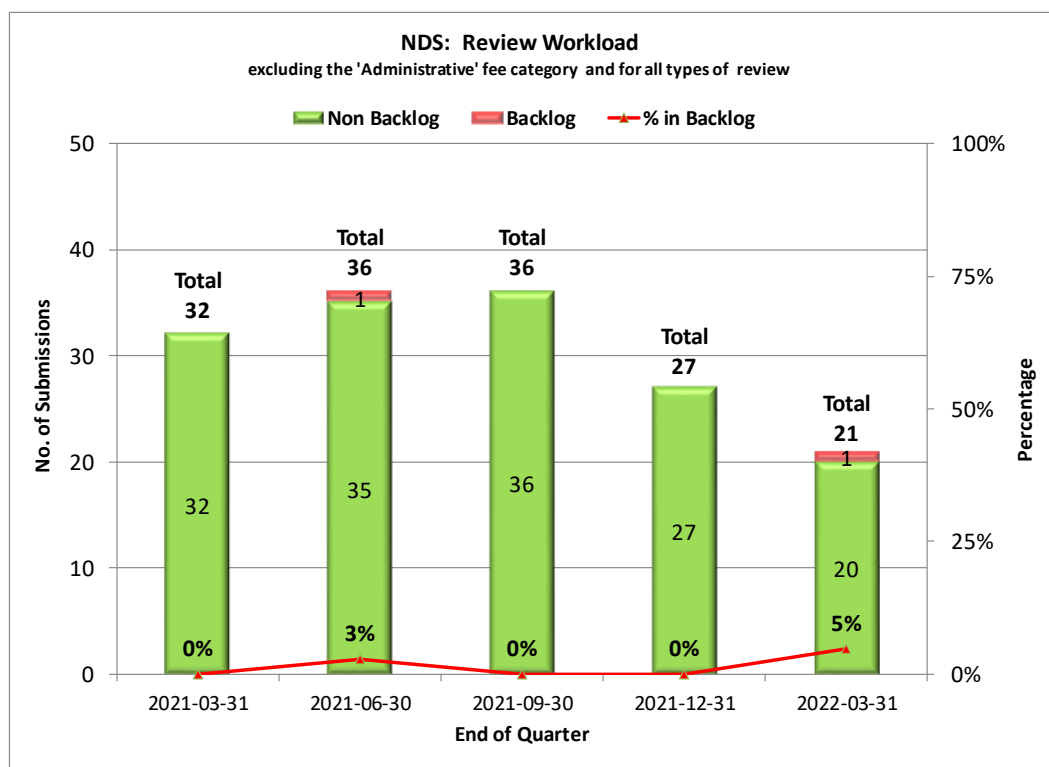
### SNDS: Received by Fee Category



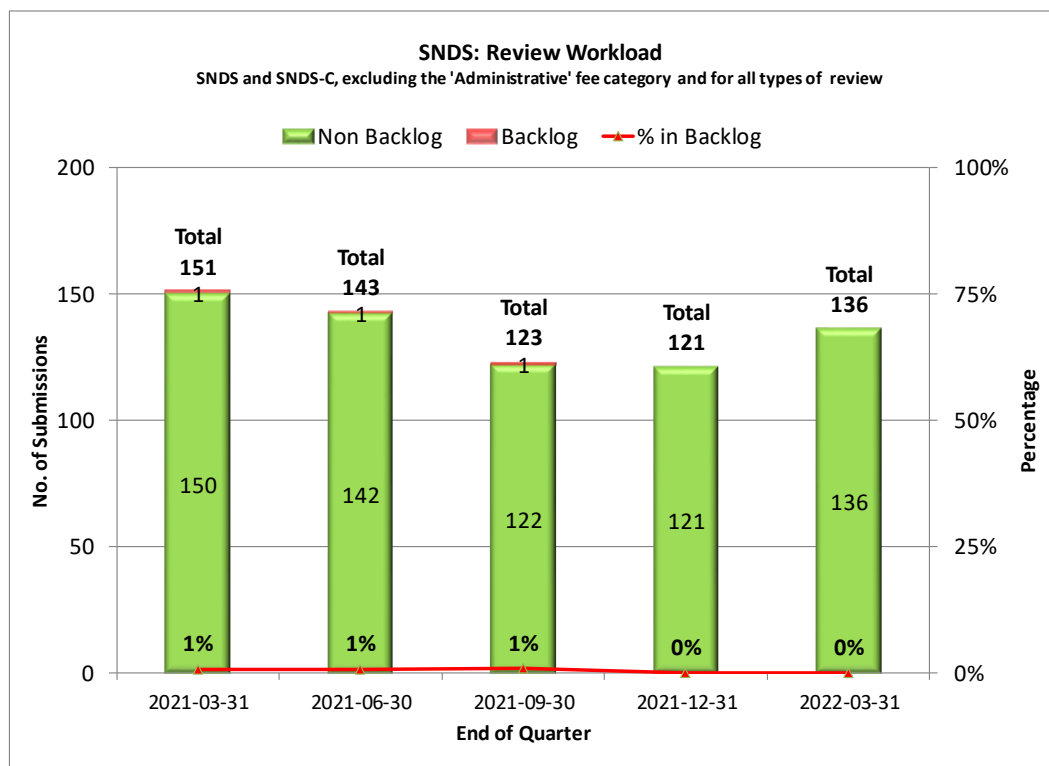
<sup>7</sup> Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the [Priority Review of Drug Submissions Policy](#), the [Notice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

## WORKLOAD

### NDS: Review Workload



### SNDS: Review Workload



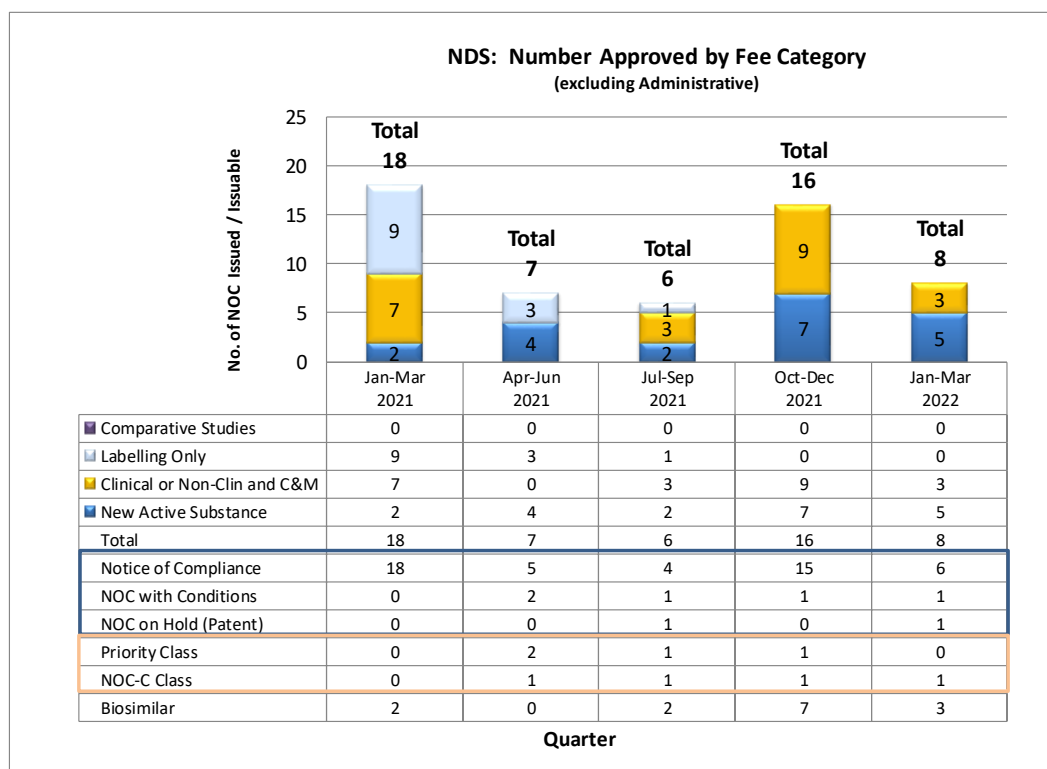
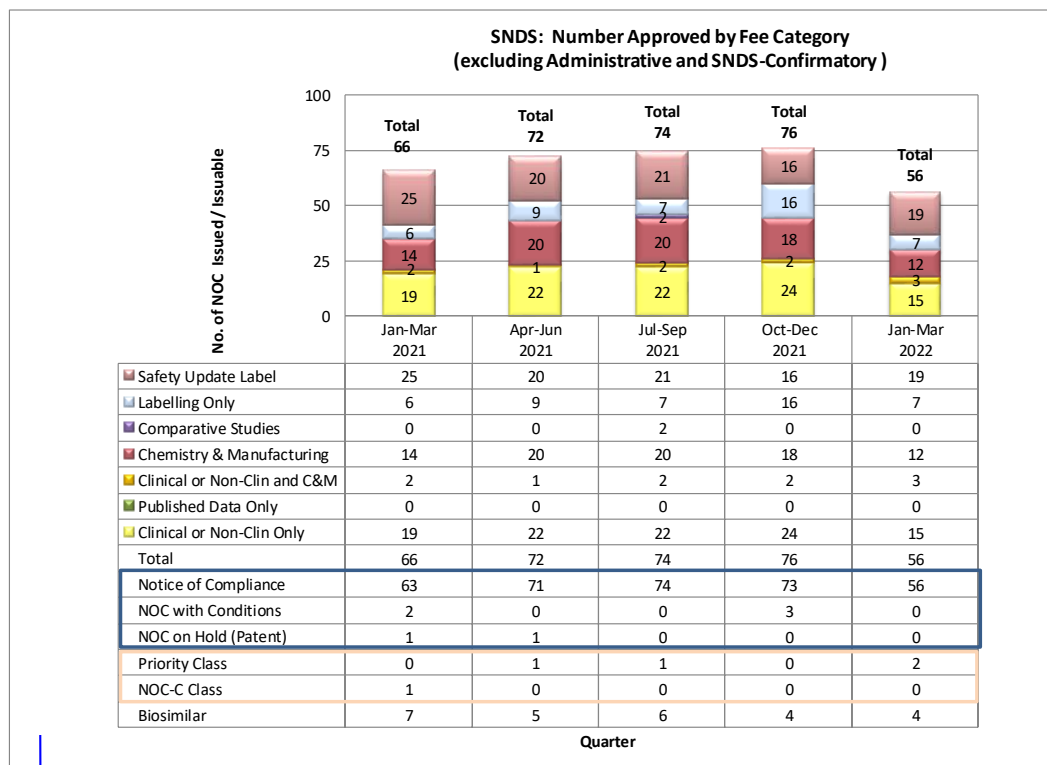
## WORKLOAD

### NDS: Review Workload by Fee Category

NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2021-03-31	2021-06-30	2021-09-30	2021-12-31	2022-03-31
Clinical or Non-Clin and C&M	14	17	19	13	10
Backlog	0	0	0	0	1
New Active Substance	14	18	17	14	11
Backlog	0	1	0	0	0
Labelling Only	4	1	0	0	0
Backlog	0	0	0	0	0
Total	32	36	36	27	21
Non Backlog	32	35	36	27	20
Backlog	0	1	0	0	1
% in Backlog	0%	3%	0%	0%	5%
Priority (subset)	3	2	2	2	3
Backlog	0	0	0	0	1

### SNDS: Review Workload by Fee Category

SNDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2021-03-31	2021-06-30	2021-09-30	2021-12-31	2022-03-31
Comparative Studies	2	2	0	0	2
Backlog	0	0	0	0	0
Chemistry & Manufacturing	31	30	25	26	31
Backlog	0	0	0	0	0
Clinical or Non-Clin Only	75	65	57	53	64
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	5	7	5	10	7
Backlog	0	0	0	0	0
Published Data	0	0	0	0	0
Backlog	0	0	0	0	0
Labelling Only	13	12	17	13	14
Backlog	0	0	0	0	0
Safety Update Label	25	27	19	19	18
Backlog	1	1	1	0	0
Total	151	143	123	121	136
Non Backlog	150	142	122	121	136
Backlog	1	1	1	0	0
% in Backlog	1%	1%	1%	0%	0%
Priority (subset)	2	1	2	4	6
Backlog	0	0	0	0	0
SNDS-C (Confirmatory)	5	7	6	3	5
Backlog	0	0	0	0	0

**APPROVALS <sup>8</sup>****NDS: Number Approved by Fee Category and NOC Type****SNDS: Number Approved by Fee Category and NOC Type**

<sup>8</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 Guidance](#).

# BIOSIMILARS: NDS & SNDS Market Authorizations

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

Submission Type	Class	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021	Jan-Mar 2022
NDS	CLIN/C&M	3	0	1	7	3
<b>NDS Total</b>		<b>3</b>	<b>0</b>	<b>1</b>	<b>7</b>	<b>3</b>
SNDS	C&M ONLY	4	2	2	2	1
	C&M/LABELLING	0	0	1	1	0
	CLIN ONLY	1	4	2	1	0
	CLIN/C&M	1	0	0	0	0
	COMP/C&M	0	0	0	0	0
	LABELLING ONLY	0	0	1	0	0
	SAFETY UPDATE LABEL	1	1	0	0	3
<b>SNDS Total</b>		<b>7</b>	<b>7</b>	<b>6</b>	<b>4</b>	<b>4</b>

### 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
ABEVMY	CLIN/C&M	BGP PHARMA ULC	BEVACIZUMAB	Q3	2021-Nov-5
AYBINTIO	CLIN/C&M	SAMSUNG BIOEPIS CO., LTD	BEVACIZUMAB	Q3	2021-Nov-30
AYBINTIO	CLIN/C&M	SAMSUNG BIOEPIS CO., LTD	BEVACIZUMAB	Q3	2021-Nov-30
BAMBEVI	CLIN/C&M	APOTEX INC.	BEVACIZUMAB	Q2	2021-Sep-23
BYOOVIZ	CLIN/C&M	SAMSUNG BIOEPIS CO., LTD	RANIBIZUMAB	Q4	2022-Mar-8
IXIFI	CLIN/C&M	PFIZER CANADA ULC	INFLIXIMAB	Q3	2021-Dec-21
KIRSTY	CLIN/C&M	BGP PHARMA ULC	INSULIN ASPART	Q3	2021-Oct-12
NYPOZI	CLIN/C&M	TANVEX BIOPHARMA USA, INC	FILGRASTIM (R-METHUG-CSF)	Q3	2021-Oct-8
ONTRUZANT	CLIN/C&M	SAMSUNG BIOEPIS CO., LTD	TRASTUZUMAB	Q4	2022-Jan-28
SIMLANDI	CLIN/C&M	JAMP PHARMA CORPORATION	ADALIMUMAB	Q4	2022-Jan-5
YUFLYMA	CLIN/C&M	CELLTRION HEALTHCARE CO LTD	ADALIMUMAB	Q3	2021-Dec-24
New Drug Submission Total					11

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

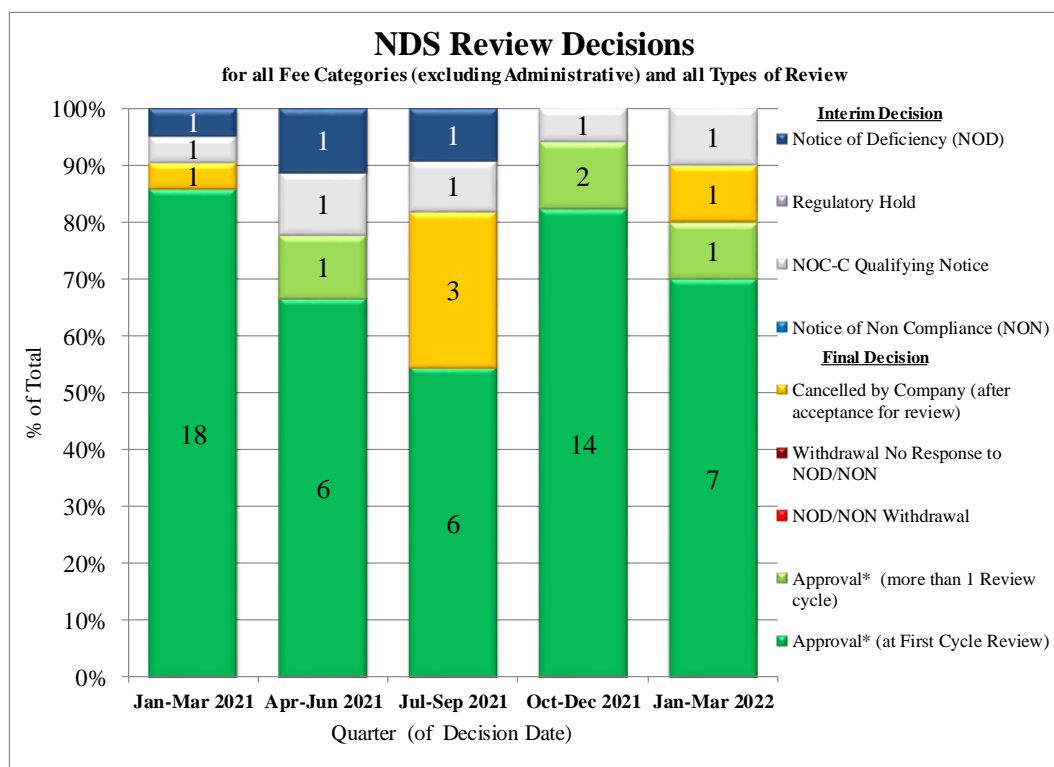
Brand Name	Class	Company	Active Ingredient(s)	Quarter FY 2021-22	Notice of Compliance (NOC) Date
AVSOLA	C&M ONLY	AMGEN CANADA INC	INFLIXIMAB	Q3	2021-Oct-27
BRENZYS	SAFETY UPDATE LABEL	SAMSUNG BIOEPIS CO., LTD	ETANERCEPT	Q4	2022-Mar-17
ERELZI	C&M ONLY	SANDOZ CANADA INCORPORATED	ETANERCEPT	Q1	2021-Jun-24
GRASTOFIL	CLIN ONLY	APOTEX INC.	FILGRASTIM (R-METHUG-CSF)	Q2	2021-Sep-29
FILGRASTIM (R-METHUG-CSF)	C&M ONLY	SAMSUNG BIOEPIS CO., LTD	ADALIMUMAB	Q2	2021-Aug-4
HERZUMA	CLIN ONLY	CELLTRION HEALTHCARE CO LTD	TRASTUZUMAB	Q1	2021-Apr-16
HULIO	C&M ONLY	BGP PHARMA ULC	ADALIMUMAB	Q1	2021-May-14
HYRIMOZ	CLIN ONLY	SANDOZ CANADA INCORPORATED	ADALIMUMAB	Q2	2021-Sep-10
KANJINTI	CLIN ONLY	AMGEN CANADA INC	TRASTUZUMAB	Q1	2021-Apr-14
KANJINTI	LABELLING ONLY	AMGEN CANADA INC	ABP 980	Q2	2021-Jul-20
KANJINTI	C&M/LABELLING	AMGEN CANADA INC	ABP 980, TRASTUZUMAB	Q2	2021-Aug-4
LAPELGA	C&M/LABELLING	APOTEX INC.	PEGFILGRASTIM	Q3	2021-Dec-24
NYVEPRIA	C&M ONLY	PFIZER CANADA ULC	PEGFILGRASTIM	Q3	2021-Nov-9
NYVEPRIA	SAFETY UPDATE LABEL	PFIZER CANADA ULC	PEGFILGRASTIM	Q4	2022-Feb-14
OGIVRI	CLIN ONLY	BGP PHARMA ULC	TRASTUZUMAB	Q3	2021-Dec-6
OMNITROPE	C&M ONLY	SANDOZ CANADA INCORPORATED	SOMATROPIN	Q2	2021-Aug-11
OSNUVO	SAFETY UPDATE LABEL	AVIR PHARMA INC.	TERIPARATIDE	Q4	2022-Mar-14
REDESCA, REDESCA HP	C&M ONLY	SHENZHEN TECHDOW PHARMACEUTICAL CO LTD	ENOXAPARIN SODIUM	Q4	2022-Feb-22
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	21

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

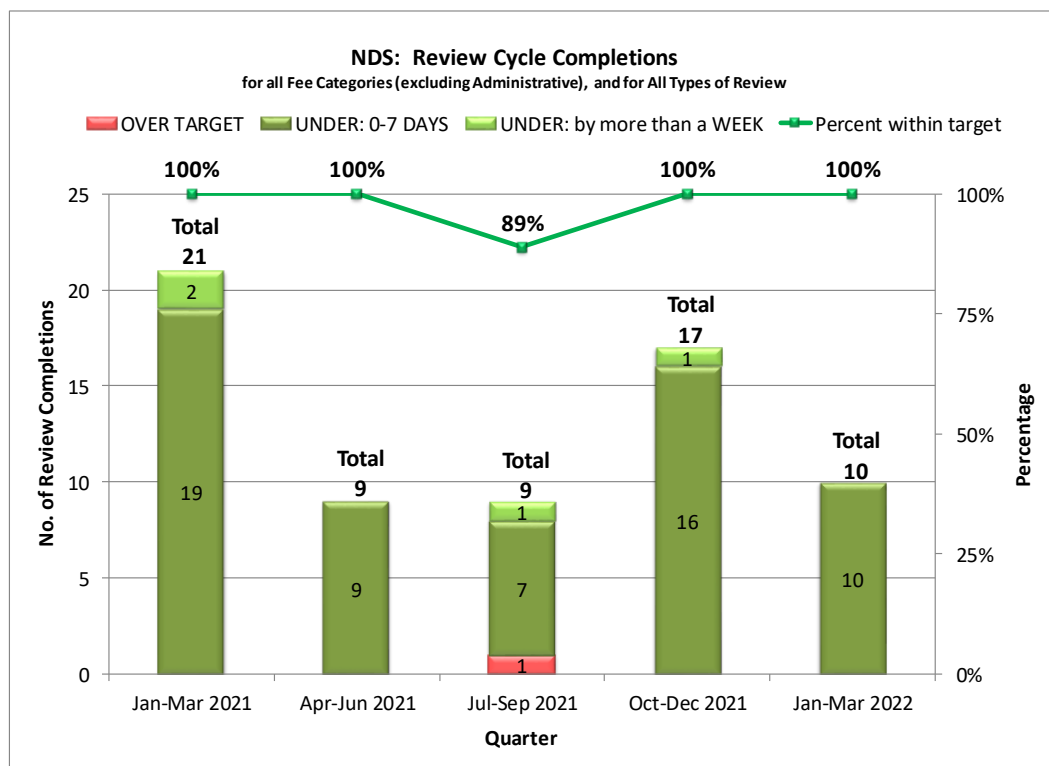
**Biosimilar:** A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration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



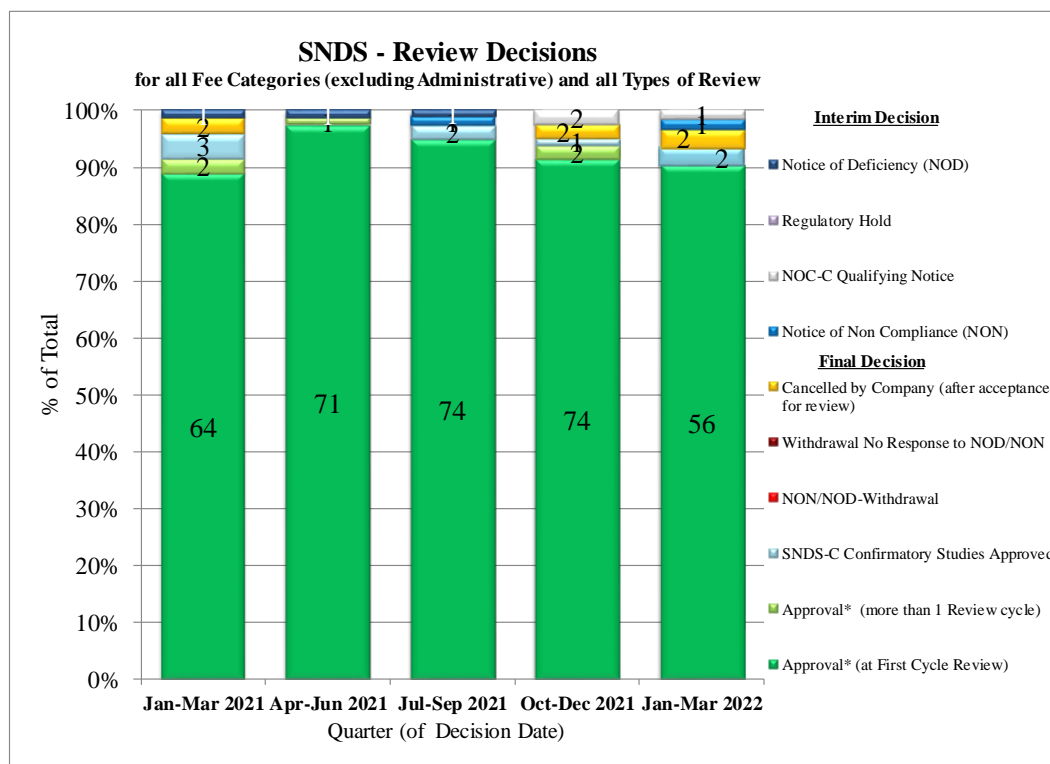
### NDS: Review Cycle Completions



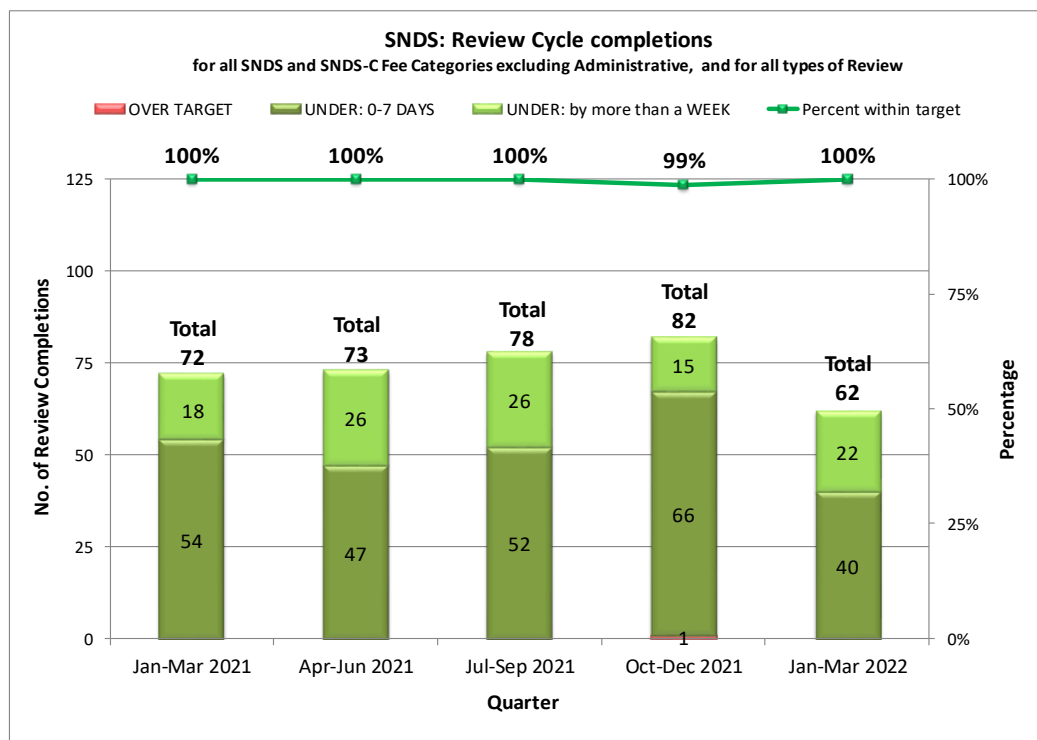


## REVIEW PERFORMANCE

### SNDS: Review Decisions by Type

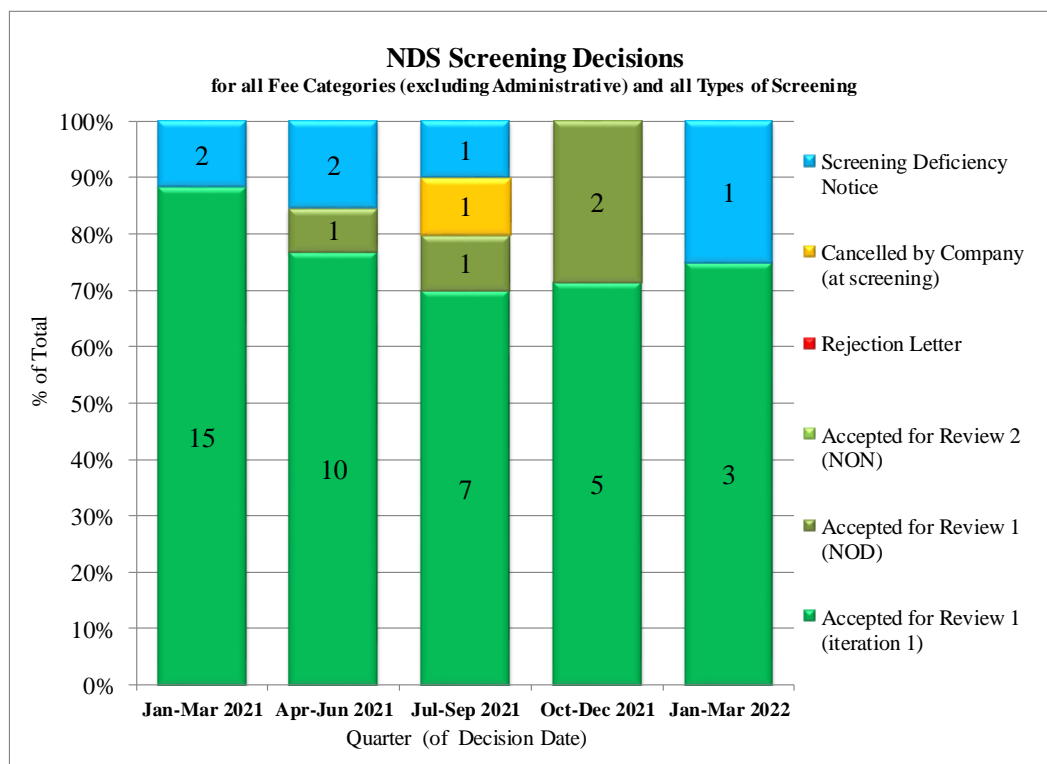


### SNDS: Review Cycle Completions

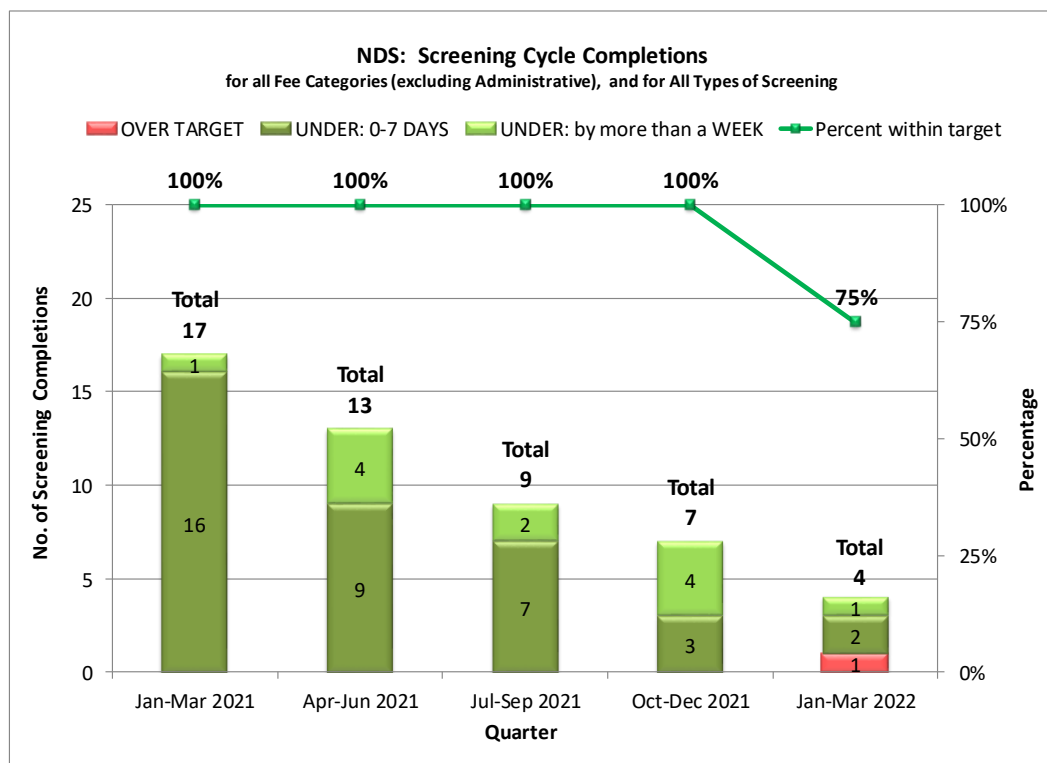


## SCREENING PERFORMANCE

### NDS: Screening Decisions by Type

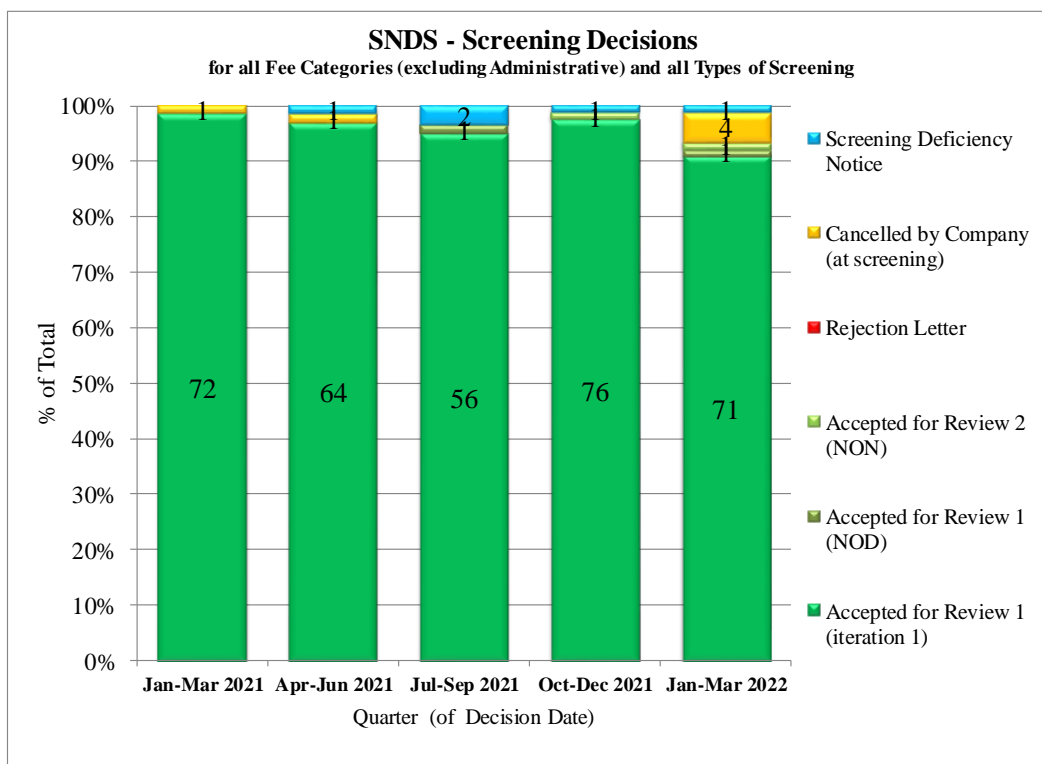


### NDS: Screening Cycle Completions

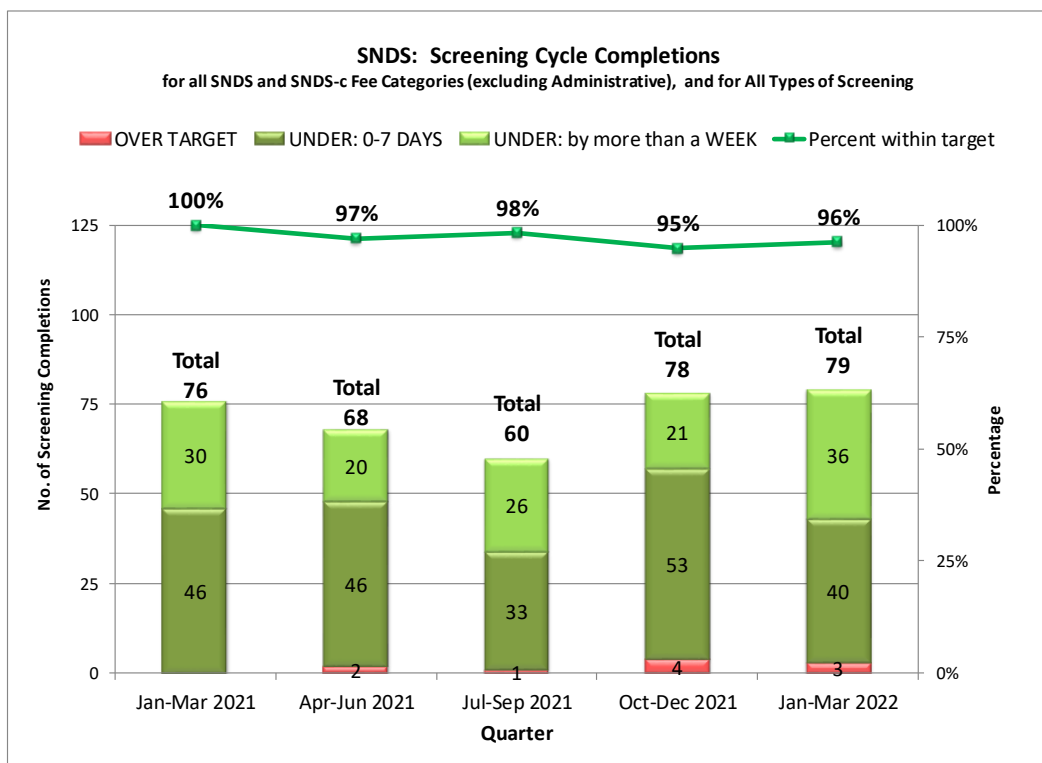


## SCREENING PERFORMANCE

### SNDS: Screening Decisions by Type

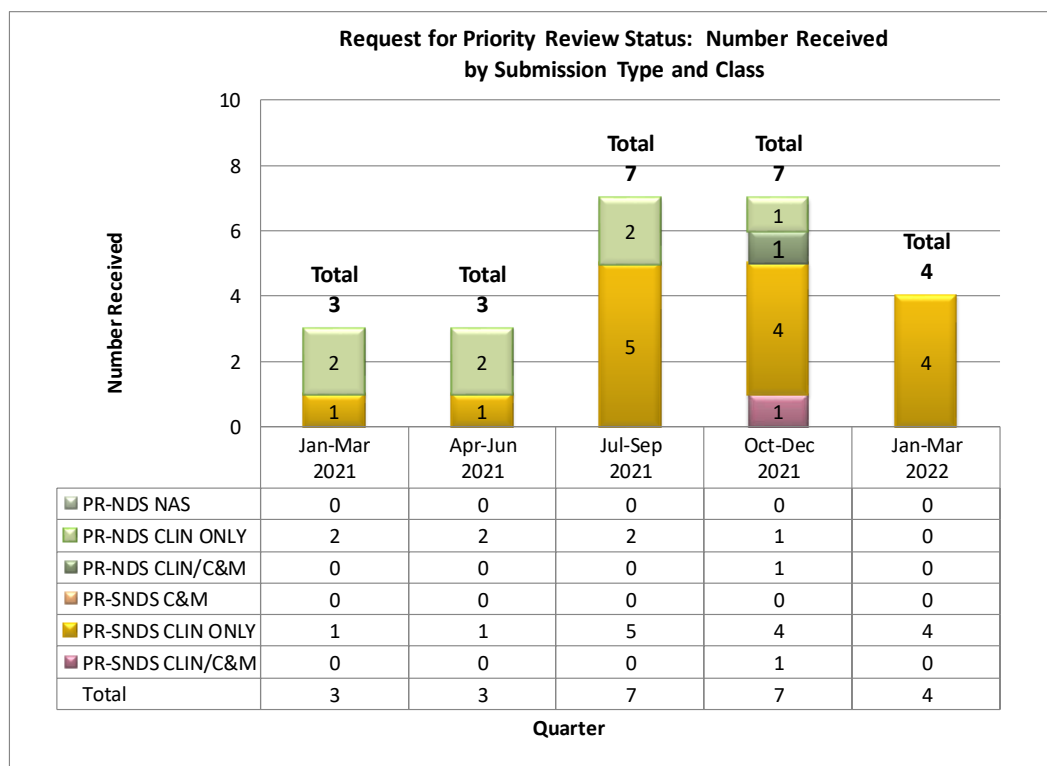


### SNDS: Screening Cycle Completions

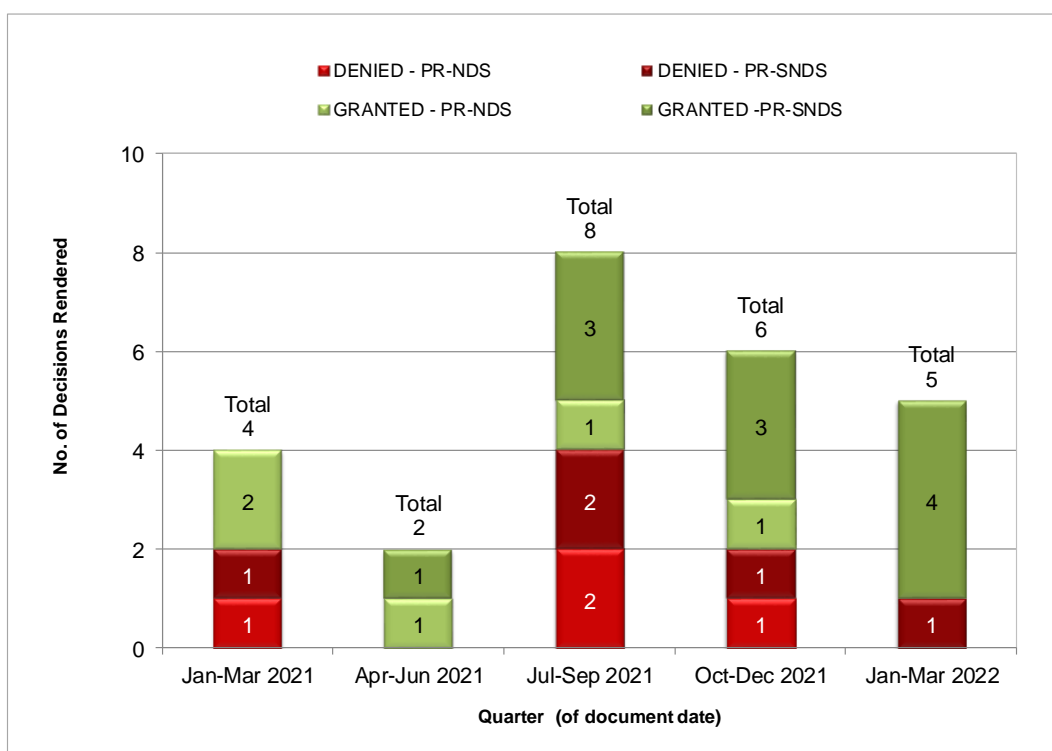


# REQUEST FOR PRIORITY REVIEW STATUS (NDS & SNDS)

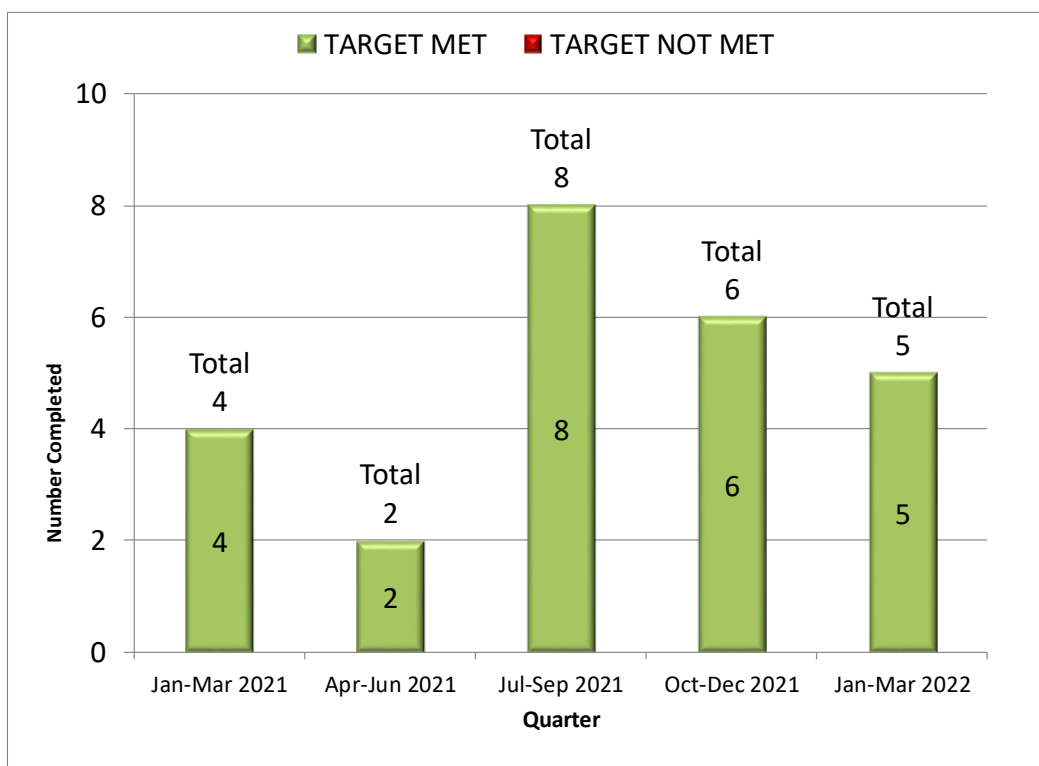
## Request for Priority Review Status: Number Received



## Request for Priority Review Status: Decisions Rendered



## Request for Priority Review Status: Performance



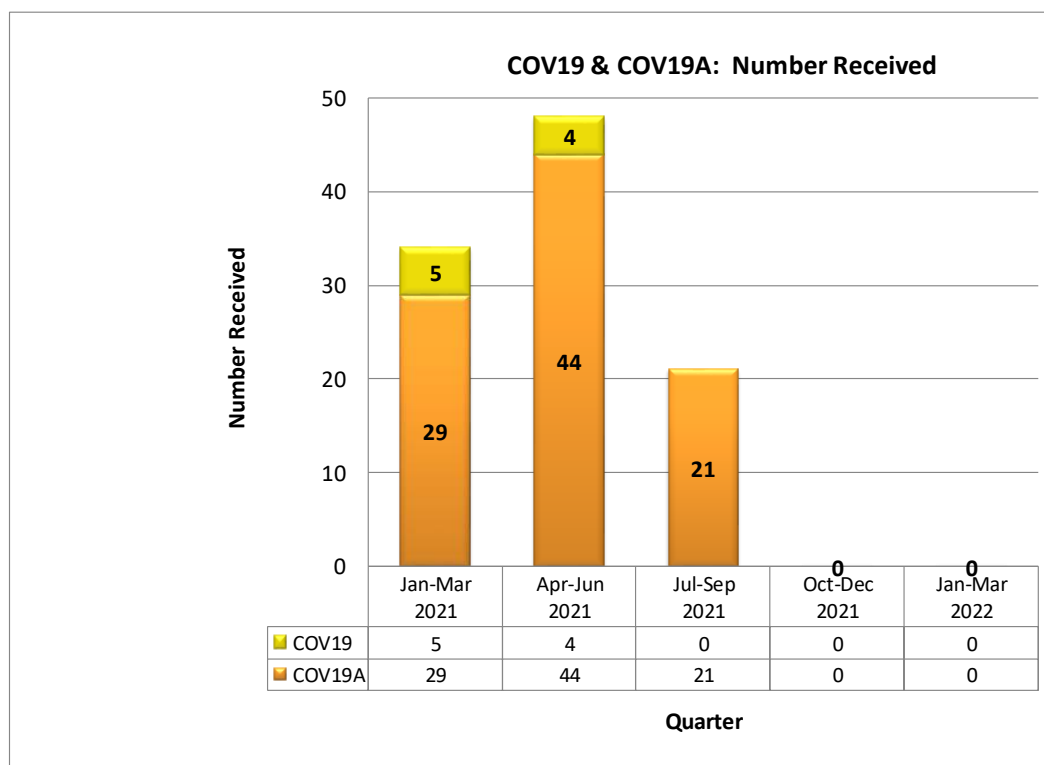
**Application under the Interim Order Respecting the  
Importation, Sale and Advertising of Drugs for Use in  
Relation to COVID-19  
(COV19)**

**&**

**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)**

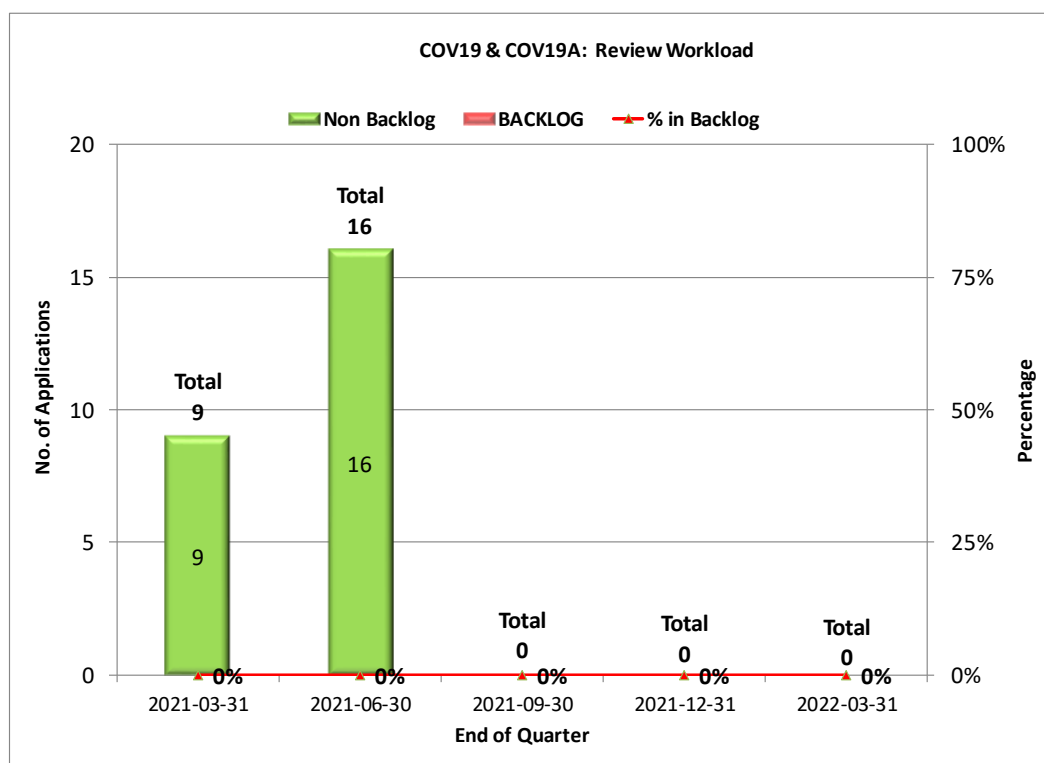
## RECEIVED

### COVID19 & COVID19A: Number Received



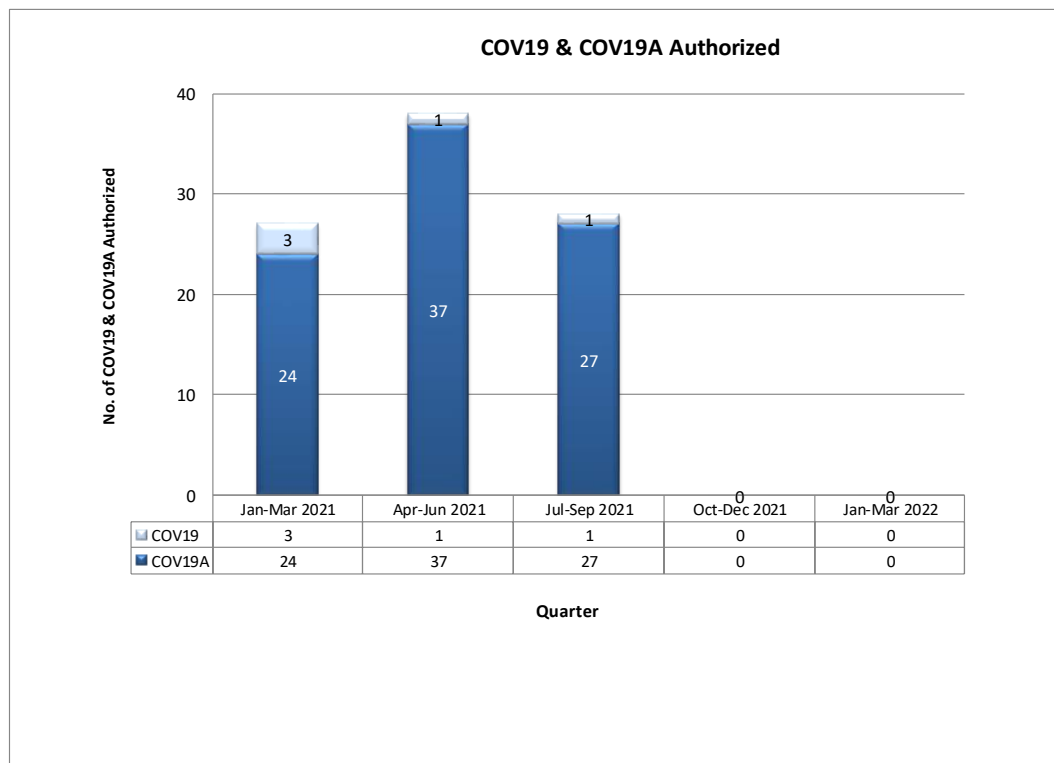
## WORKLOAD

### COVID19 & COVID19A: Review Workload



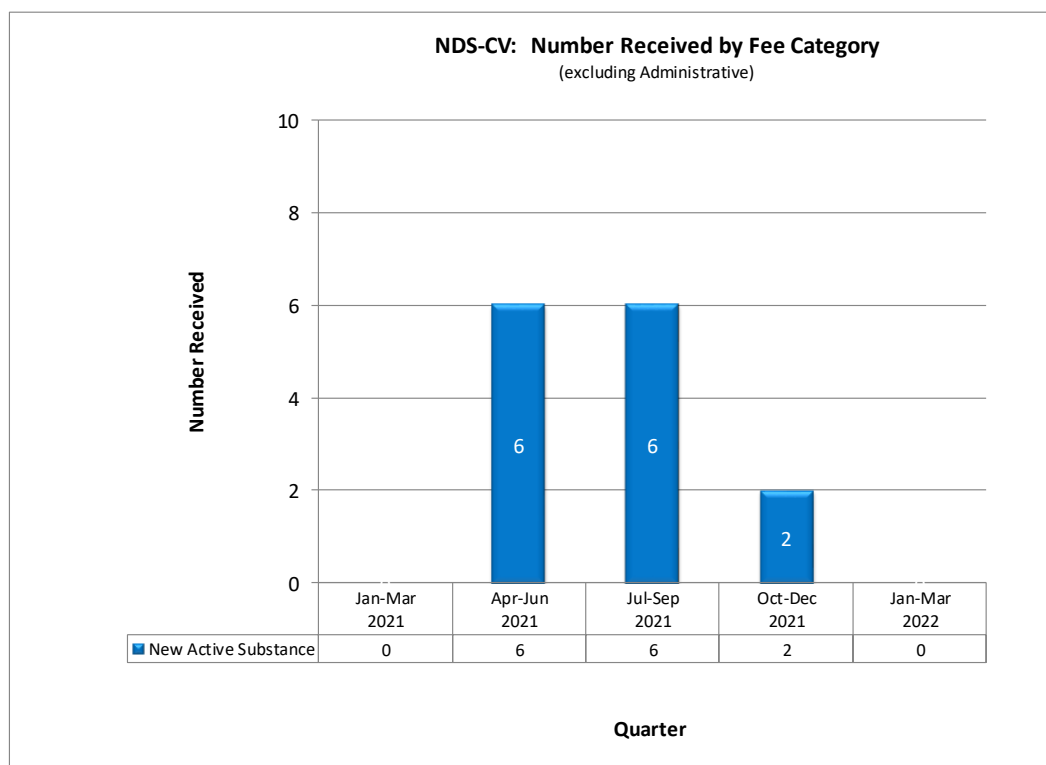
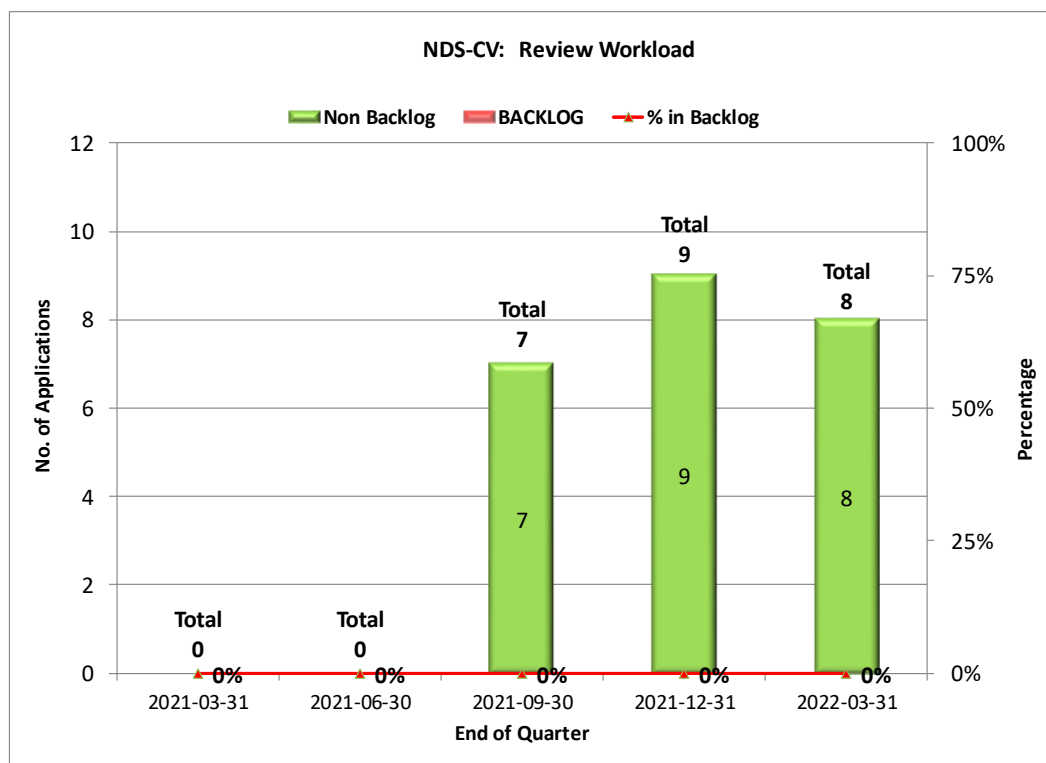
## AUTHORIZATIONS

### COVID19 & COVID19A: Number Authorized



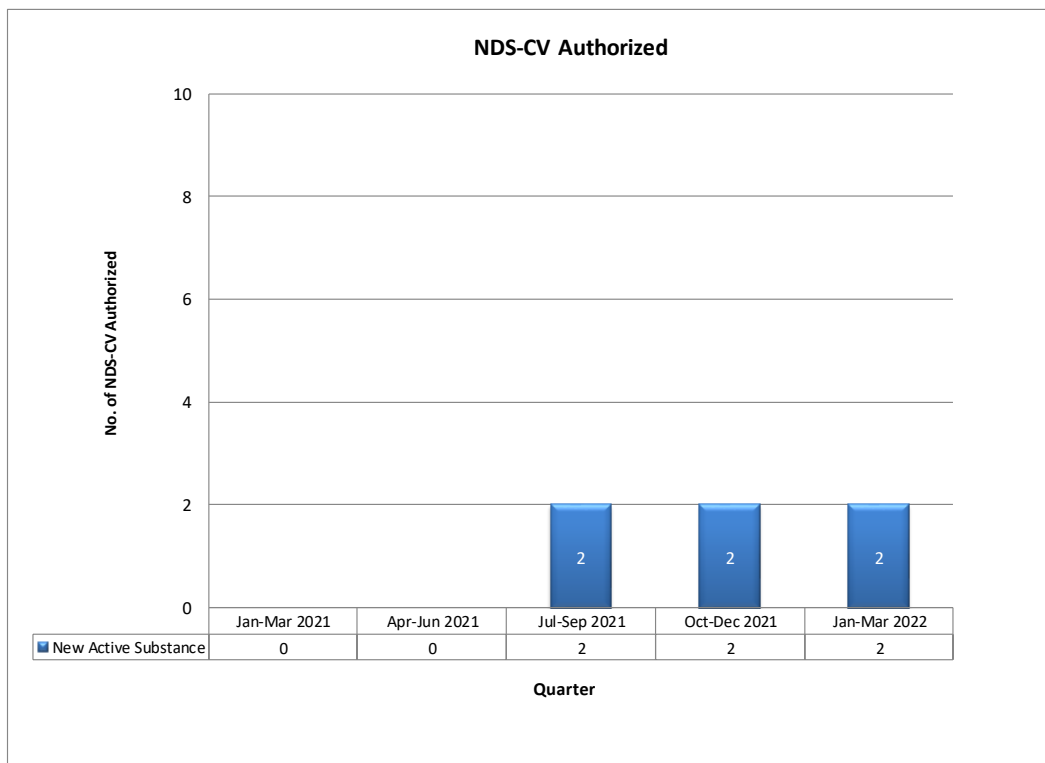


## **New Drug Submissions for Designated COVID-19 Drugs (NDS-CV)**

**RECEIVED****NDS-CV: Number Received****WORKLOAD****NDS-CV: Review Workload**

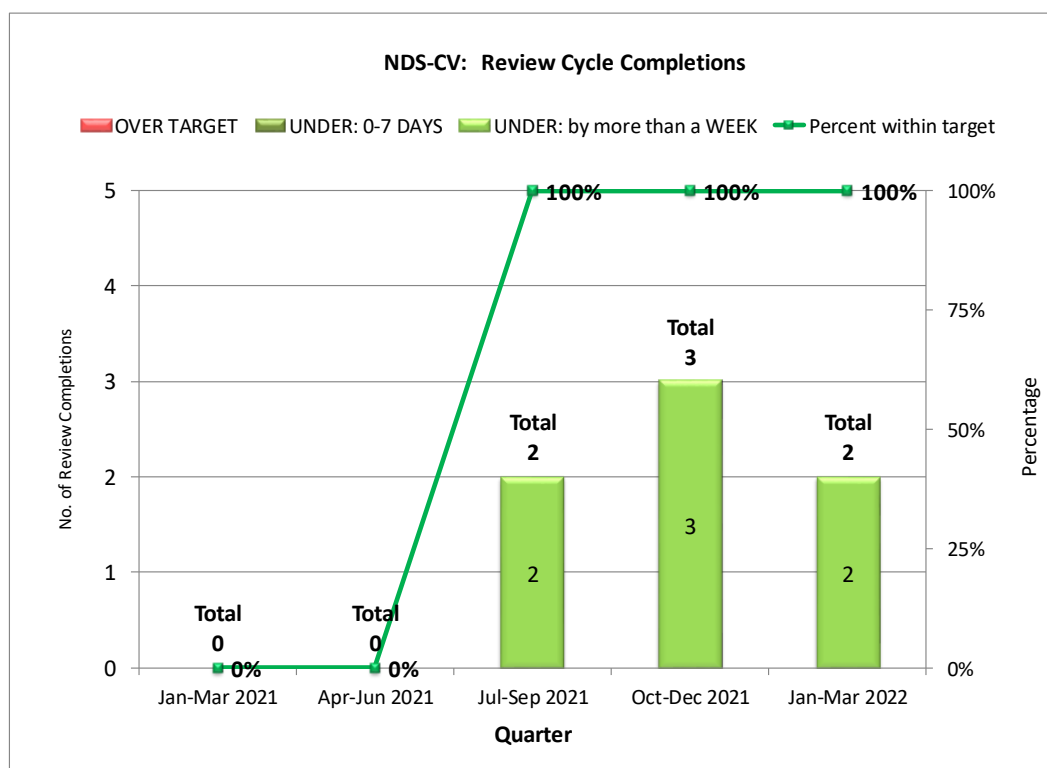
## AUTHORIZATIONS

### NDS-CV: Number Authorized

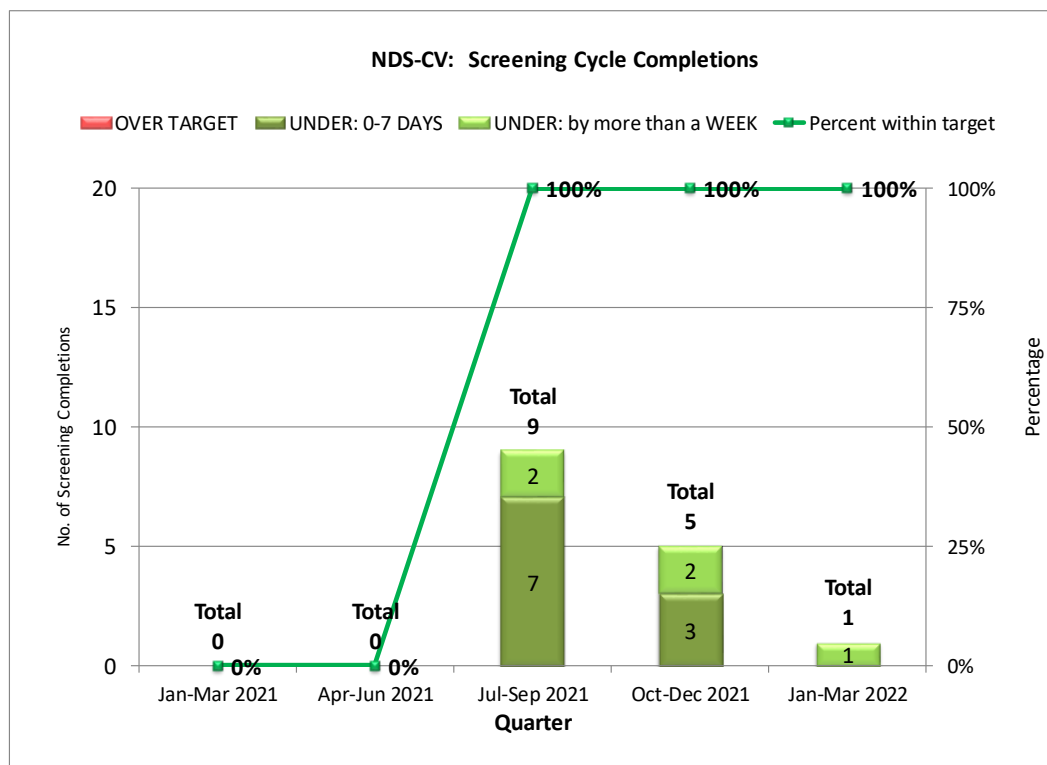


## PERFORMANCE

### NDS-CV: Review Cycle Completions



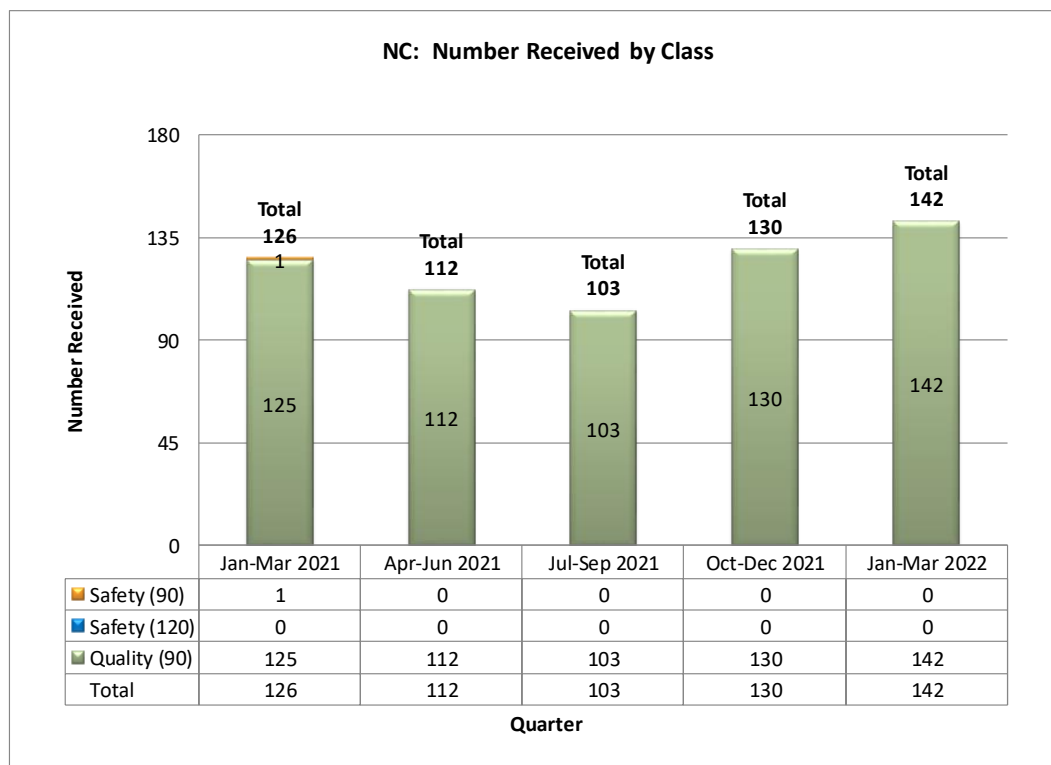
### NDS-CV: Screening Cycle Completions



**NC: NOTIFIABLE CHANGE**

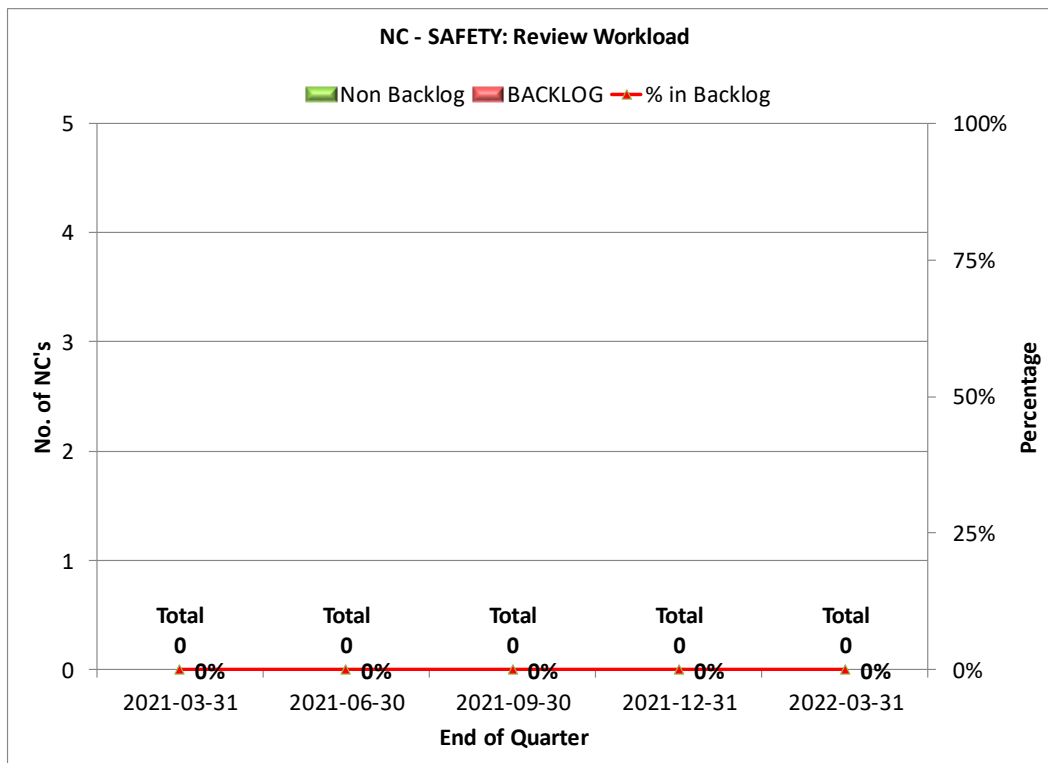
# NC: NOTIFIABLE CHANGE

## NC: Number Received by Class

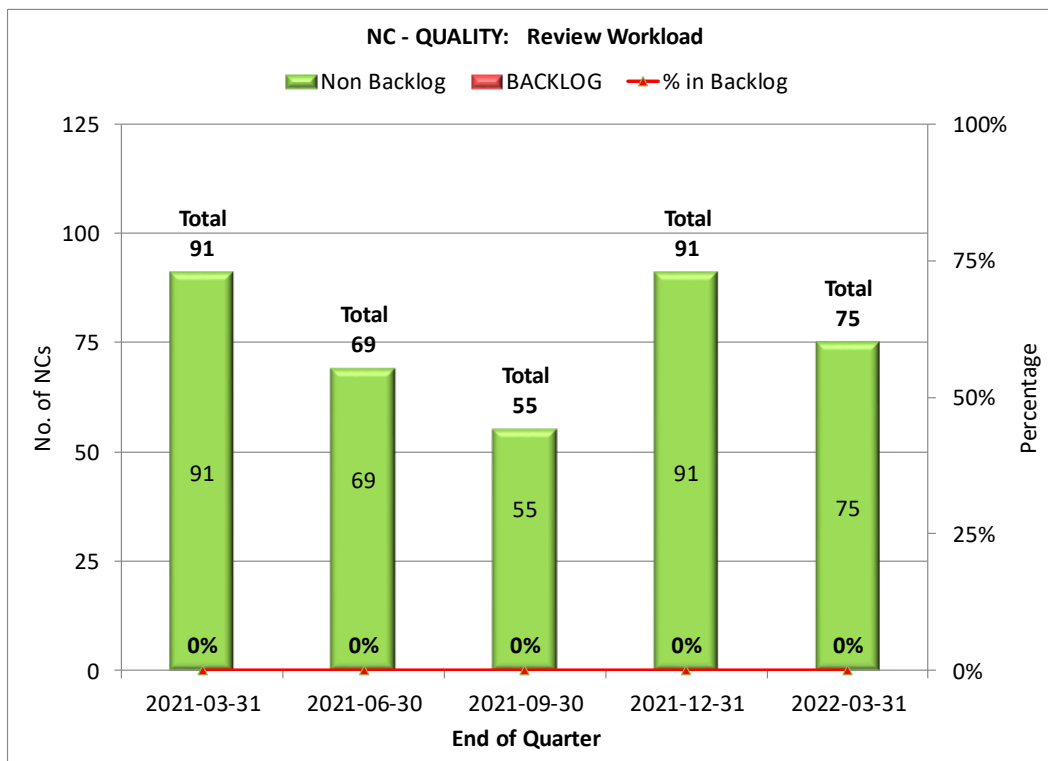


## WORKLOAD

### 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	2021-03-31	2021-06-30	2021-09-30	2021-12-31	2022-03-31
SAFETY - 90 day	0	0	0	0	0
Backlog	0	0	0	0	0
SAFETY - 120 day	0	0	0	0	0
Backlog	0	0	0	0	0
Total	0	0	0	0	0
Non Backlog	0	0	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

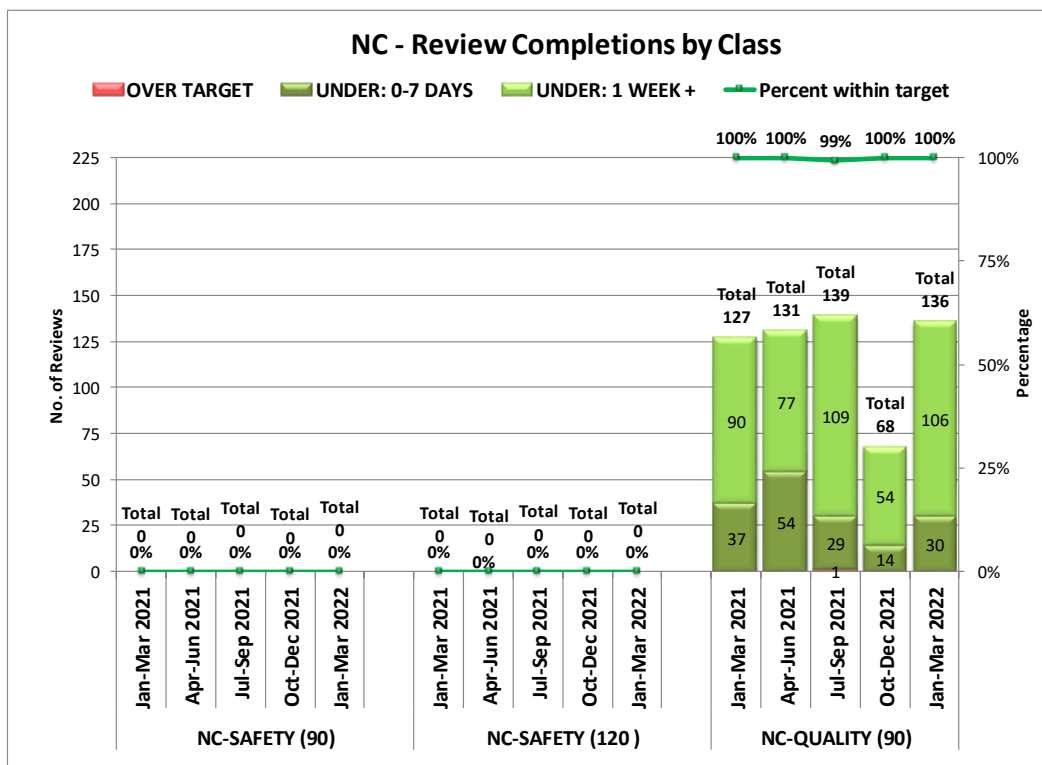
### NC-QUALITY: Review Workload by Class

BRDD NC - QUALITY: REVIEW WORKLOAD AT END OF QUARTER					
CLASS	2021-03-31	2021-06-30	2021-09-30	2021-12-31	2022-03-31
QUALITY - 90 day	91	69	55	91	75
Backlog	0	0	0	0	0
Total	91	69	55	91	75
Non Backlog	91	69	55	91	75
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

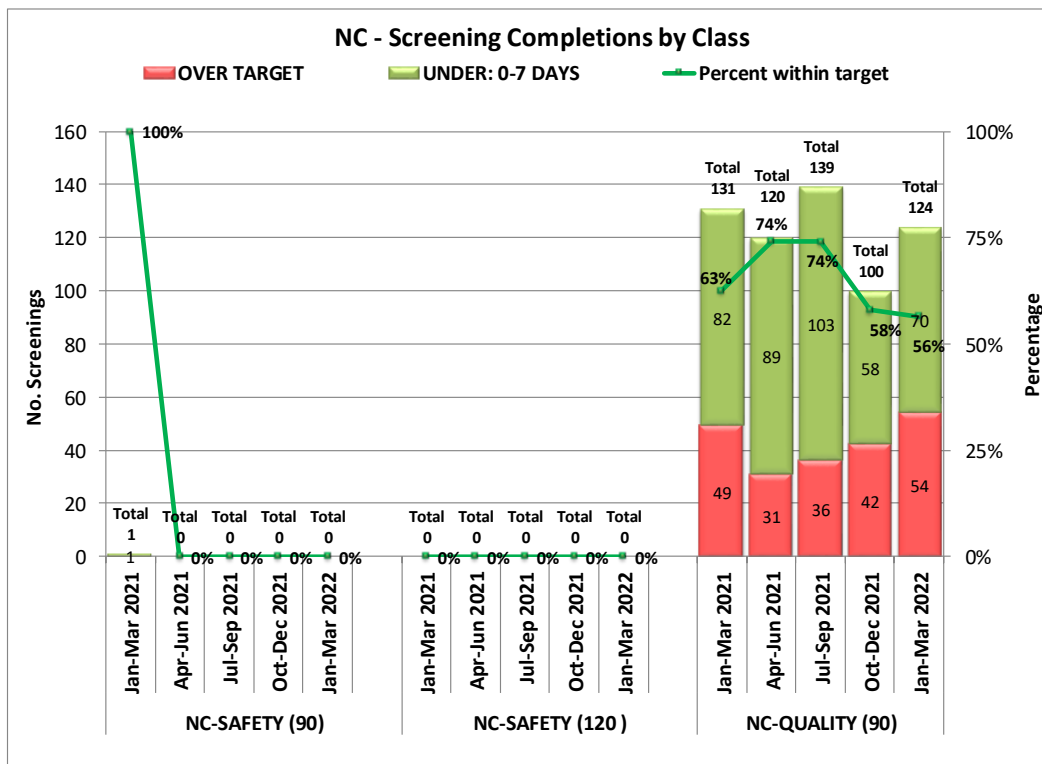


## PERFORMANCE

### NC: Review Completions by Class



### NC: Screening Completions by Class



## NC: Decision Documents by Class

NC - SAFETY (90)					
DOCUMENT TYPE	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021	Jan-Mar 2022
NO OBJECTION LETTER	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
CANCELLED BY COMPANY	1	0	0	0	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	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021	Jan-Mar 2022
NO OBJECTION LETTER	133	136	97	95	135
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	5	8	0	1
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	4	1	14	3	4
NC - HOLD (PATENT)	0	0	0	0	0

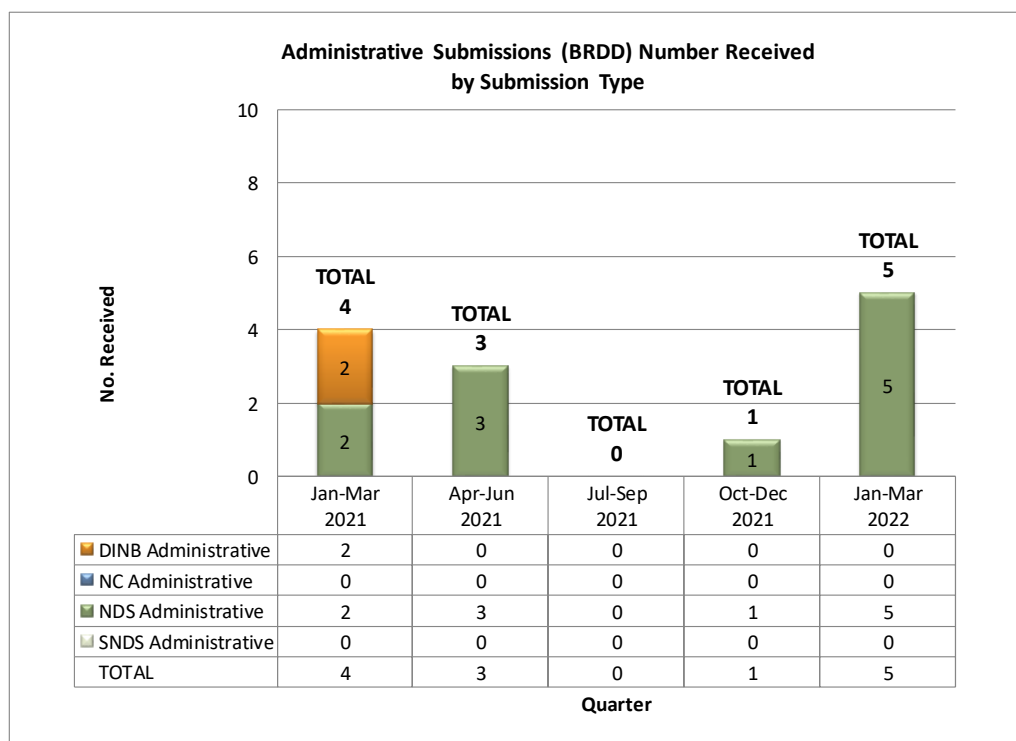
NC - SAFETY (120)					
DOCUMENT TYPE	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021	Jan-Mar 2022
NO OBJECTION LETTER	0	0	0	0	0
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

NC - ADMINISTRATIVE					
DOCUMENT TYPE	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021	Jan-Mar 2022
NO OBJECTION LETTER	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

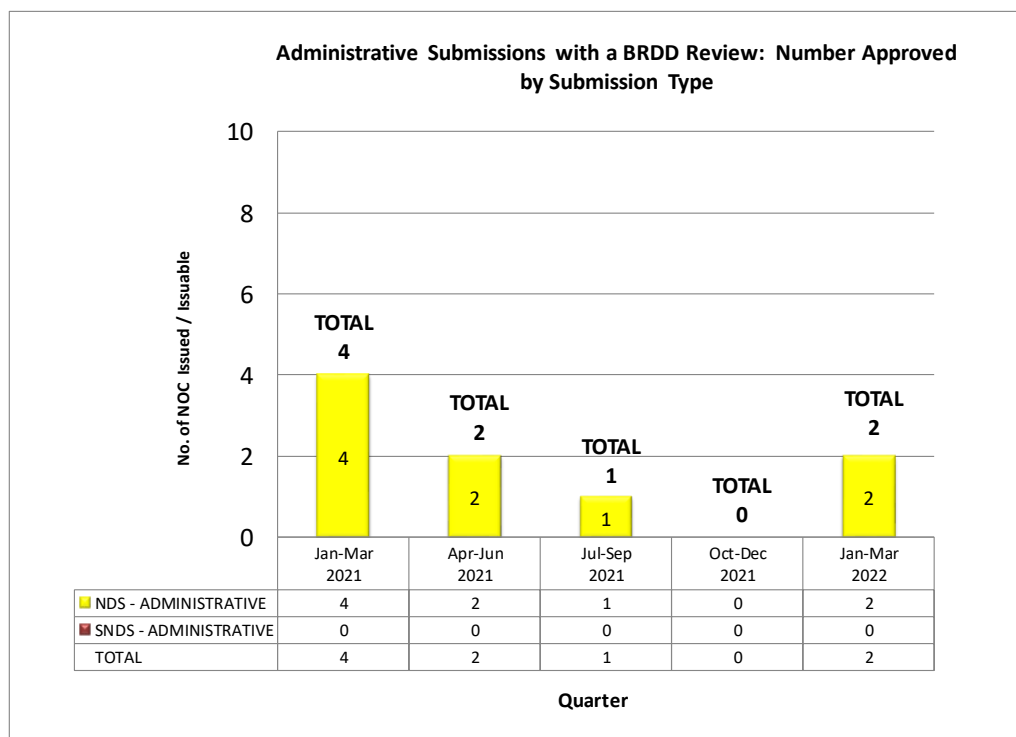
## ADMINISTRATIVE SUBMISSIONS (Processed by BRDD)

(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

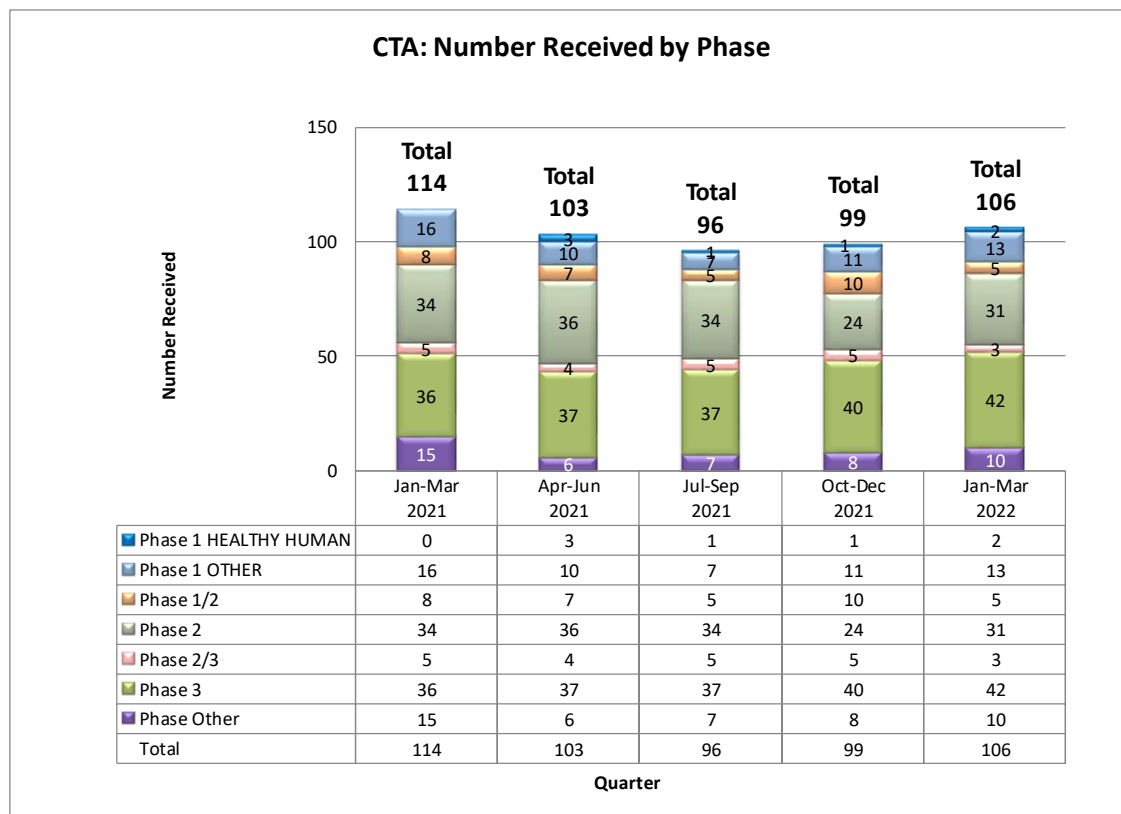




# **CLINICAL TRIAL APPLICATIONS AND AMENDMENTS (CTA & CTA-A)**

# CLINICAL TRIAL APPLICATIONS(CTA)

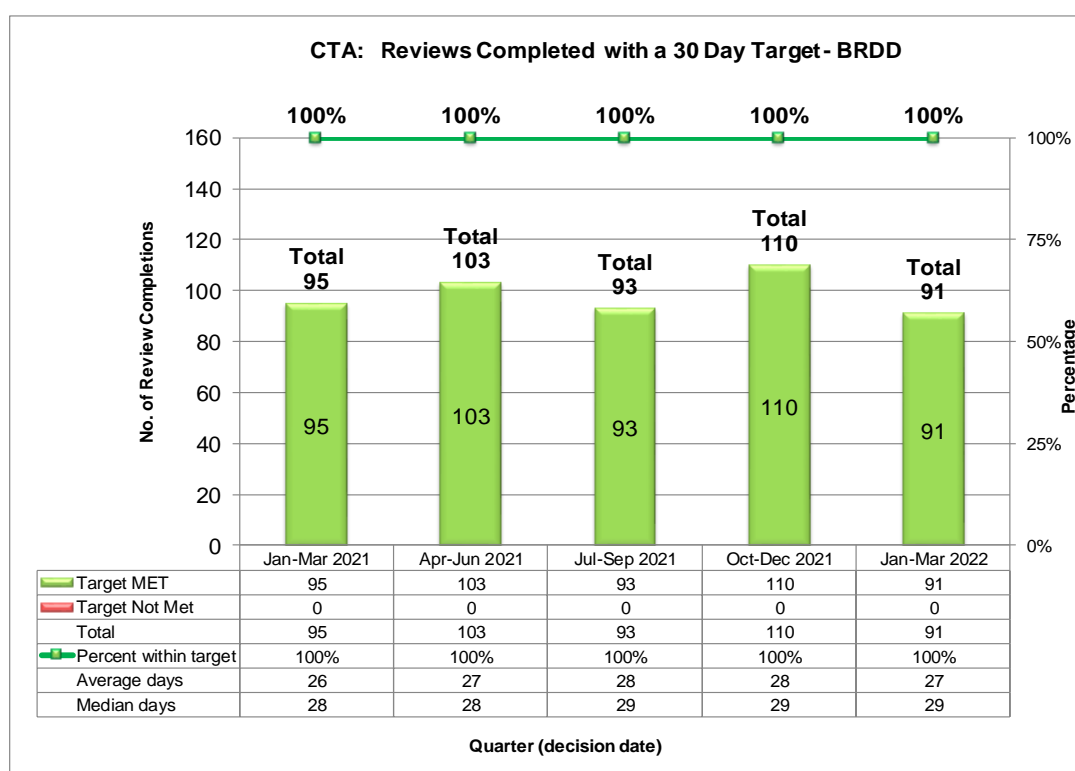
## CTA: Number Received by Phase



## CTA: Number of Decisions by Document Type

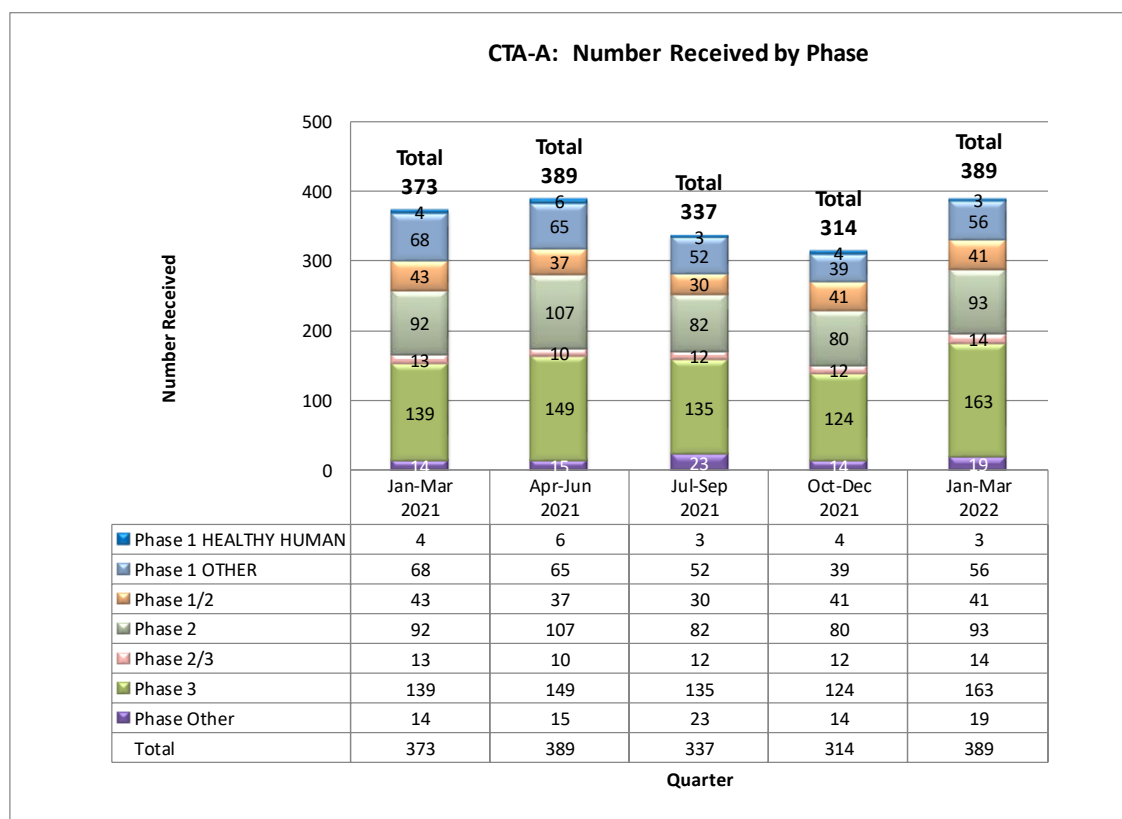
CTA					
DOCUMENT TYPE	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021	Jan-Mar 2022
NO OBJECTION LETTER	85	100	91	105	89
CANCELLED BY COMPANY DURING REVIEW	7	3	2	5	4
CANCELLED BY COMPANY AT PROCESSING	2	1	1	1	2
REJECTION LETTER (SCR)	0	0	0	0	0
NOT SATISFACTORY NOTICE	0	0	0	0	0
NOTICE OF AUTHORIZATION	3	4	3	2	2
NOTICE OF AUTHORIZA/ TC	0	1	1	0	0

## CTA: Review Completed with a 30 Day Target



# CLINICAL TRIAL APPLICATION-AMENDMENTS (CTA-A)

## CTA-A: Number Received by Phase

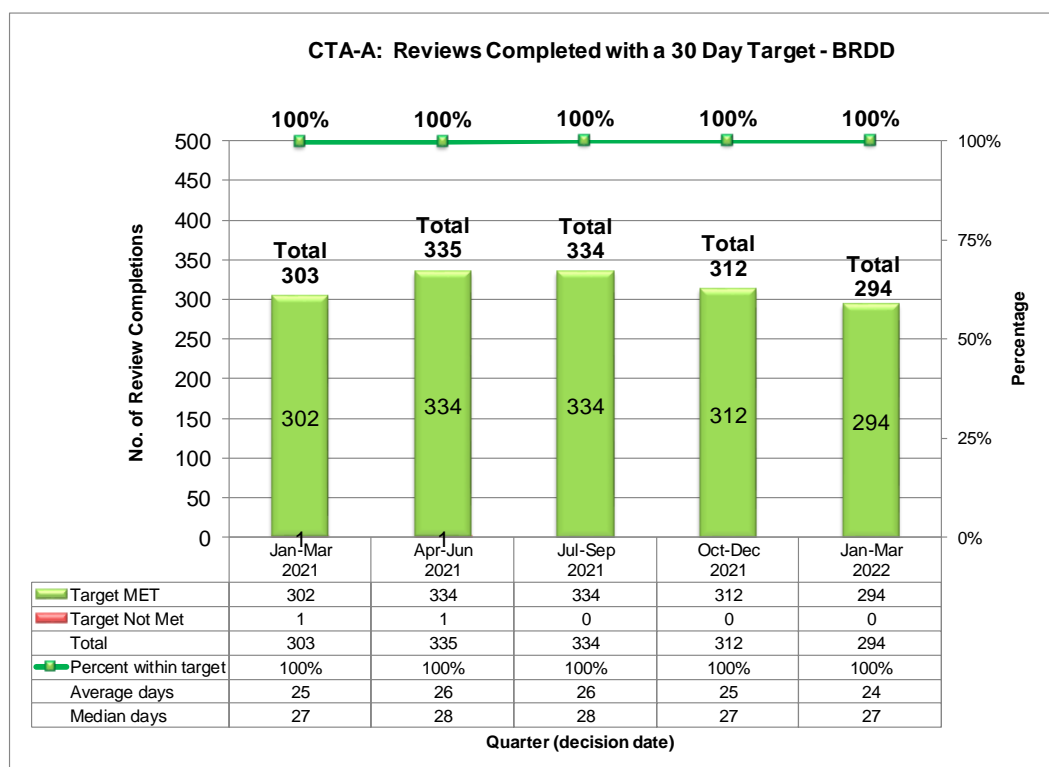




## CTA-A: Decisions by Type

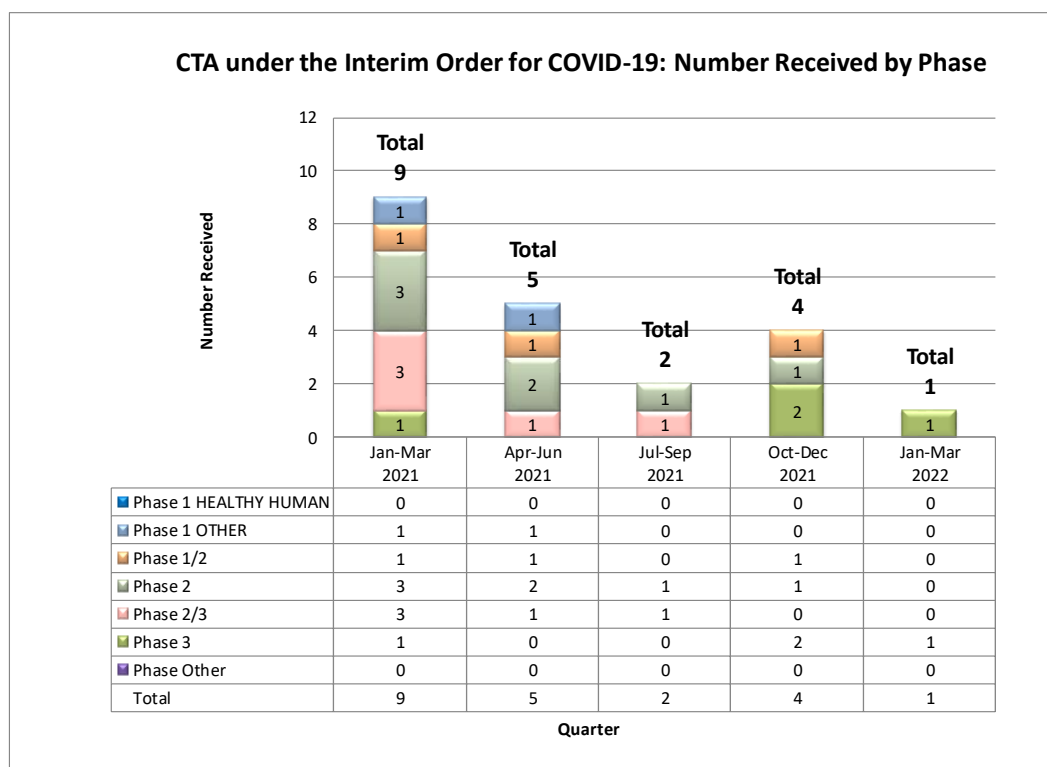
CTA-A					
DOCUMENT TYPE	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021	Jan-Mar 2022
NO OBJECTION LETTER	294	351	343	329	312
REJECTION LETTER (SCR)	2	9	2	6	2
CANCELLED BY COMPANY DURING REVIEW	7	3	4	2	4
CANCELLED BY COMPANY AT PROCESSING	2	0	3	5	0
NOTICE OF AUTHORIZ A/TC	0	0	0	1	0
NOTICE OF AUTHORIZA/ TC	0	0	0	1	0
NOTICE OF AUTHORIZATION	10	14	11	10	8

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

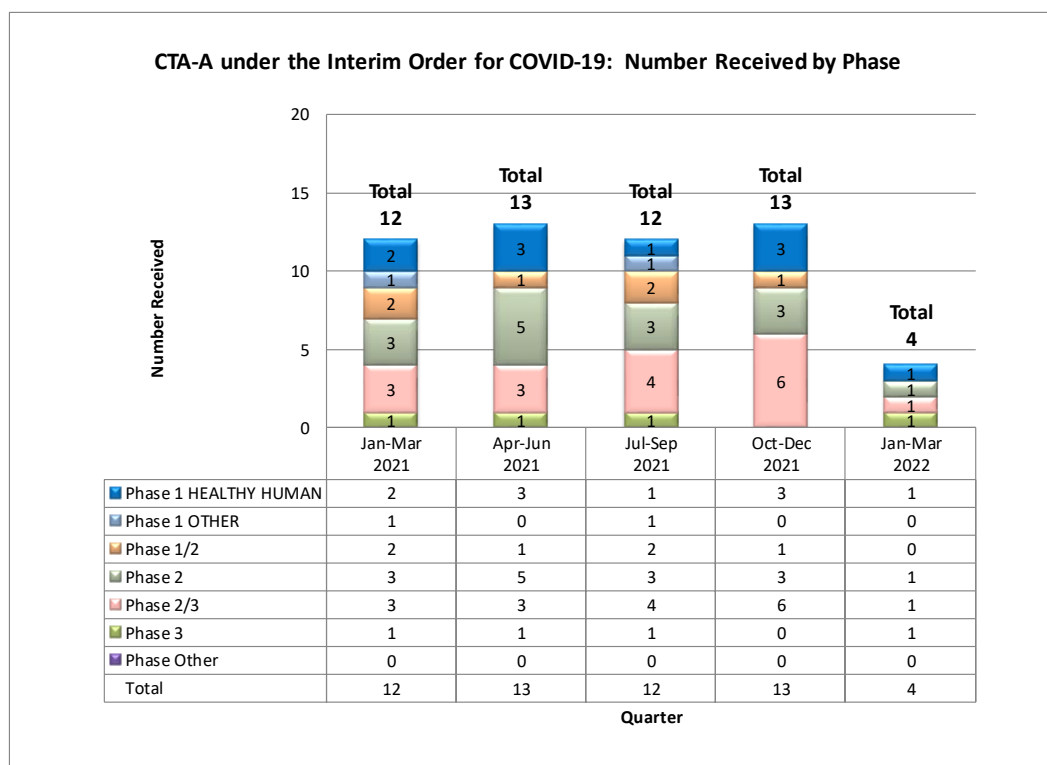


## CTA & CTA-A RECEIVED UNDER THE INTERIM ORDER COVID-19

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



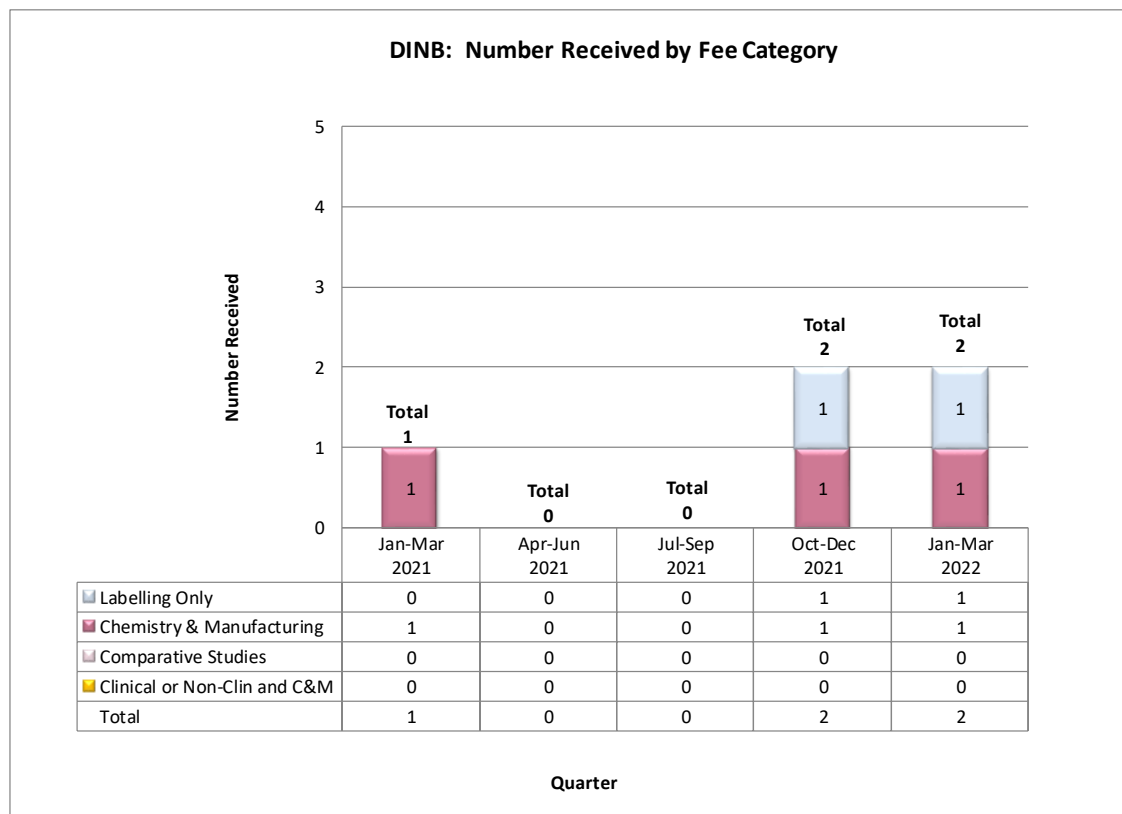
### CTA-A: Number Received under the Interim Order Covid-19 by phase



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

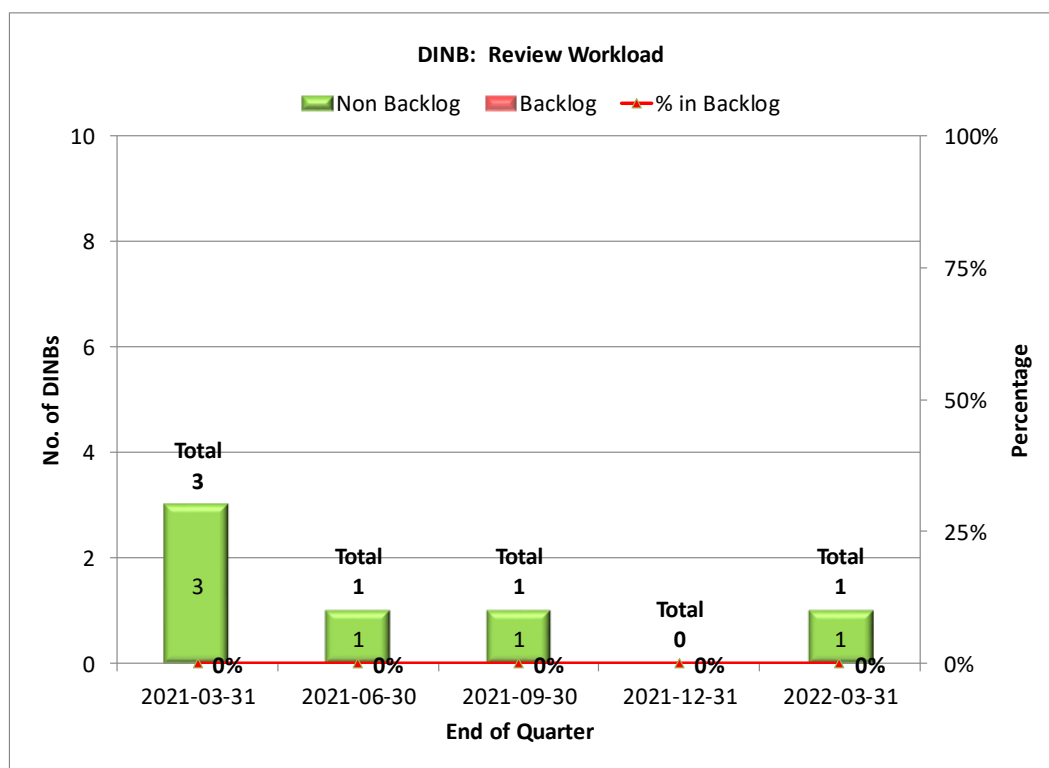
## DINB: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - BIOLOGICAL PRODUCT

### DINB: Number Received by Fee Category



## REVIEW WORKLOAD

### DINB: Review Workload

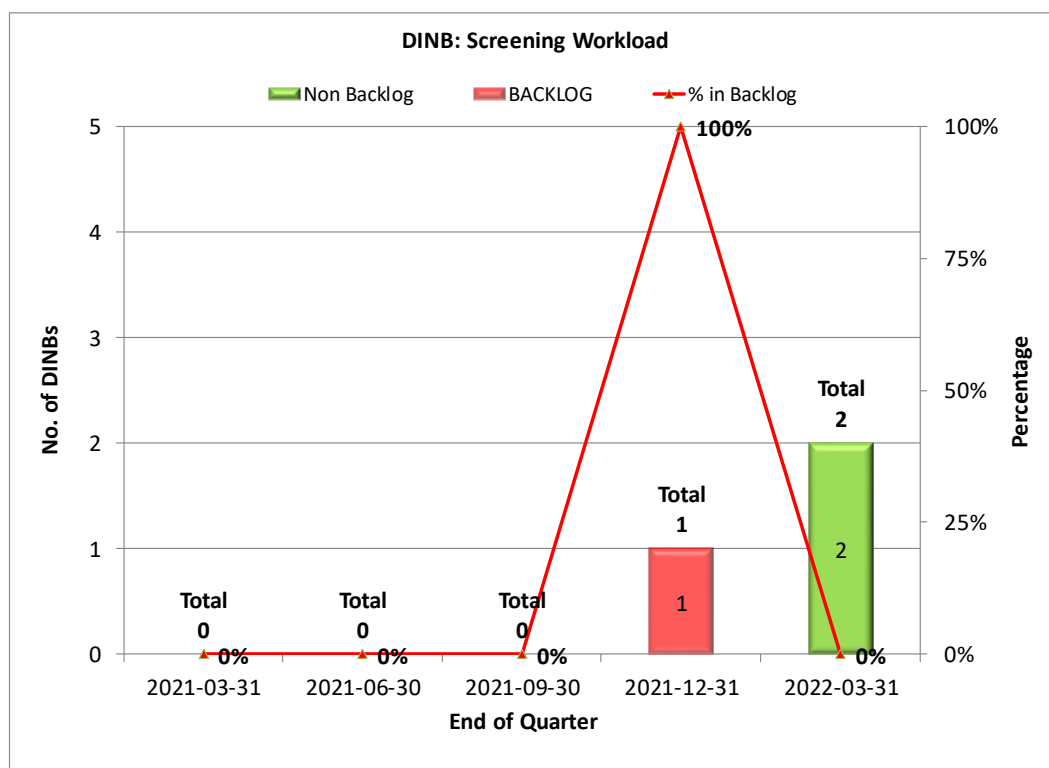


### DINB: Review Workload by Fee Category

DINB: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2021-03-31	2021-06-30	2021-09-30	2021-12-31	2022-03-31
Labelling Only	1	0	0	0	0
Backlog	0	0	0	0	0
Chemistry & Manufacturing	2	1	1	0	1
Backlog	0	0	0	0	0
Total	3	1	1	0	1
Non Backlog	3	1	1	0	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	2021-03-31	2021-06-30	2021-09-30	2021-12-31	2022-03-31
Labelling Only	0	0	0	0	1
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	1	1
Backlog	0	0	0	1	0
<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>2</b>
Non Backlog	0	0	0	0	2
BACKLOG	0	0	0	1	0
% in Backlog	0%	0%	0%	100%	0%

## DECISIONS

### DINB: Number of Decisions by Fee Category

DINB - LABELLING ONLY					
DOCUMENT TYPE	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021	Jan-Mar 2022
DINB APPROVAL LETTER	1	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0

DINB - CLINICAL OR NON CLINICAL DATA AND C&M					
DOCUMENT TYPE	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021	Jan-Mar 2022
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

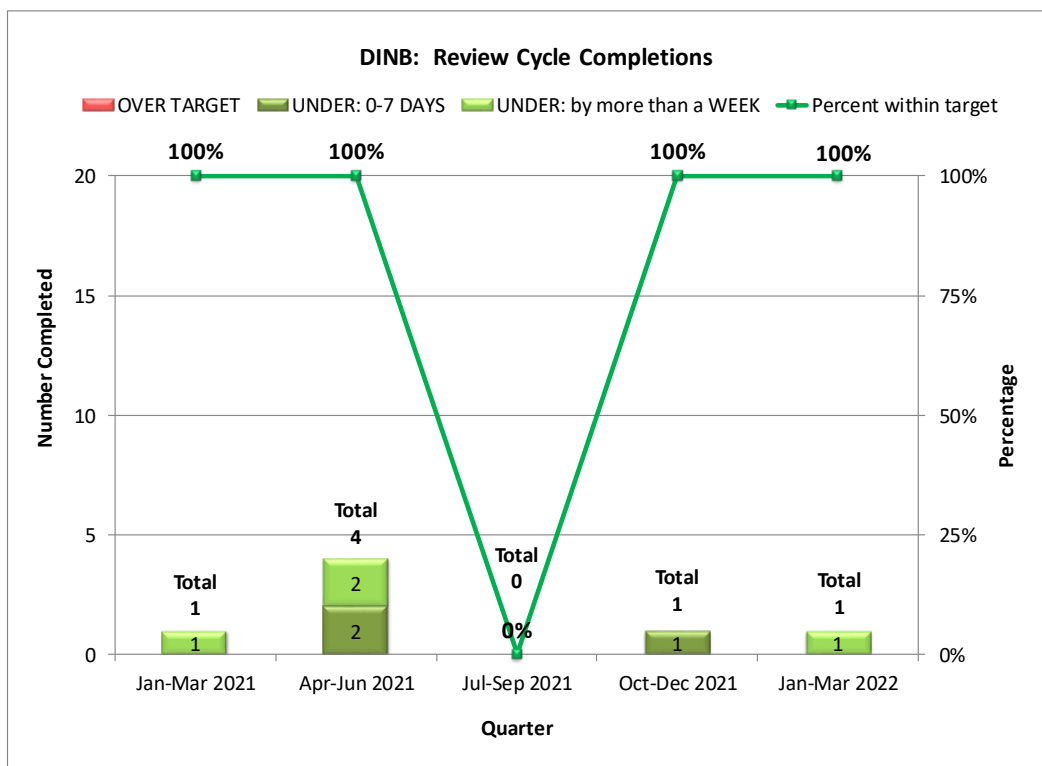
DINB - CHEMISTRY & MANUFACTURING					
DOCUMENT TYPE	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021	Jan-Mar 2022
DINB APPROVAL LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

DINB - COMPARATIVE STUDIES					
DOCUMENT TYPE	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021	Jan-Mar 2022
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0

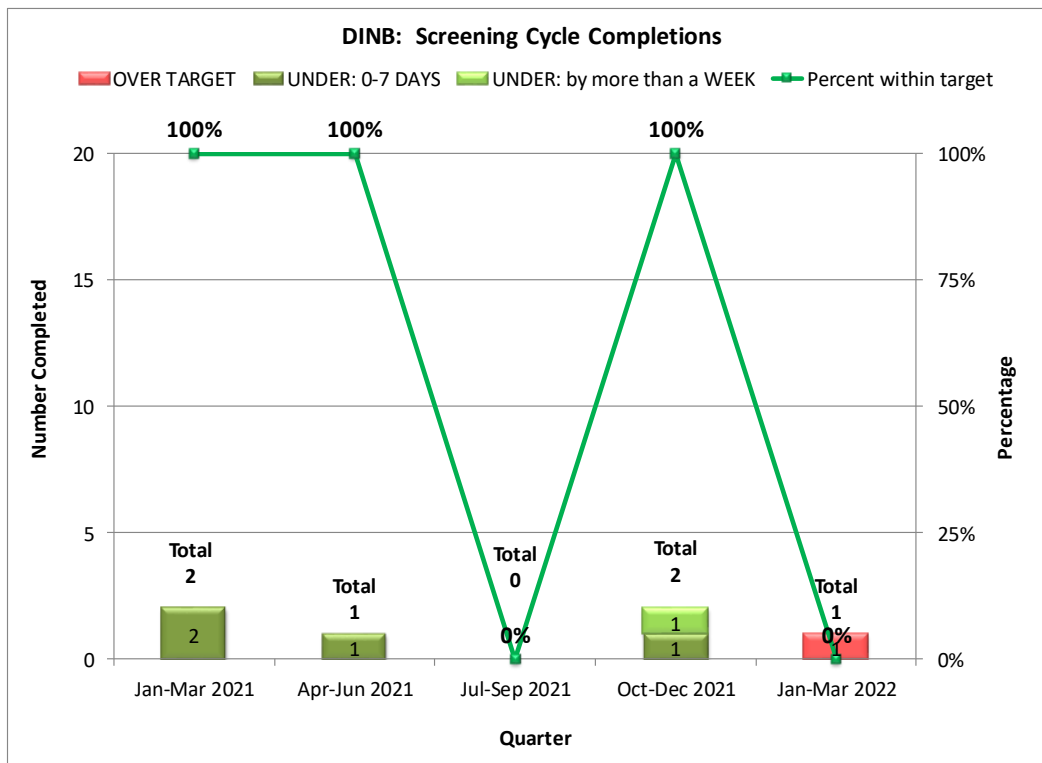
DINB - Administrative					
DOCUMENT TYPE	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021	Jan-Mar 2022
DINB APPROVAL LETTER	2	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

## PERFORMANCE

### DINB: Review Cycle Completions

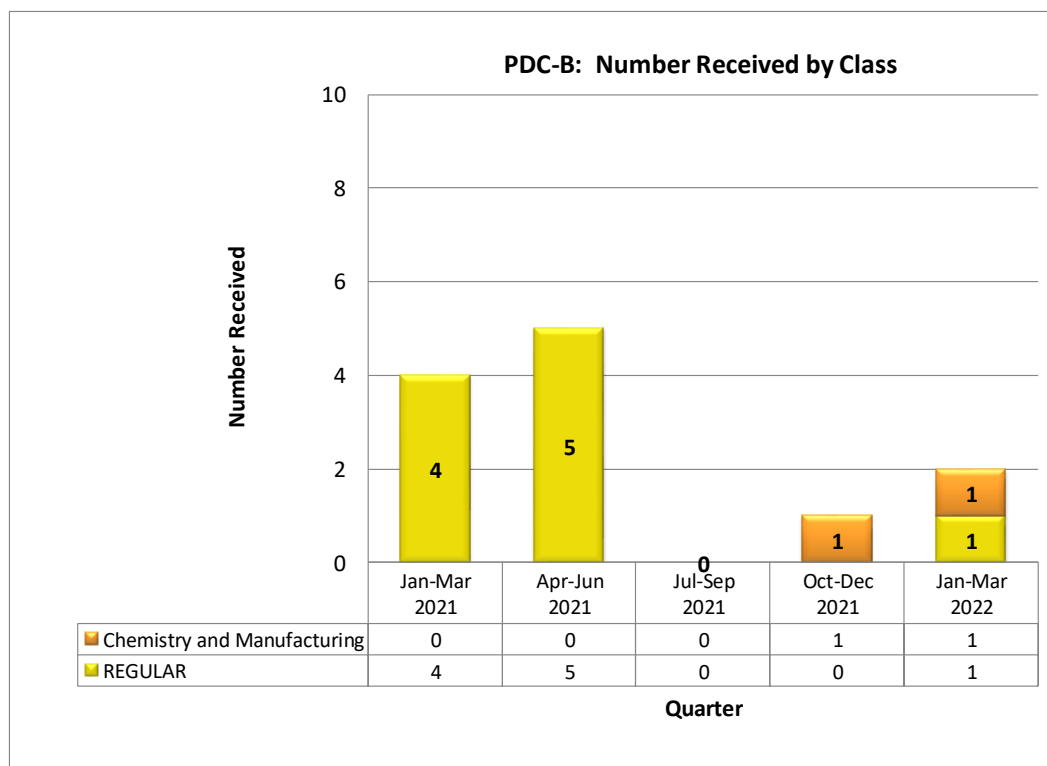


### DINB: Screening Cycle Completions



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

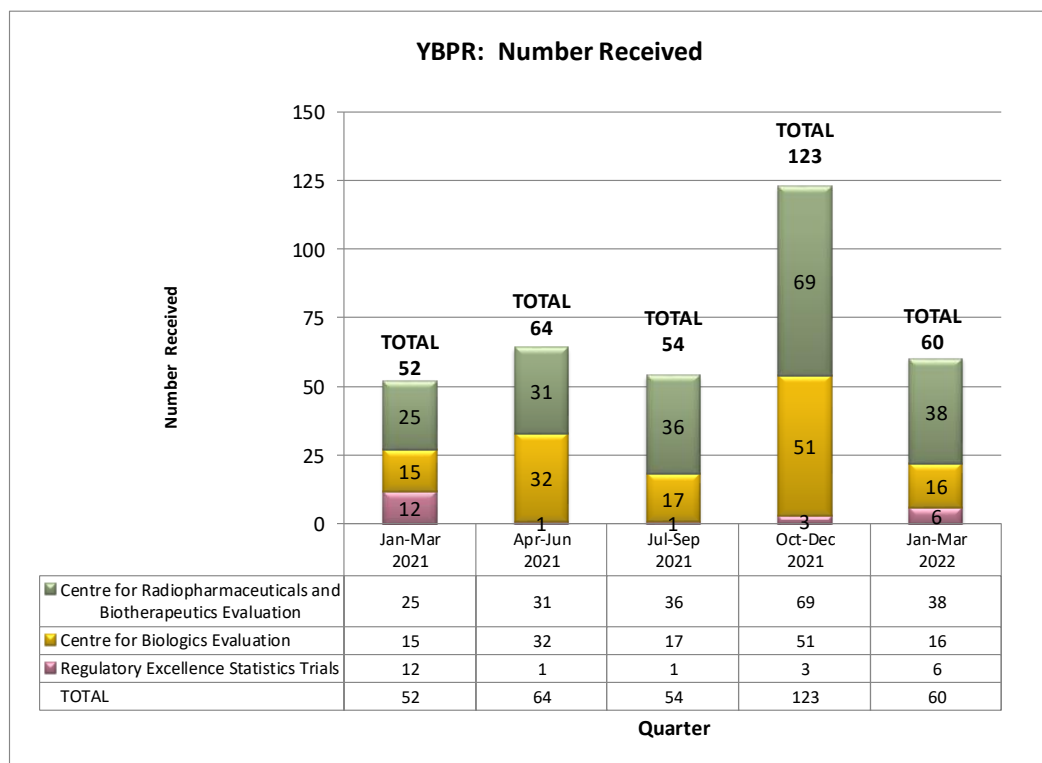
## PDC-B: Number Received





## YEARLY BIOLOGIC PRODUCT REPORTS (YBPR)<sup>9</sup>

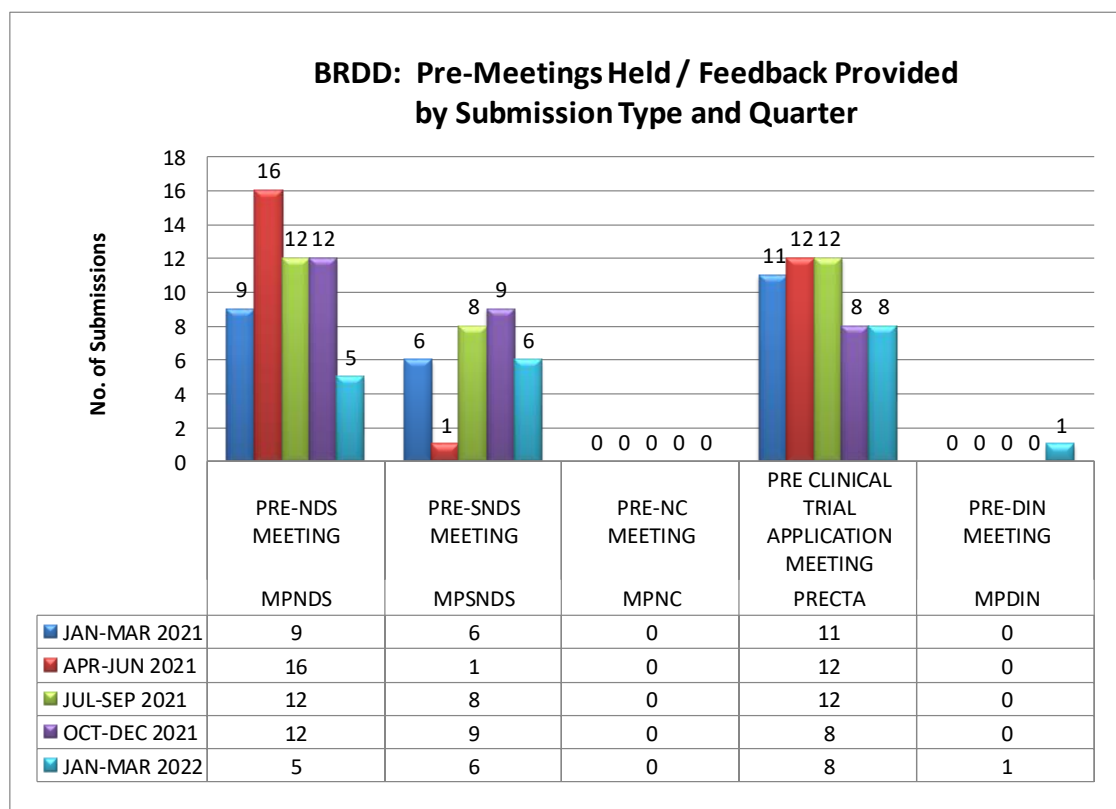
### YBPR: Number Received



<sup>9</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>10</sup>

## Pre-submission Meetings Held / Feedback Provided



<sup>10</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](#).