



Health
Canada

Santé
Canada

Therapeutic Products Directorate

Drug Submission Performance Quarterly Report

January - March
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.

Également disponible en français sous le titre :
Direction des produits thérapeutiques - Rapport trimestriel du rendement des présentations de drogue - janvier - mars 2021

To obtain additional information, please contact:

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

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health, 2021

Publication date: July 2021

This publication may be reproduced for personal or internal use only without permission provided the source is fully acknowledged.

Cat H167-2E-PDF
ISSN 2561-553X
Pub 210103

Table of Contents

TABLE OF CONTENTS	3
OVERVIEW	7
ACRONYMS.....	11
Submission Types.....	11
Documents.....	13
FEE CATEGORIES.....	14
NDS & SNDS.....	16
SUBMISSIONS RECEIVED	17
NDS: Number Received by Fee Category	17
SNDS: Number 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 by NOC Type.....	20
SNDS: Number Approved by Fee Category and by NOC Type	20
REVIEW PERFORMANCE.....	22
NDS: Review Decisions by Type	22
NDS: Review Cycle Completions	22
SNDS: Review Decisions by Type.....	23
SNDS: Review Cycle Completions	23
SCREENING PERFORMANCE.....	24
NDS: Screening Decisions by Type	24
NDS: Screening Cycle Completions	24
SNDS: Screening Decisions by Type	25
SNDS: Screening Cycle Completions	25

COV19 & COV19A.....	26
SUBMISSIONS RECEIVED.....	27
COV19 & COV19A: Number Received.....	27
WORKLOAD	27
COV19: Review Workload.....	27
AUTHORIZATIONS.....	28
COV19 & COV19A: Number Authorized.....	28
ANDS & SANDS.....	29
SUBMISSIONS RECEIVED.....	30
ANDS: Number Received by Fee Category	30
SANDS: Number Received by Fee Category	30
WORKLOAD	31
ANDS: Review Workload	31
SANDS: Review Workload.....	31
ANDS: Review Workload by Fee Category	32
SANDS: Review Workload by Fee Category	32
APPROVALS.....	33
ANDS: Number Approved by Fee Category and by NOC Type	33
SANDS: Number Approved by Fee Category and by NOC Type	33
REVIEW PERFORMANCE	35
ANDS: Review Decisions by Type	35
ANDS: Review Cycle Completions.....	35
SANDS: Review Decisions by Type	36
SANDS: Review Cycle Completions	36
SCREENING PERFORMANCE	37
ANDS: Screening Decisions by Type.....	37
ANDS: Screening Cycle Completions.....	37
SANDS: Screening Decisions by Type	38
SANDS: Screening Cycle Completions.....	38
REQUEST FOR PRIORITY REVIEW STATUS (FOR NDS & SNDS)	39
Request for Priority Review Status: Number Received	39
Request for Priority Review Status: Decisions Rendered	40
Request for Priority Review Status: Performance	40

NC: NOTIFIABLE CHANGE	41
RECEIVED.....	42
NC: Number Received by Class	42
NC-SAFETY: Number Received by Lead Bureau	42
WORKLOAD	43
NC-SAFETY: Review Workload	43
NC-SAFETY: Review Workload by Class	43
PERFORMANCE	44
NC-SAFETY: Review Completions by Class	44
NC-SAFETY: Screening Completions by Class	44
NC-SAFETY: Number of Decisions by Class	45
ADMINISTRATIVE SUBMISSIONS	46
RECEIVED.....	46
Administrative Submissions: Number Received by Submission Type	46
APPROVALS.....	46
Administrative Submissions: Number Approved (NDS, SNDS, ANDS and SANDS)	46
DECISIONS	47
Administrative Submissions/Applications: Number of Decisions by Submission Type	47
CTA: CLINICAL TRIAL APPLICATIONS	49
CTA: Number Received	49
CTA: Number Received by Phase	49
CTA: Number of Decisions by Type	50
CTA: Reviews Completed (excluding Phase 1 Bioequivalence)	51
CTA: Reviews Completed for Phases with a 7 Day Administrative Target	51
CTA-A: CLINICAL TRIAL APPLICATION-AMENDMENTS	52
CTA-A: Number Received by Phase	52
CTA-A: Number of Decisions by Type	52
CTA-A: Reviews Completed (excluding Phase 1 Bioequivalence)	53
CTA-A: Reviews Completed for Phases with a 7 Day Administrative Target	53
CTA & CTA-A RECEIVED UNDER THE INTERIM ORDER COVID 19.....	54
CTA: Number Received under the Interim Order Covid-19 by phase	54
CTA-A: Number Received under the Interim Order Covid-19 by phase	54

DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER	56
DINA: Number Received by Fee Category	56
WORKLOAD	57
DINA: Review Workload	57
DINA: Review Workload by Fee Category	57
DINA: Screening Workload	58
DINA: Screening Workload by Fee Category	58
DECISIONS	59
DINA: Number of Decisions by Fee Category	59
PERFORMANCE.....	60
DINA: Review Cycle Completions	60
DINA: Screening Cycle Completions.....	60
PDC: POST-AUTHORIZATION DIVISION 1 CHANGE.....	61
PDC: Number Received.....	61
PDC: Number of Decisions by Type	61
APPENDIX A: PRE-SUBMISSION MEETINGS	62
Pre-submission Meetings Held / Feedback Provided.....	62

OVERVIEW

The Therapeutic Products Directorate's (TPD) Quarterly Drug Submission Performance Report reflects pharmaceutical drug submission review activity over five consecutive quarters: from January - March 2020 to January - March 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 an [order to temporarily extend 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 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).

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 now included in the SNDS Received, Workload and Performance figures. SNDS-Cs 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. 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.

Any questions or comments on this report should be forwarded to:

Office of Submissions and Intellectual Property,
Resource Management and Operations Directorate
Finance Building, A.L. # 0202A1
101 Tunney's Pasture Driveway, Tunney's Pasture
Ottawa, Ontario, K1A 0K9

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

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

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

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)

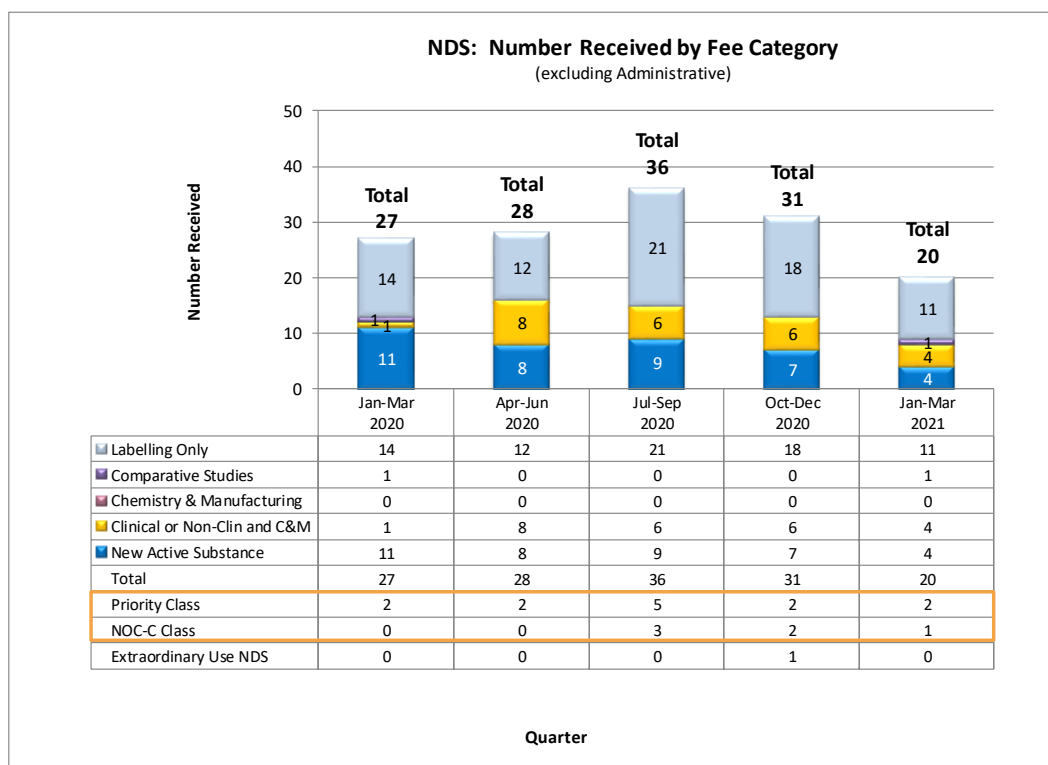
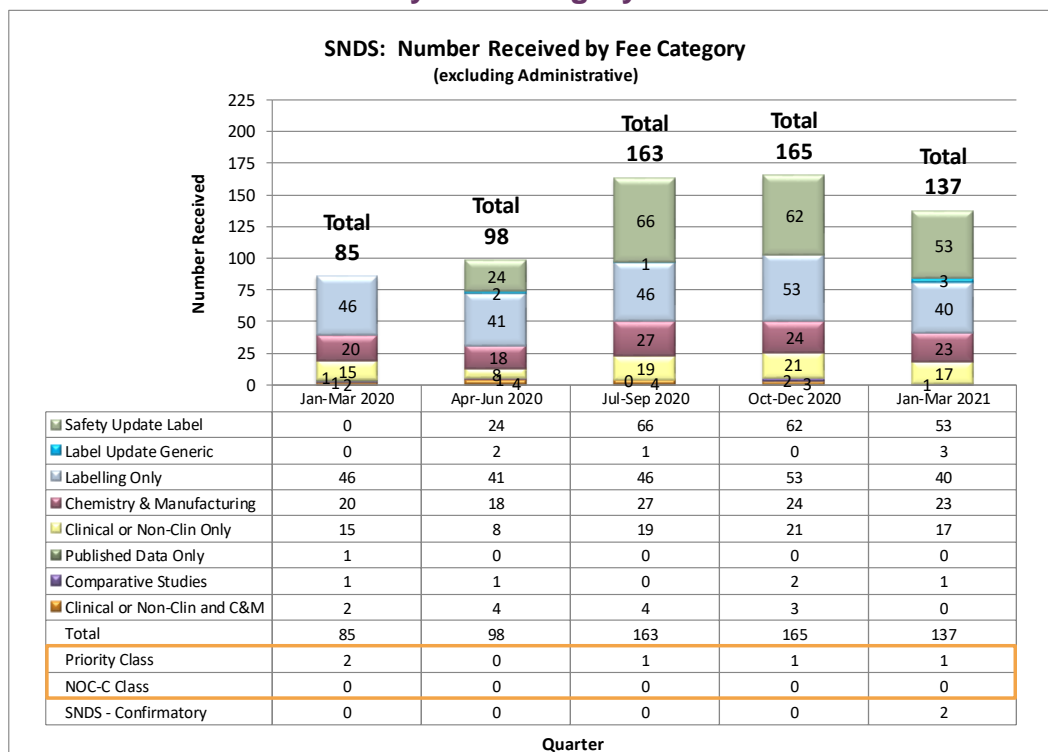
Fee Category	Description
Labelling only (generic drugs)	Submissions in support of a change to the labelling to be consistent with the Canadian reference product that do not include any additional labelling updates requiring a labelling assessment
Administrative submission	Submissions in support of a 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 SUBMISSION
(NDS)**

&

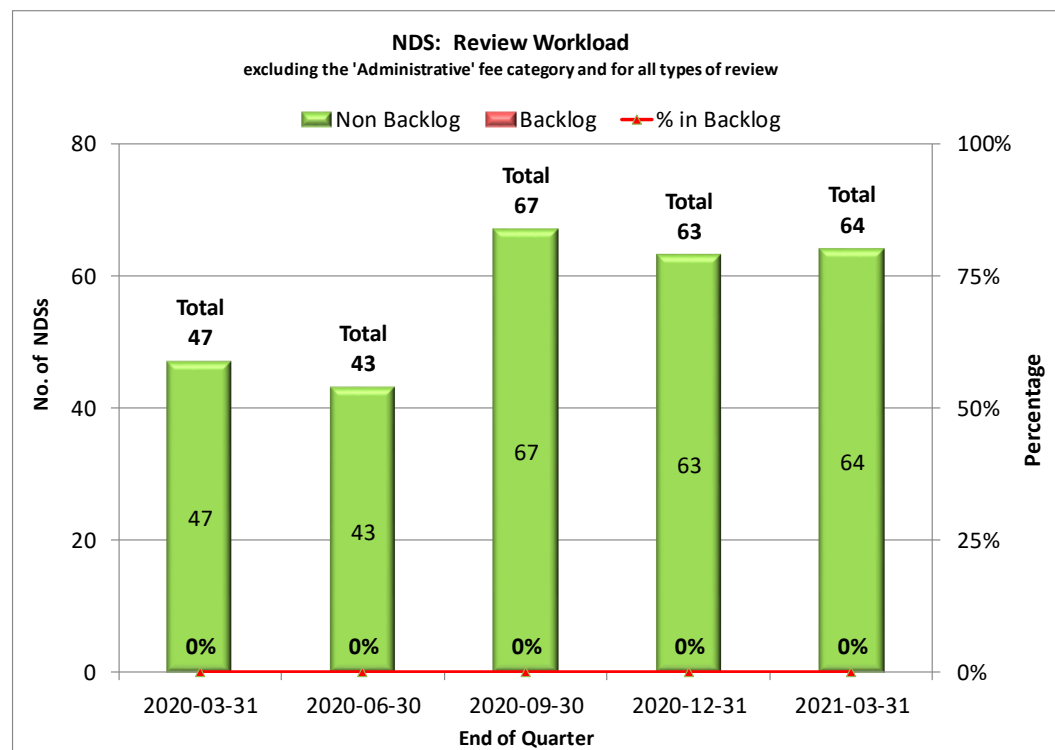
**SUPPLEMENT TO A NEW DRUG SUBMISSION
(SNDS)**

SUBMISSIONS RECEIVED ⁷**NDS: Number Received by Fee Category****SNDS: Number Received by Fee Category**

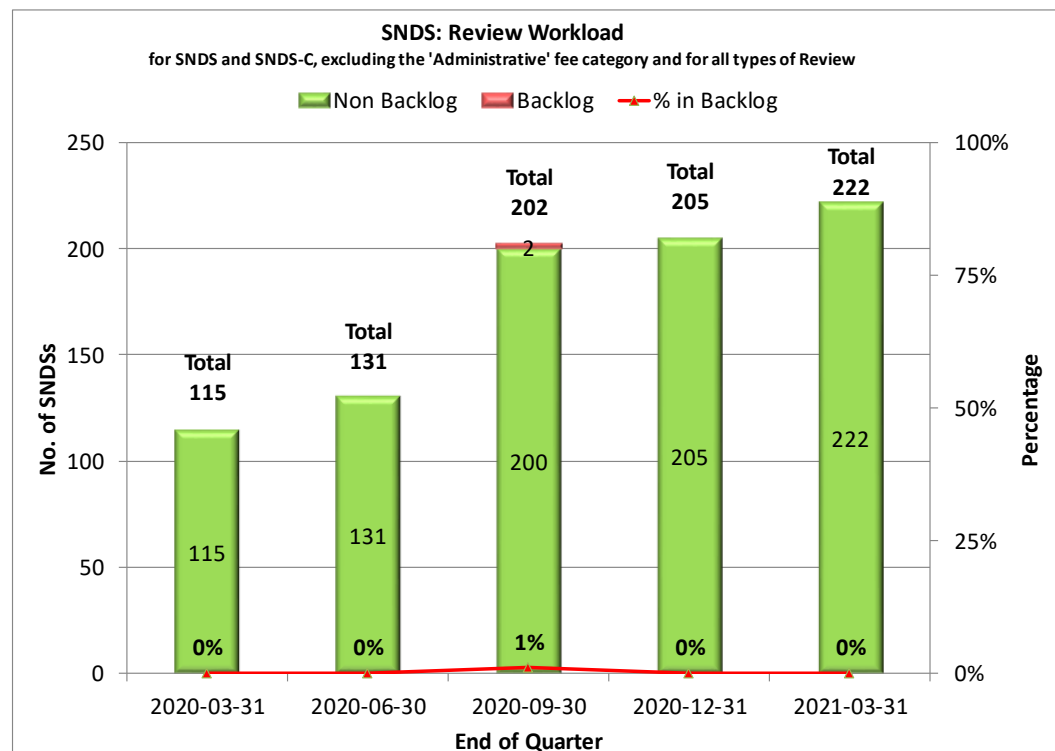
⁷ Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the [Priority Review of Drug Submissions Policy](#), the [Notice of Compliance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

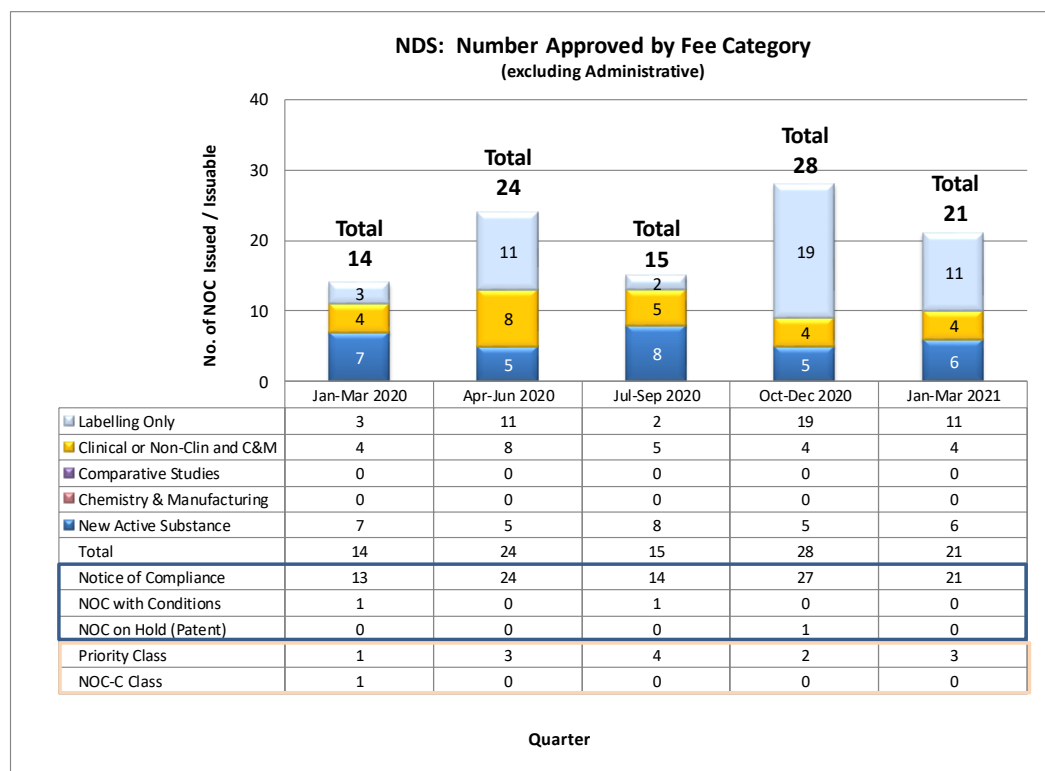
NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Labelling Only	4	4	23	16	17
Backlog	0	0	0	0	0
Comparative Studies	0	1	0	0	0
Backlog	0	0	0	0	0
Chemistry & Manufacturing	0	0	0	0	0
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	24	16	20	20	22
Backlog	0	0	0	0	0
New Active Substance	19	22	24	27	25
Backlog	0	0	0	0	0
Total	47	43	67	63	64
Non Backlog	47	43	67	63	64
Backlog	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%
Priority (subset)	8	6	5	7	6
Backlog	0	0	0	0	0

SNDS: Review Workload by Fee Category

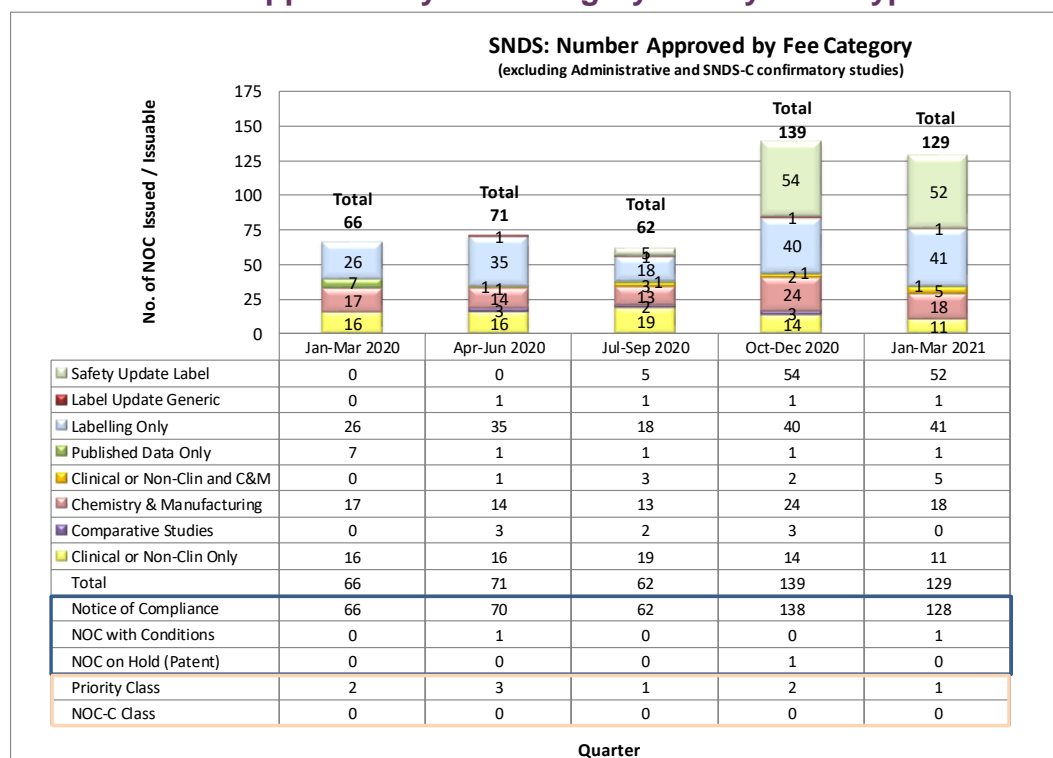
SNDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Labelling Only	24	19	48	47	49
Backlog	0	0	1	0	0
Comparative Studies	5	5	4	0	1
Backlog	0	0	0	0	0
Chemistry & Manufacturing	26	35	43	37	47
Backlog	0	0	0	0	0
Clinical or Non-Clin Only	49	47	37	44	53
Backlog	0	0	1	0	0
Clinical or Non-Clin and C&M	8	9	10	11	9
Backlog	0	0	0	0	0
Published Data	3	3	2	1	0
Backlog	0	0	0	0	0
Label Update Generic	0	1	0	0	2
Backlog	0	0	0	0	0
Safety Update Label	0	12	58	65	61
Backlog	0	0	0	0	0
Total	115	131	202	205	222
Non Backlog	115	131	200	205	222
Backlog	0	0	2	0	0
% in Backlog	0%	0%	1%	0%	0%
Priority (subset)	4	3	3	1	2
Backlog	0	0	1	0	0
SNDS-C (Confirmatory)	1	0	0	0	1
Backlog	0	0	0	0	0

APPROVALS ⁸

NDS: Number Approved by Fee Category and by NOC Type



SNDS: Number Approved by Fee Category and by NOC Type

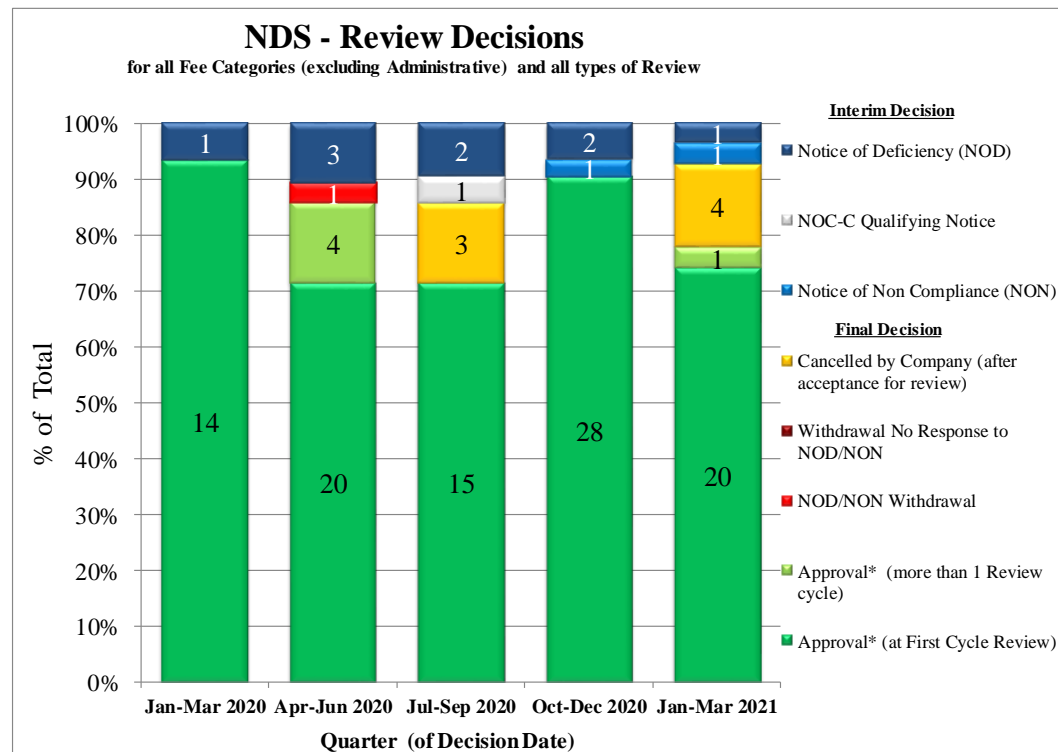


⁸ Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the [Priority Review of Drug Submissions Policy](#), the [Notice of Compliance with conditions \(NOC/c\) Guidance](#) and the [Management of Drug Submissions Guidance](#).

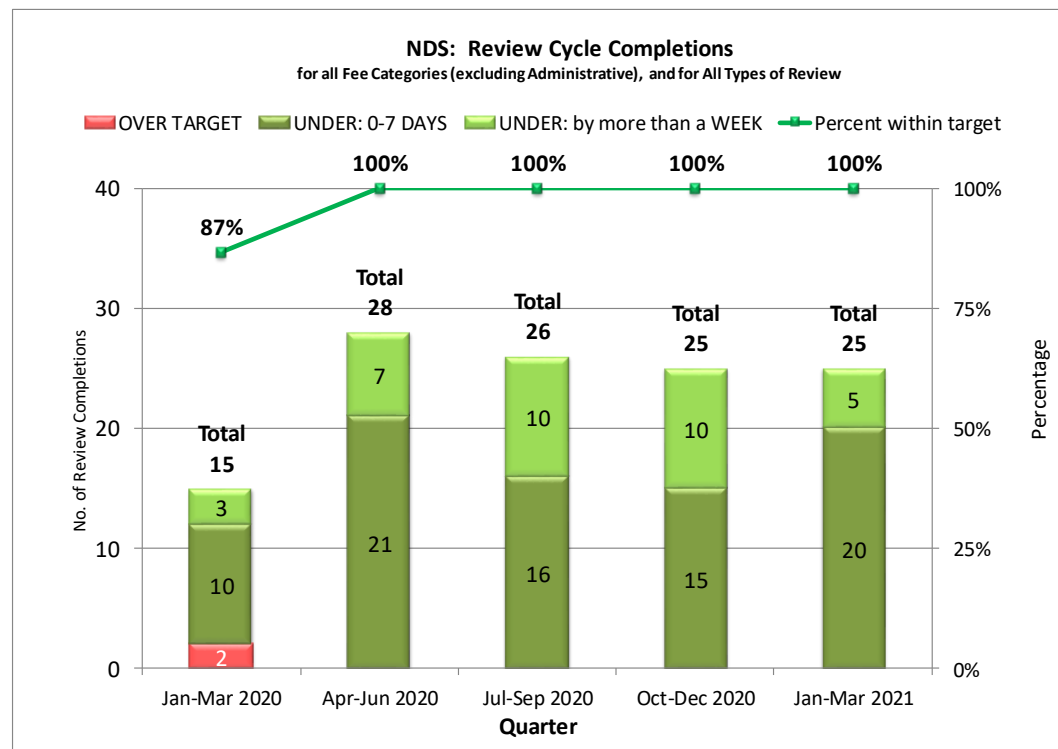
This page is left blank intentionally.

REVIEW PERFORMANCE

NDS: Review Decisions by Type

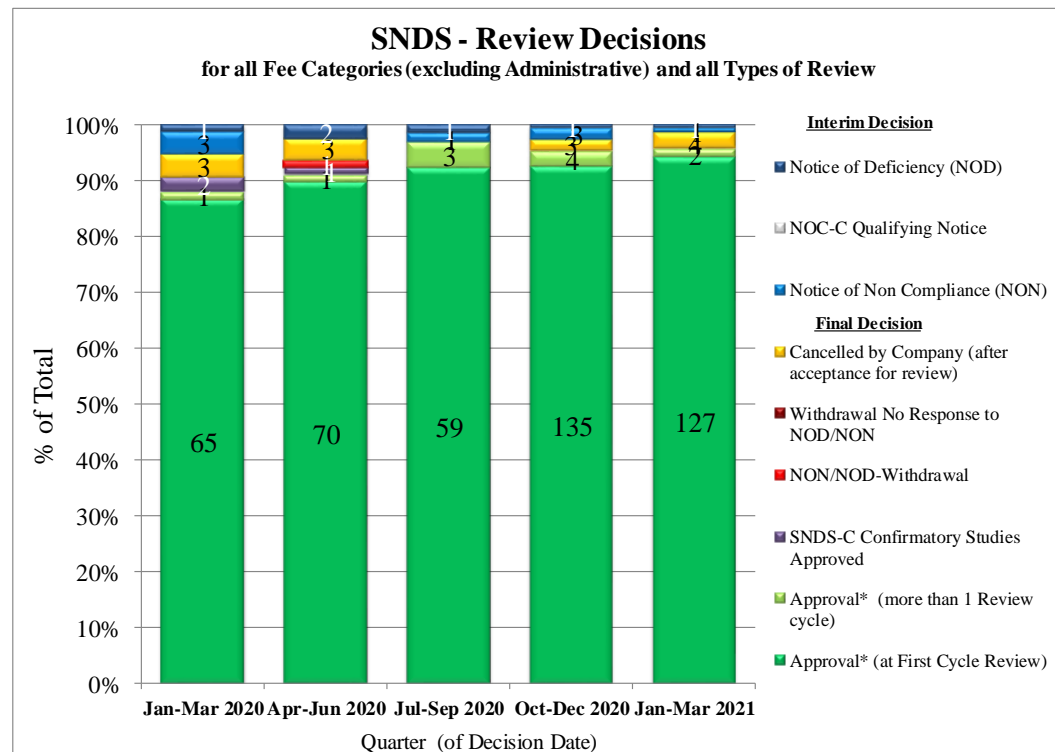


NDS: Review Cycle Completions

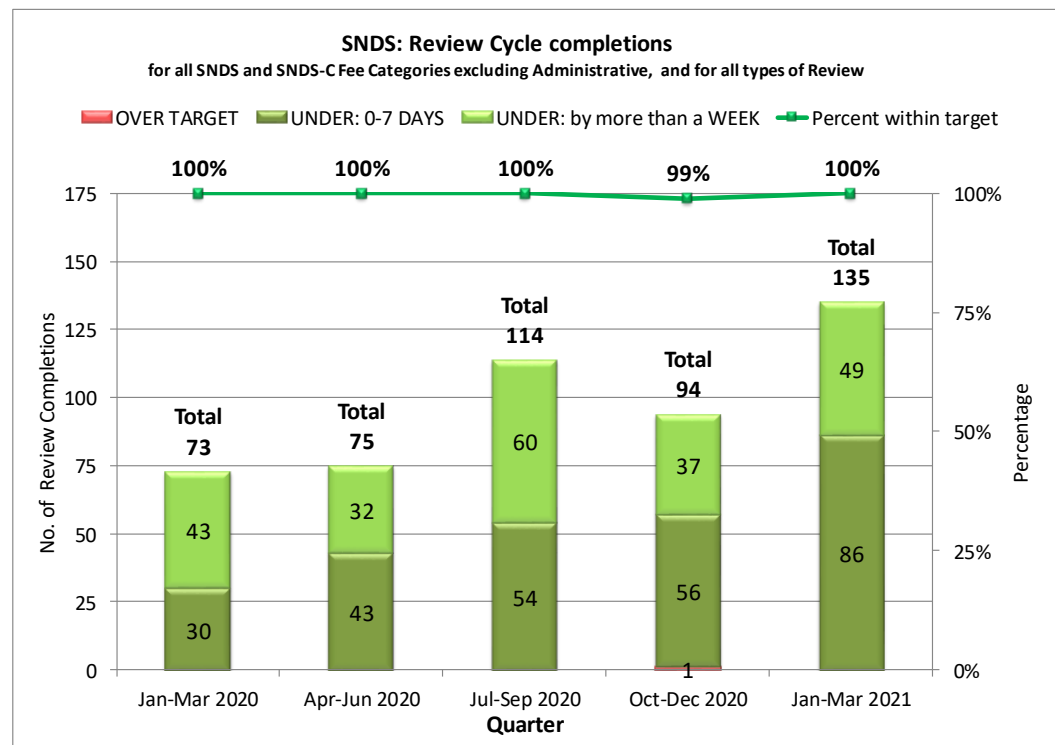


REVIEW CYCLE DECISIONS

SNDS: Review Decisions by Type

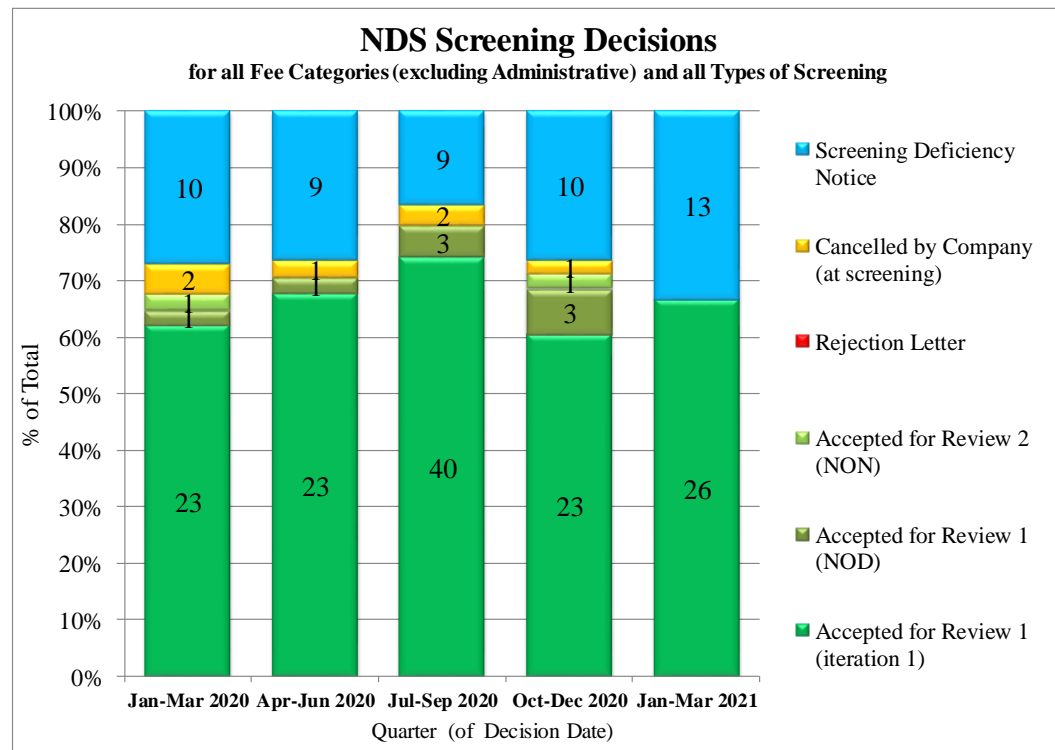


SNDS: Review Cycle Completions

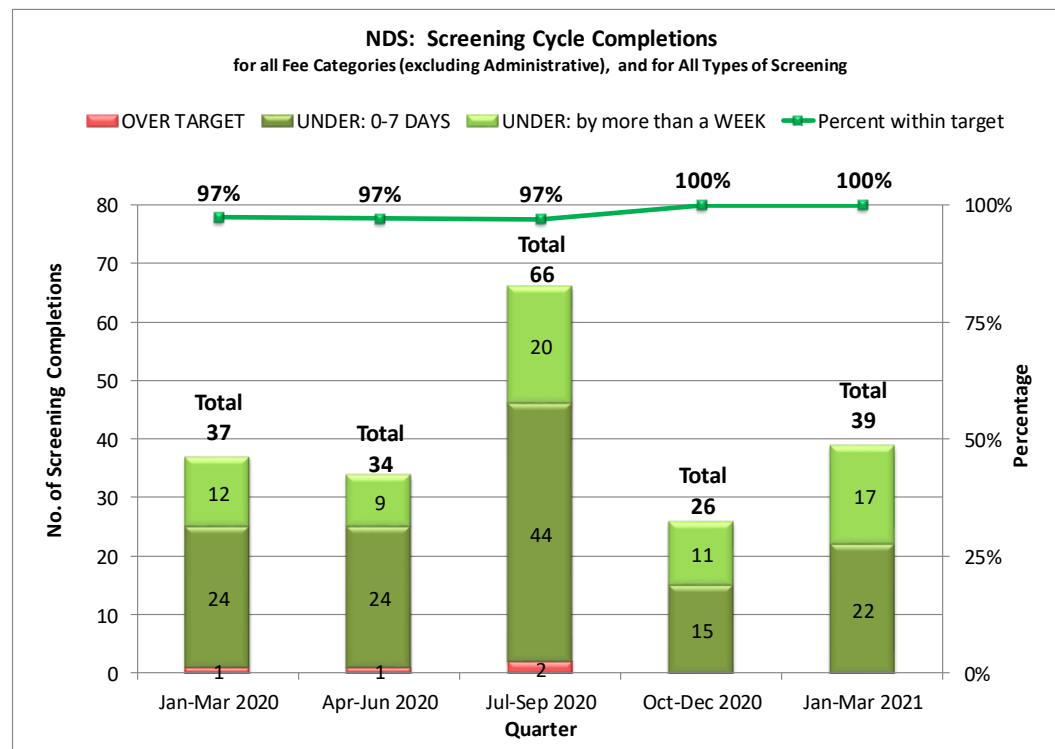


SCREENING PERFORMANCE

NDS: Screening Decisions by Type

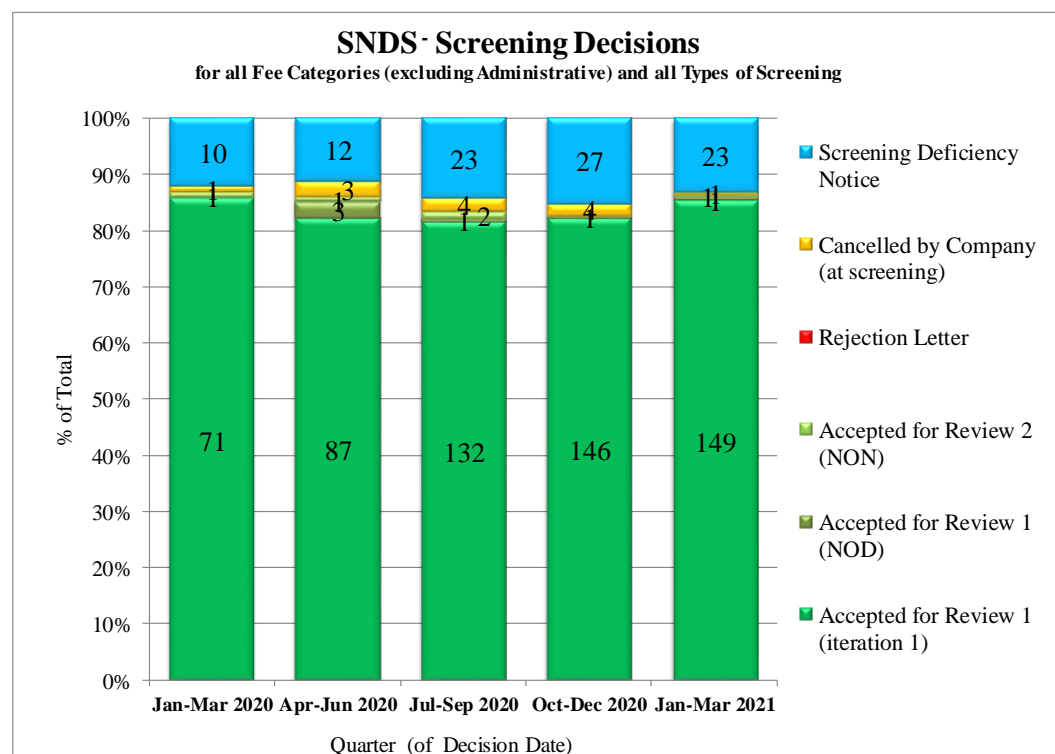


NDS: Screening Cycle Completions

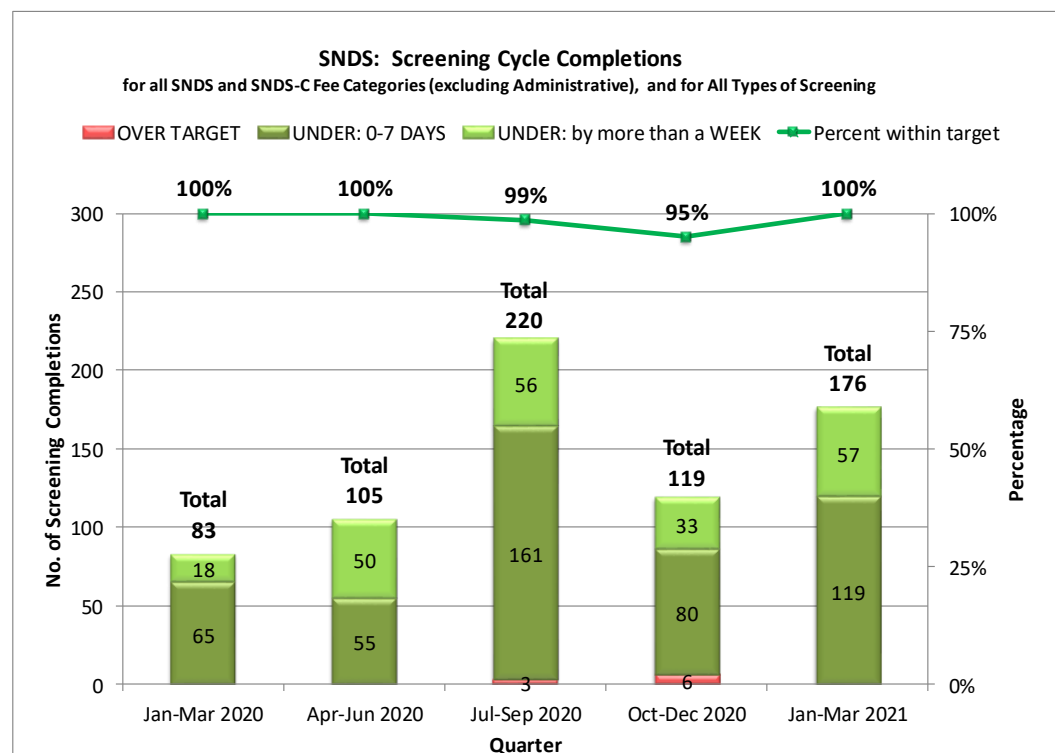


SCREENING CYCLE DECISIONS

SNDS: Screening Decisions by Type



SNDS: Screening Cycle Completions



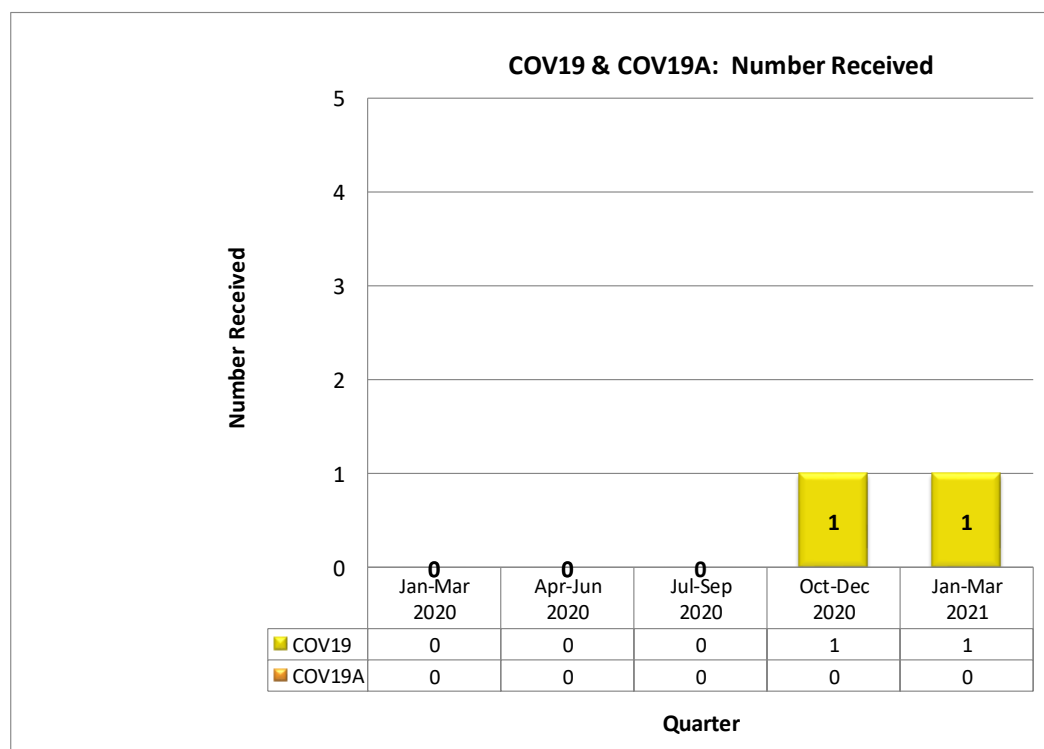
**Application under the Interim Order Respecting the
Importation, Sale and Advertising of Drugs for Use in
Relation to COVID-19
(COV19)**

&

**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)**

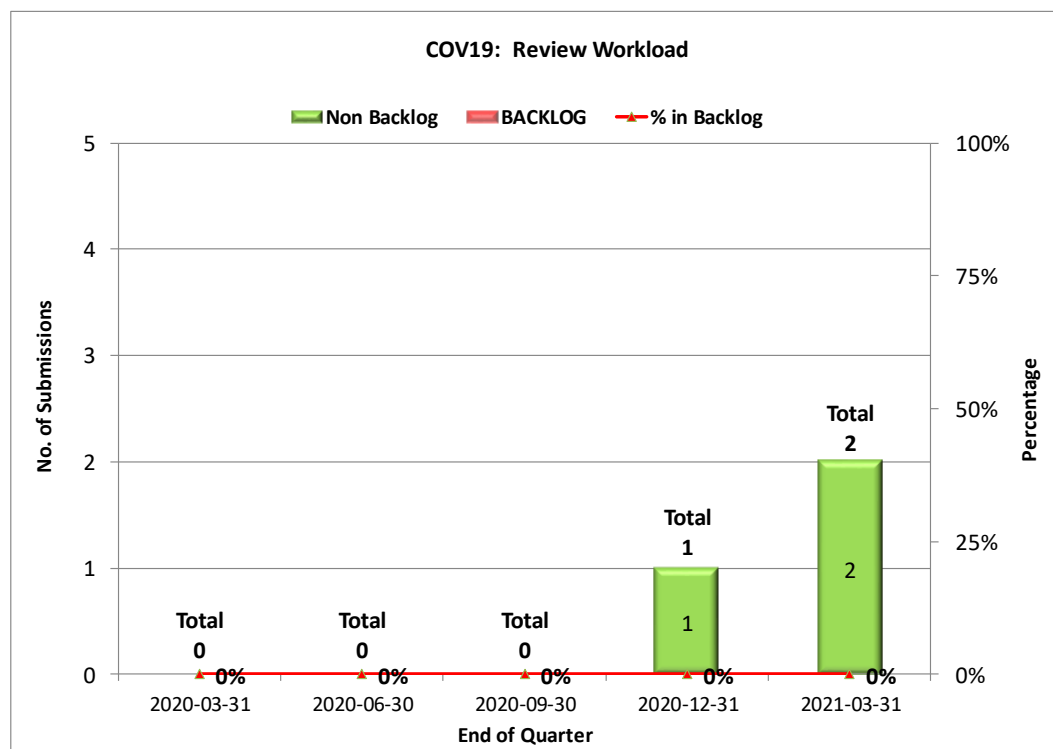
SUBMISSIONS RECEIVED

COVID19 & COVID19A: Number Received



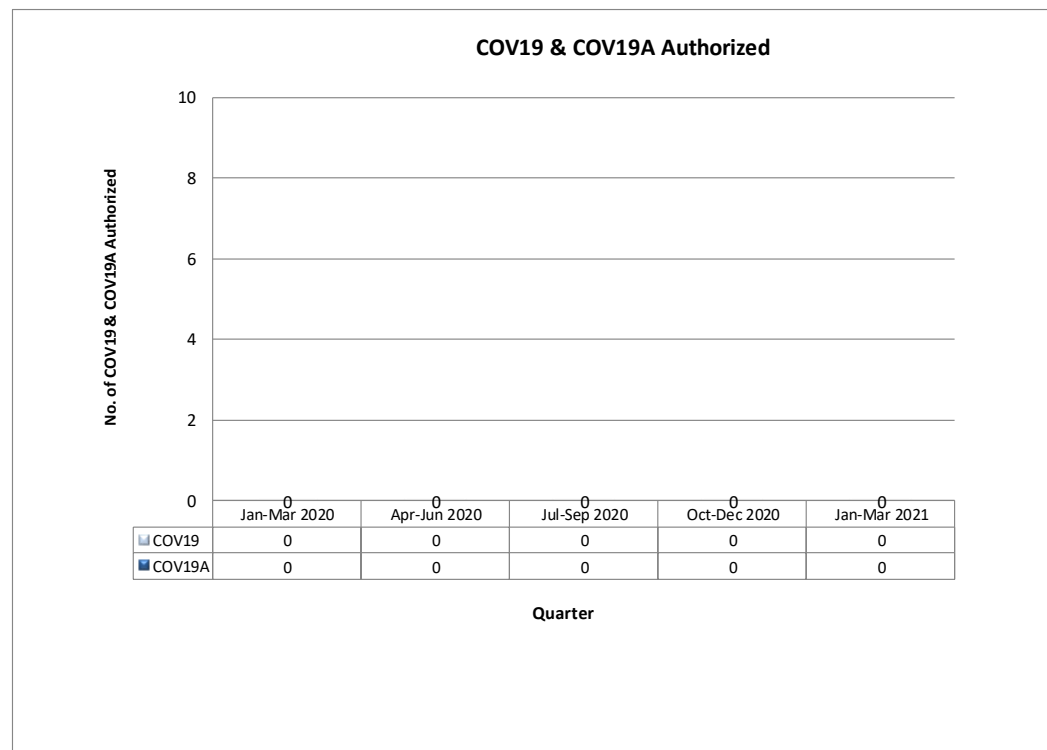
WORKLOAD

COVID19: Review Workload



AUTHORIZATIONS

COV19 & COV19A: Number Authorized



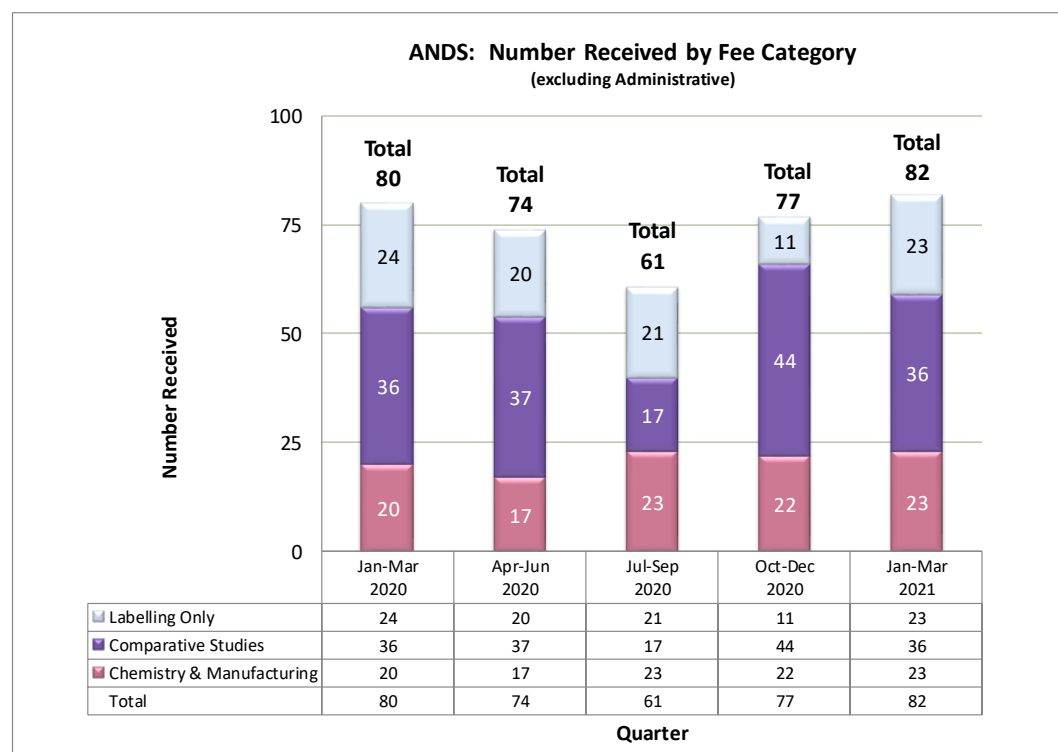
**Abbreviated New Drug Submissions
(ANDS)**

&

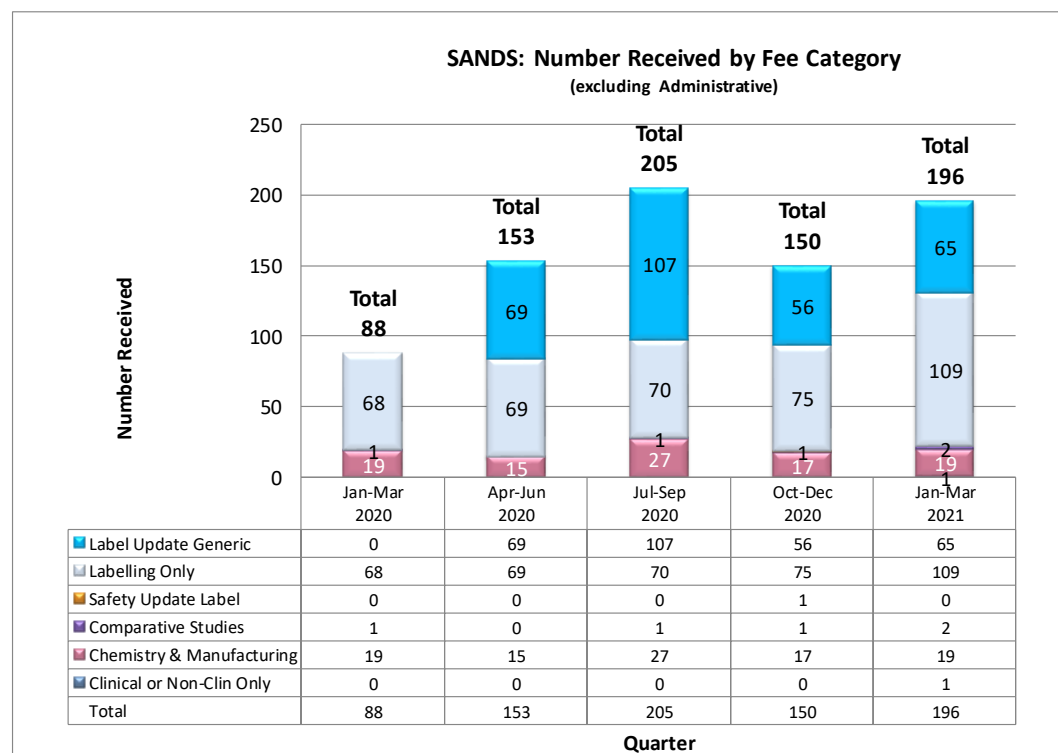
**Supplement to an Abbreviated New Drug
Submissions (SANDS)**

SUBMISSIONS RECEIVED

ANDS: Number Received by Fee Category

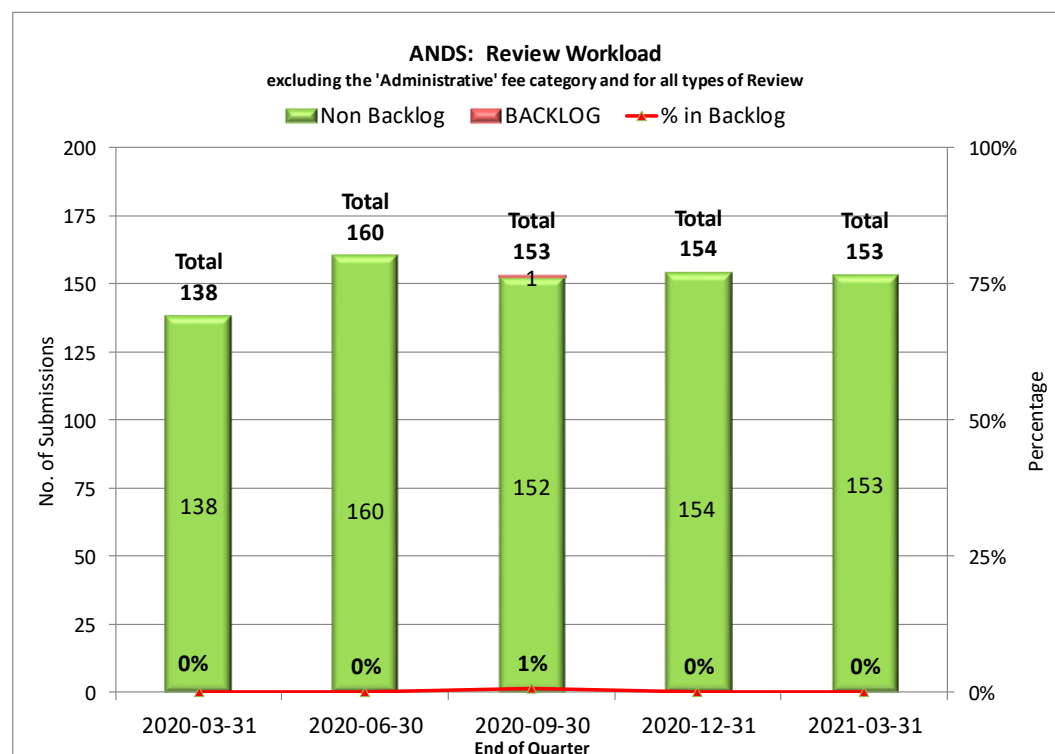


SANDS: Number Received by Fee Category

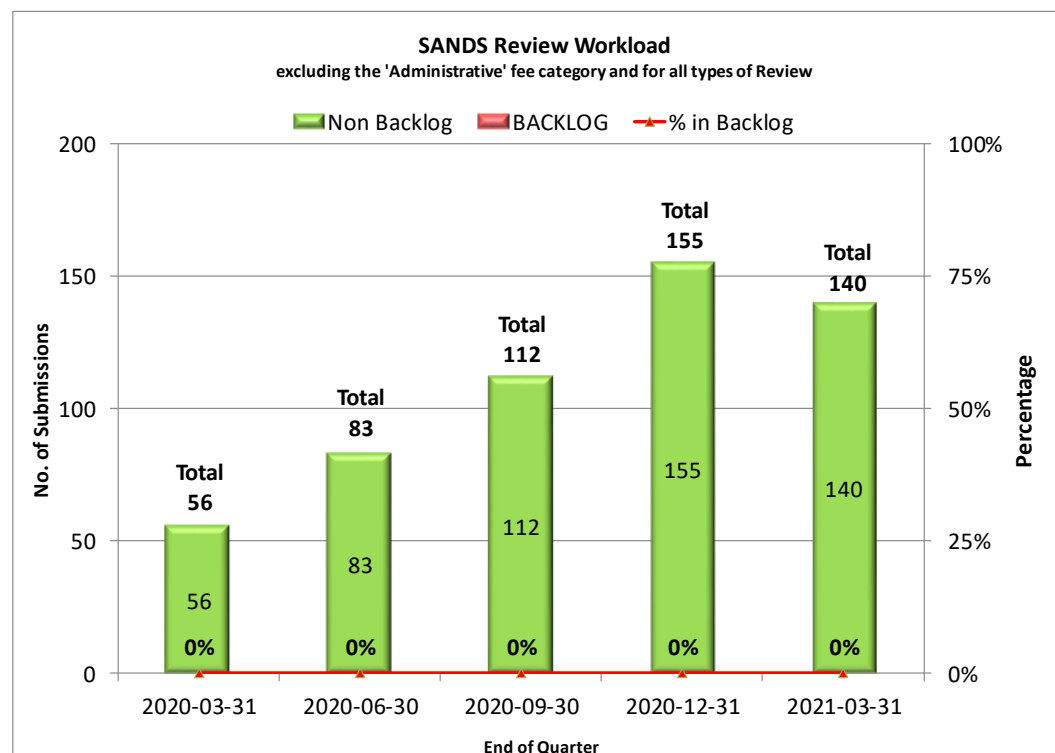


WORKLOAD

ANDS: Review Workload



SANDS: Review Workload



WORKLOAD

ANDS: Review Workload by Fee Category

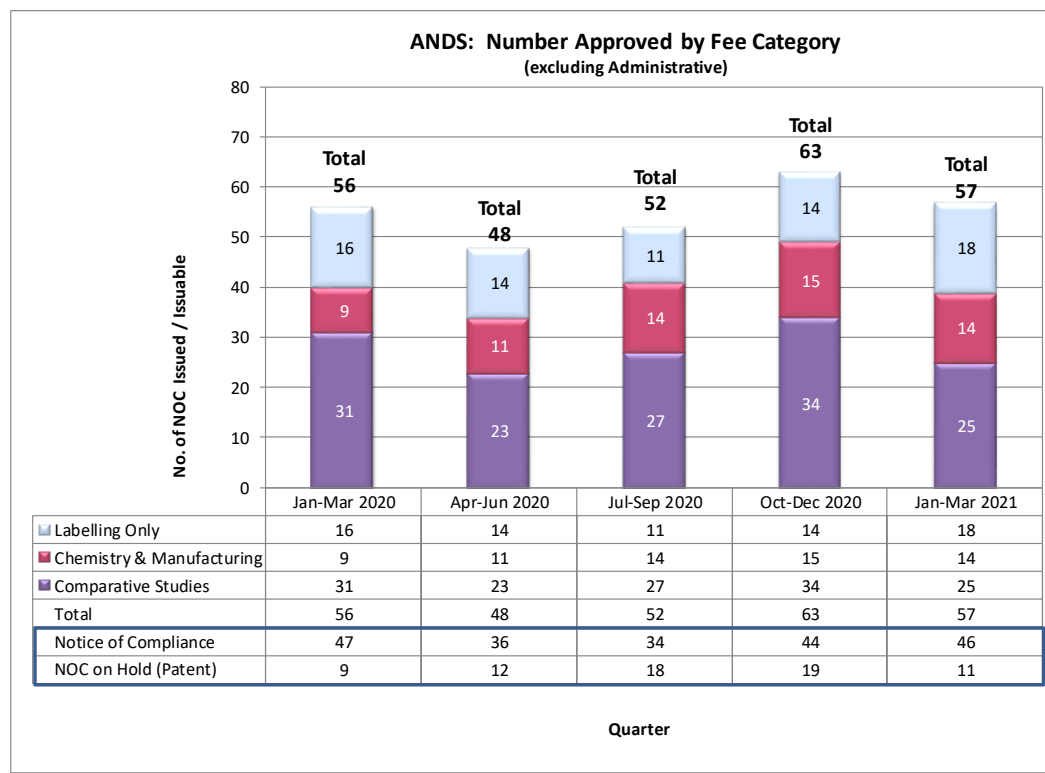
ANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Chemistry & Manufacturing	42	47	51	54	53
Backlog	0	0	1	0	0
Comparative Studies	88	103	84	79	89
Backlog	0	0	0	0	0
Labelling Only	8	10	18	21	11
Backlog	0	0	0	0	0
Total	138	160	153	154	153
Non Backlog	138	160	152	154	153
BACKLOG	0	0	1	0	0
% in Backlog	0%	0%	1%	0%	0%

SANDS: Review Workload by Fee Category

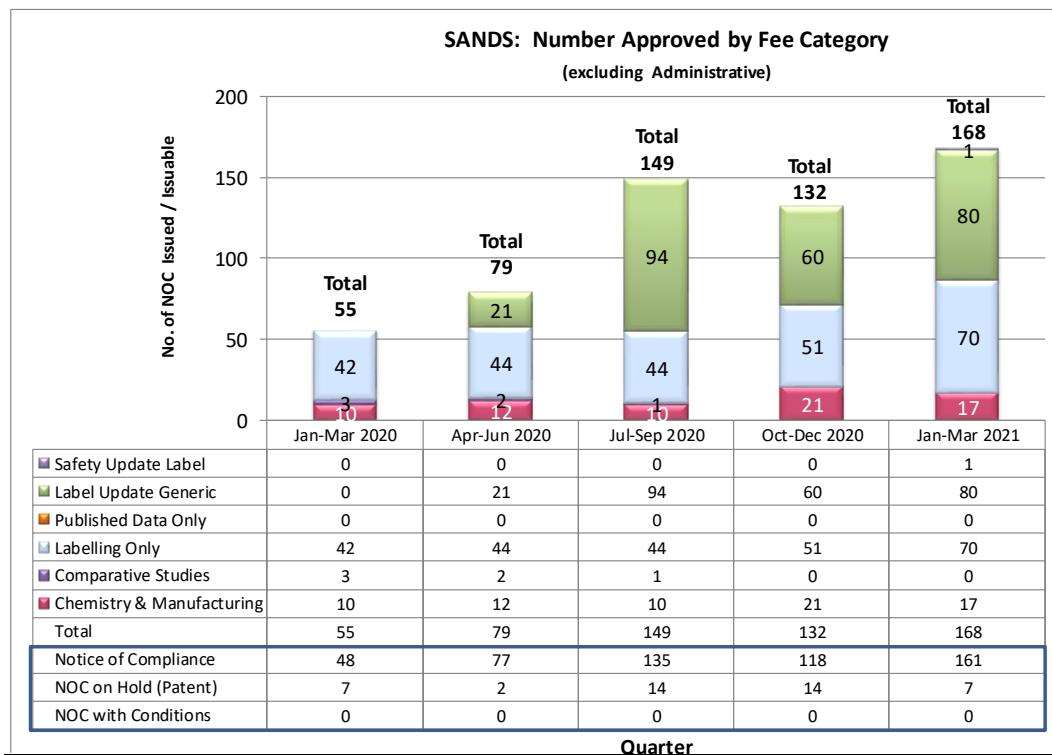
SANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Chemistry & Manufacturing	24	28	37	40	30
Backlog	0	0	0	0	0
Comparative Studies	3	1	0	0	1
Backlog	0	0	0	0	0
Labelling Only	29	31	54	85	91
Backlog	0	0	0	0	0
Label Update Generic	0	23	21	29	18
Backlog	0	0	0	0	0
Safety Update Label	0	0	0	1	0
Backlog	0	0	0	0	0
Total	56	83	112	155	140
Non Backlog	56	83	112	155	140
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

APPROVALS

ANDS: Number Approved by Fee Category and by NOC Type



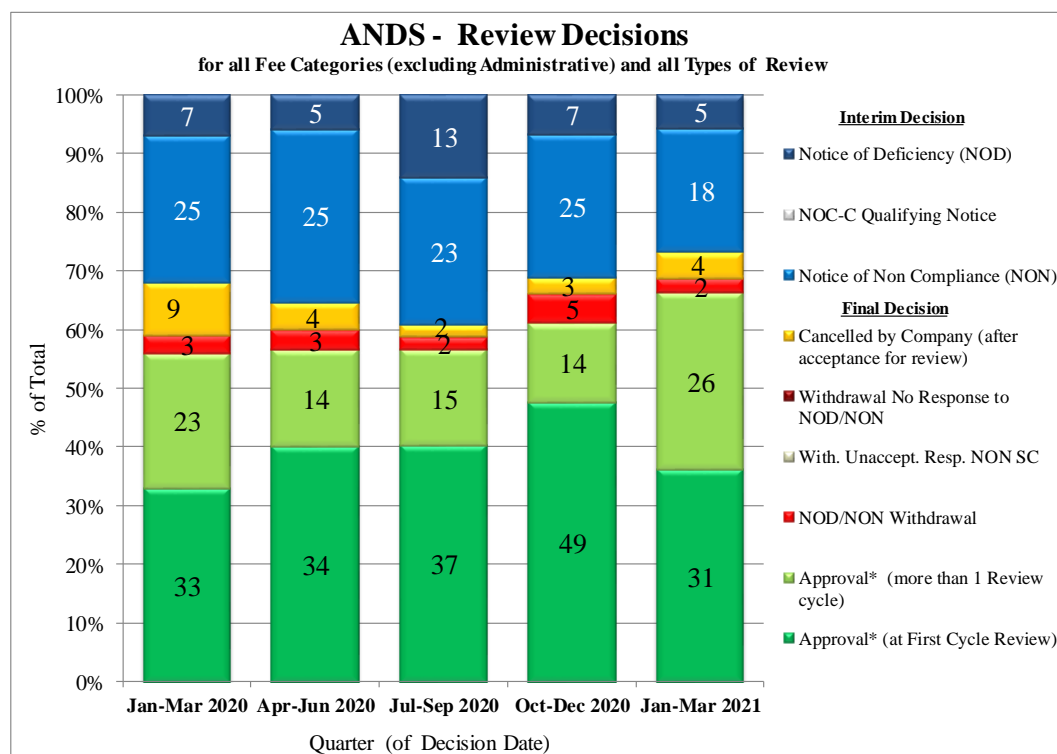
SANDS: Number Approved by Fee Category and by NOC Type



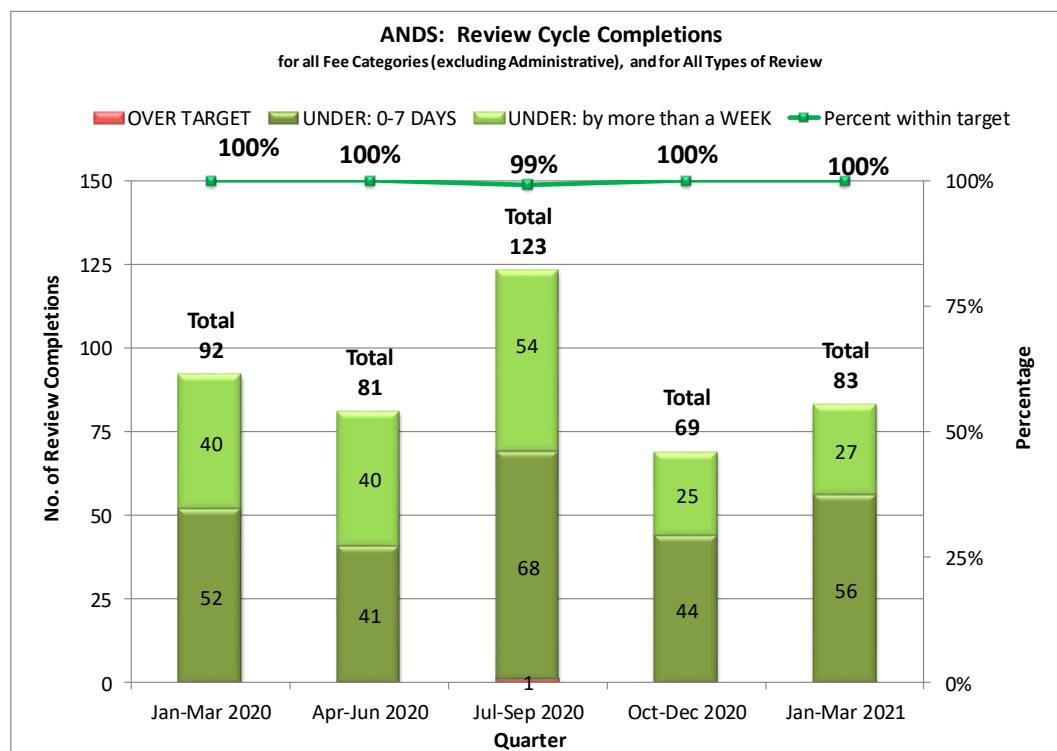
This page is left blank intentionally.

REVIEW PERFORMANCE

ANDS: Review Decisions by Type

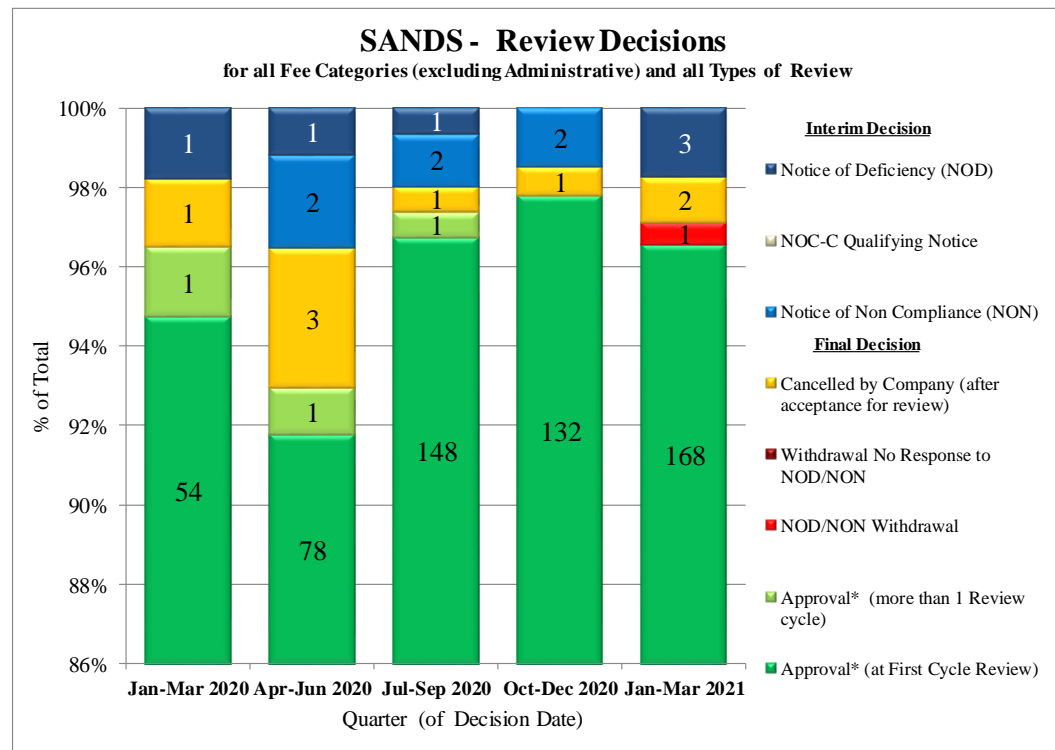


ANDS: Review Cycle Completions

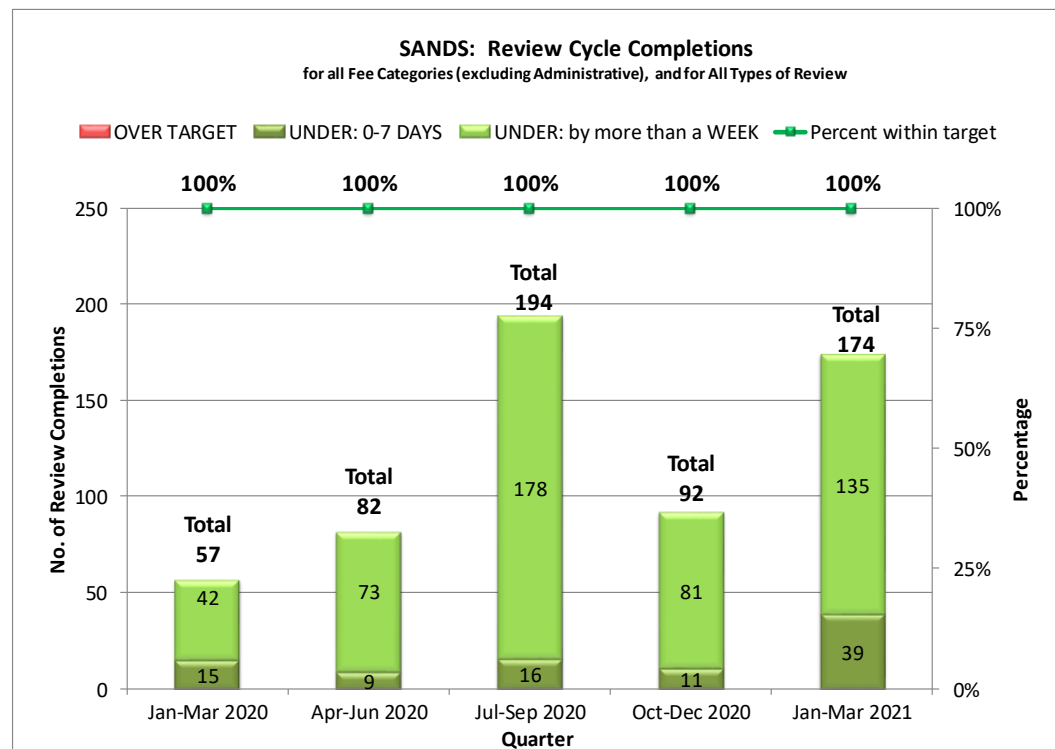


REVIEW PERFORMANCE

SANDS: Review Decisions by Type

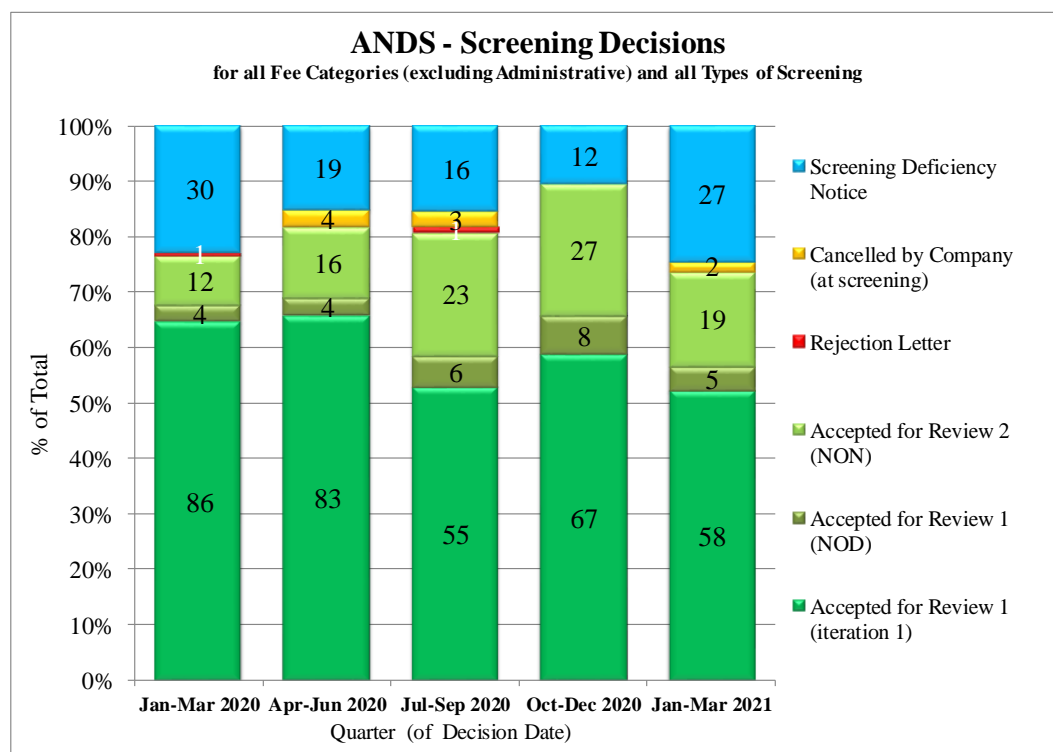


SANDS: Review Cycle Completions

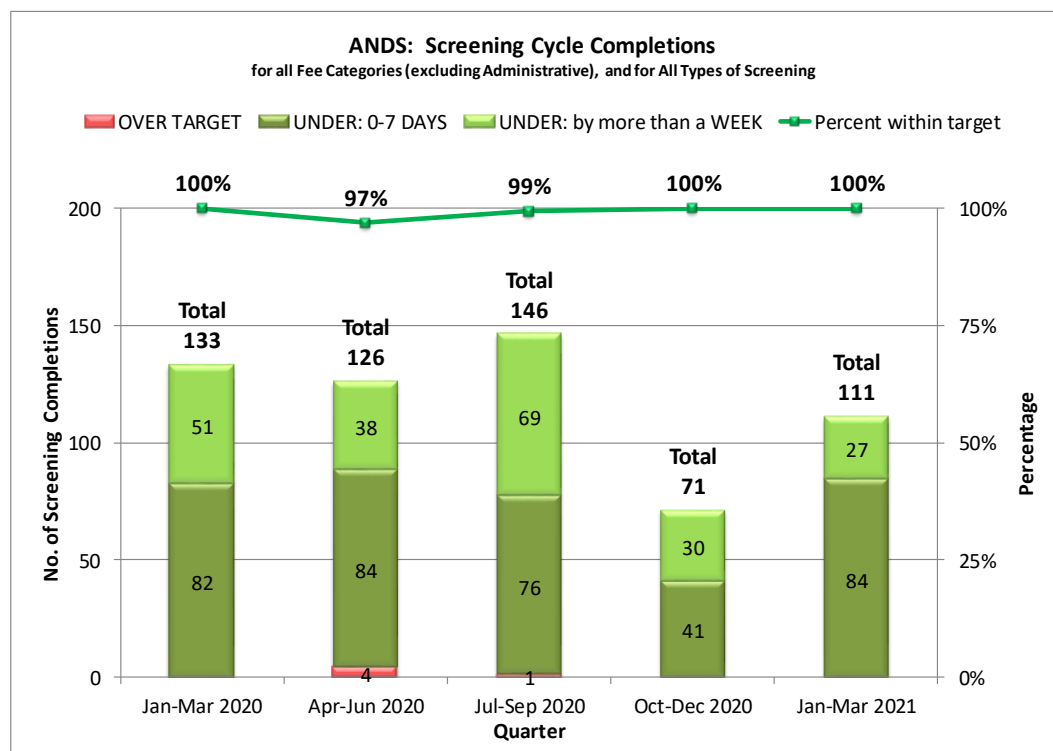


SCREENING PERFORMANCE

ANDS: Screening Decisions by Type

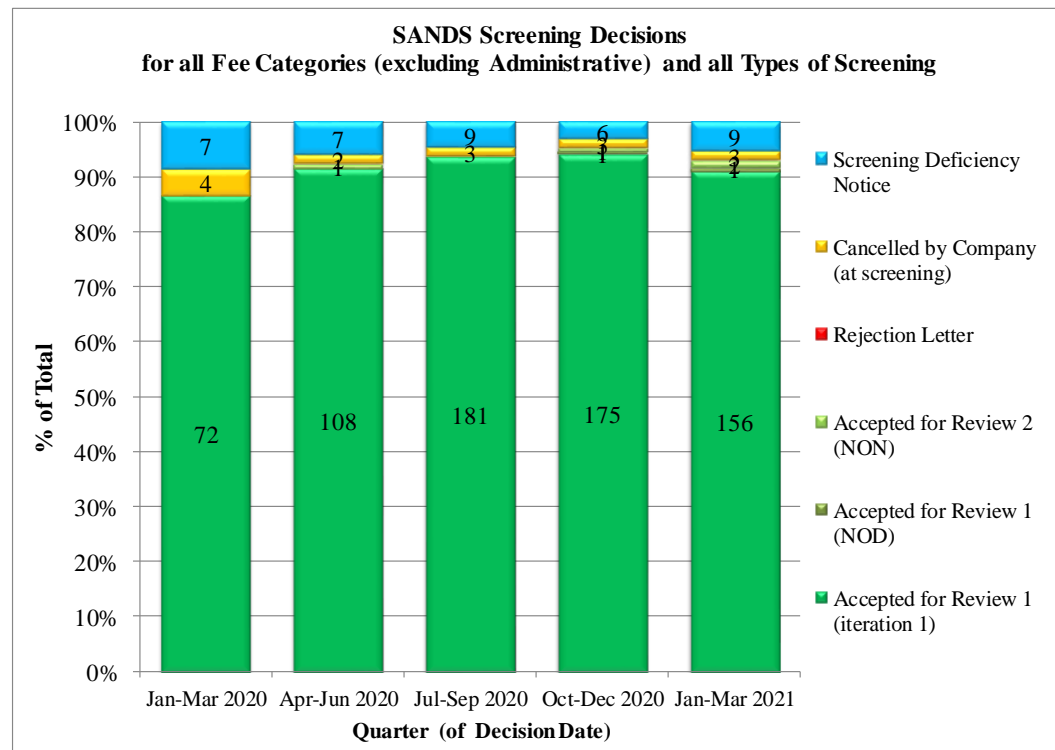


ANDS: Screening Cycle Completions

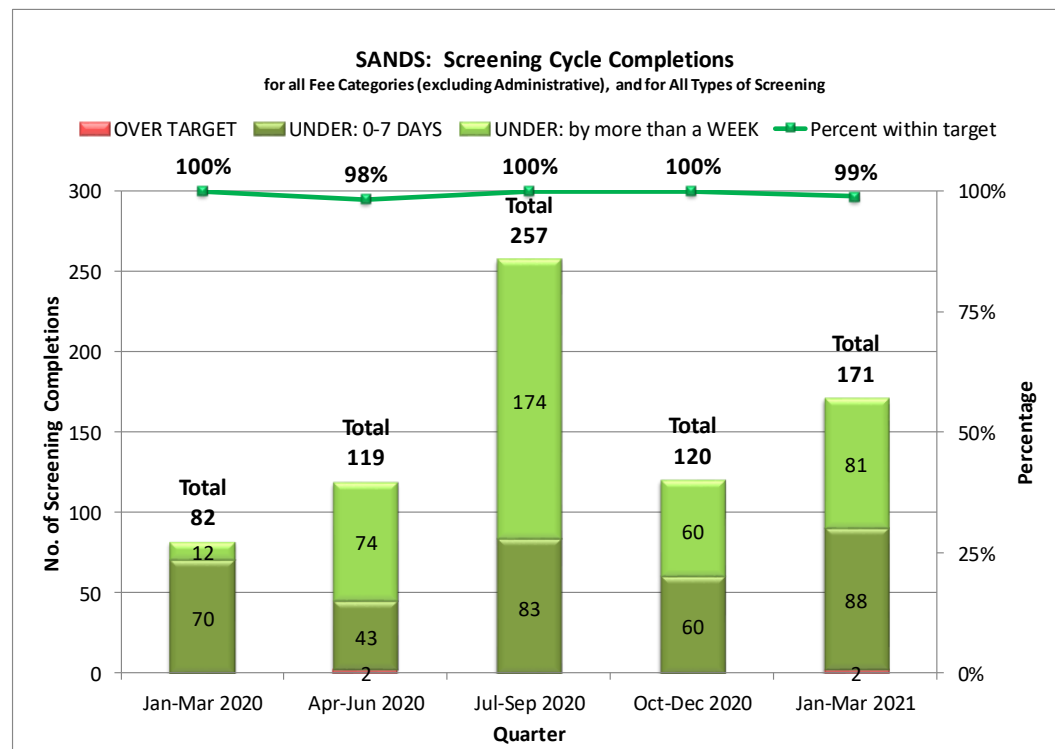


SCREENING PERFORMANCE

SANDS: Screening Decisions by Type

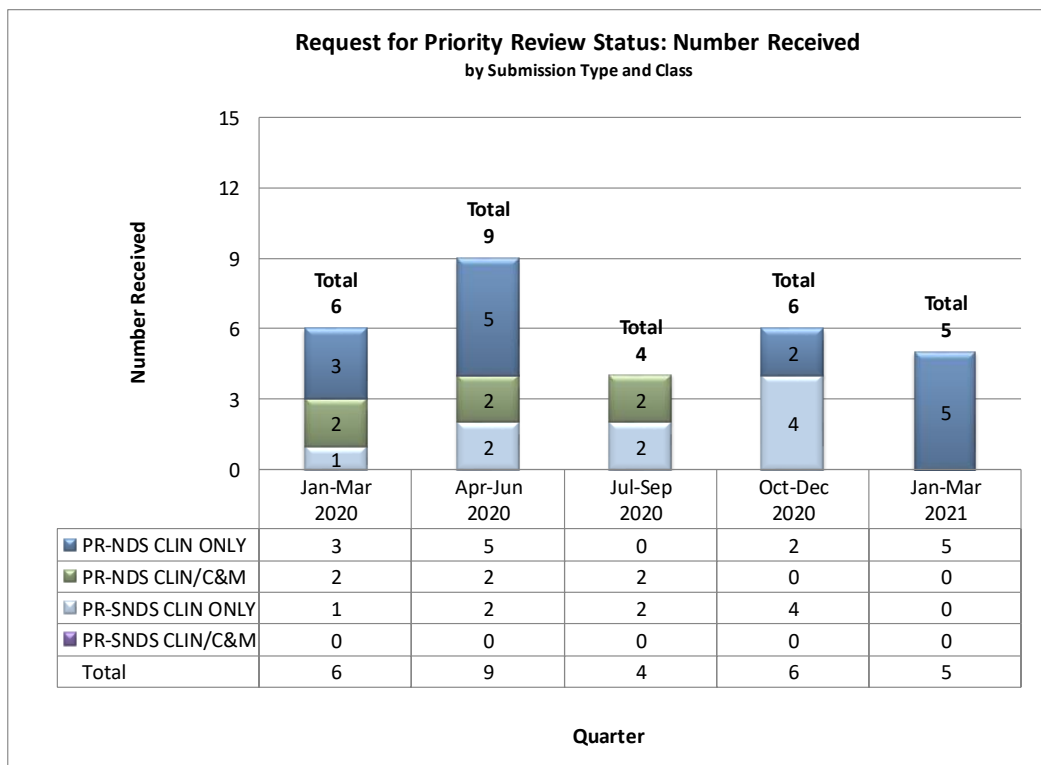


SANDS: Screening Cycle Completions

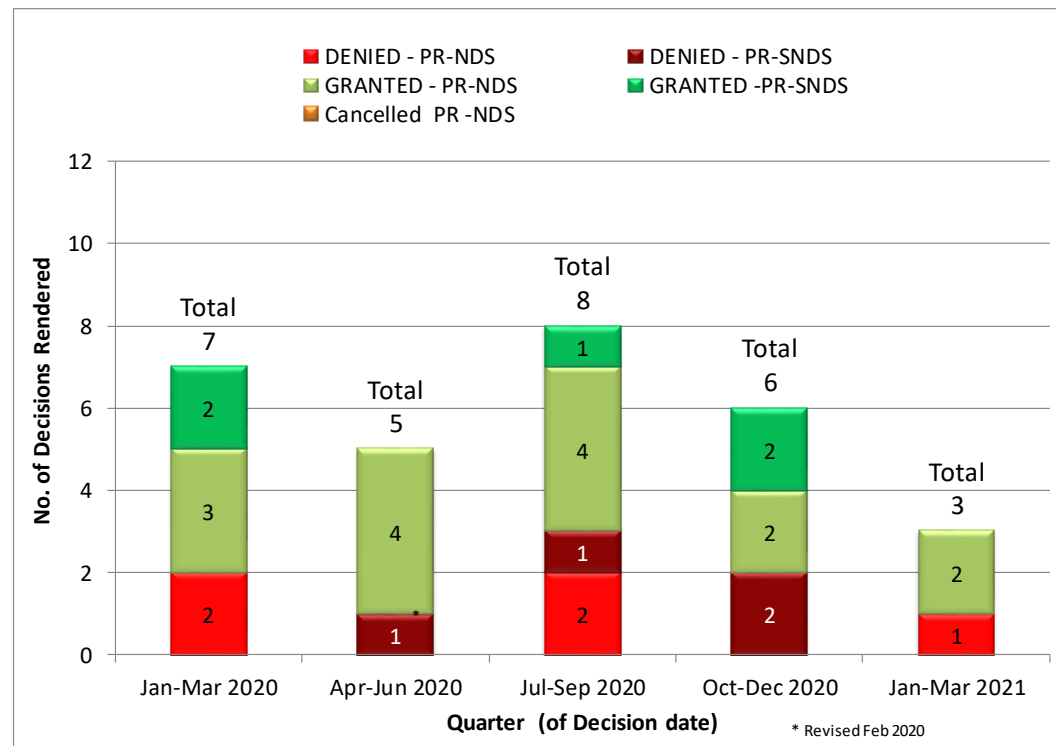


REQUEST FOR PRIORITY REVIEW STATUS (for NDS & SNDS)

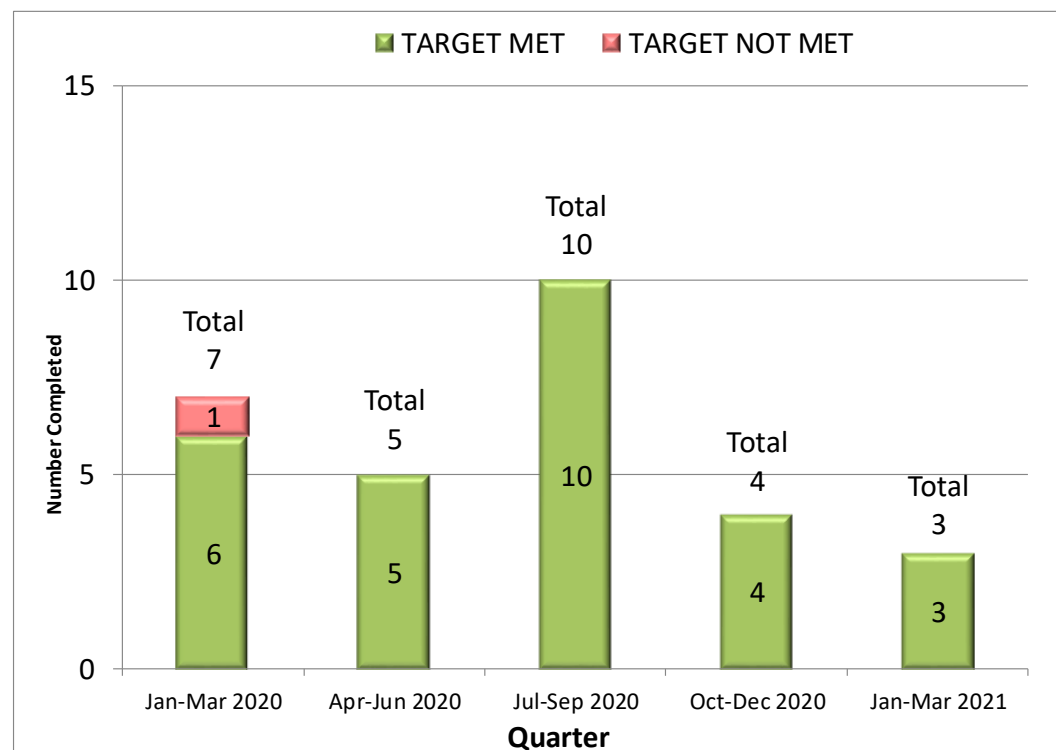
Request for Priority Review Status: Number Received



Request for Priority Review Status: Decisions Rendered



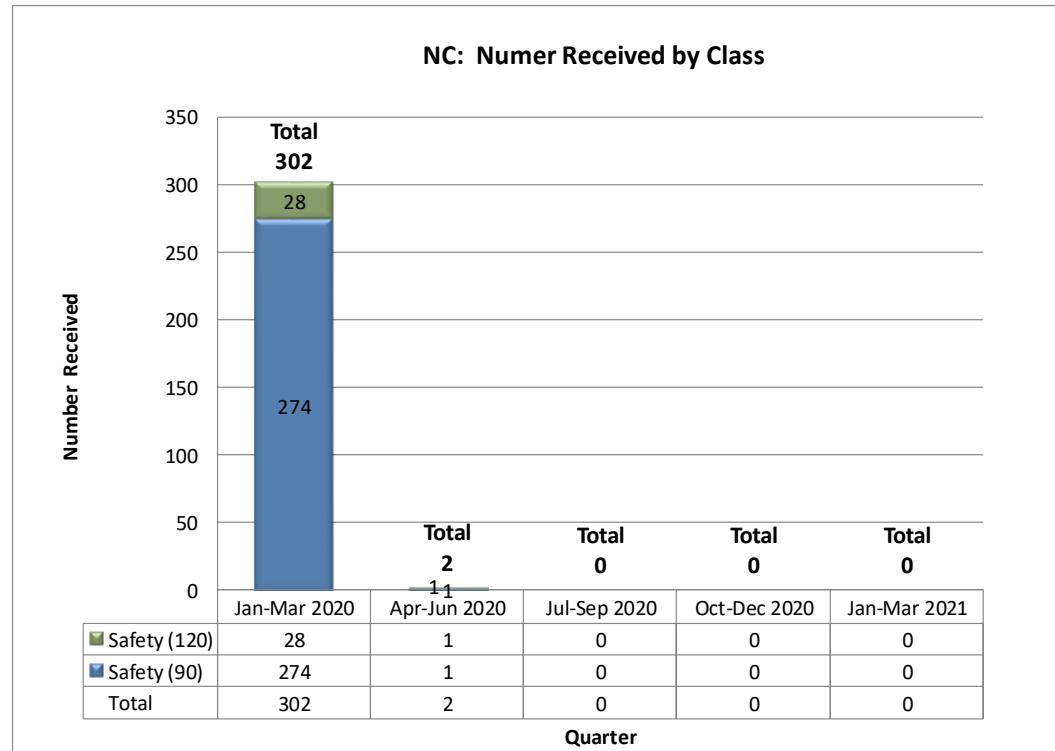
Request for Priority Review Status: Performance



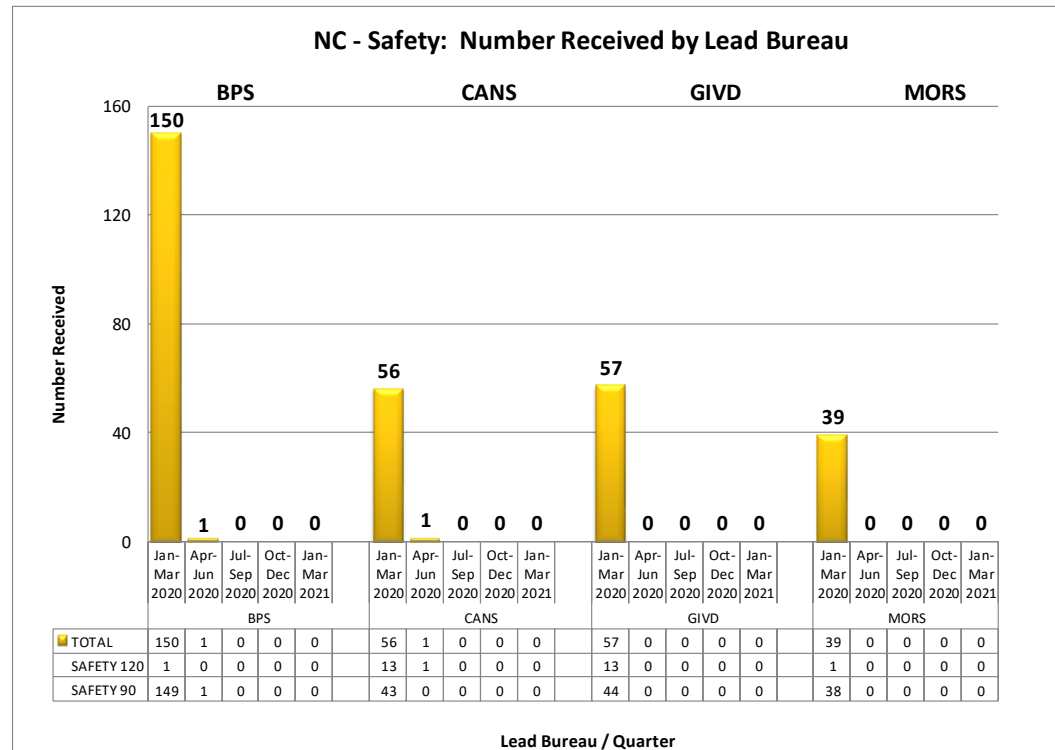
NC: NOTIFIABLE CHANGE

NOTIFIABLE CHANGE RECEIVED

NC: Number Received by Class

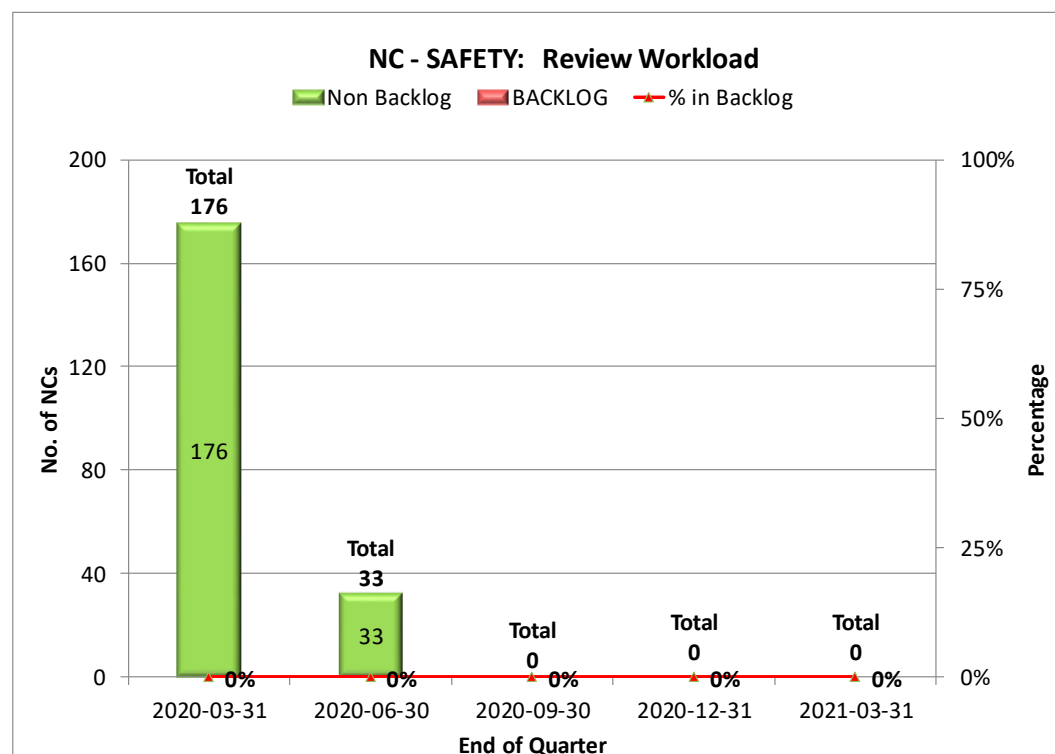


NC-SAFETY: Number Received by Lead Bureau



WORKLOAD

NC-SAFETY: Review Workload

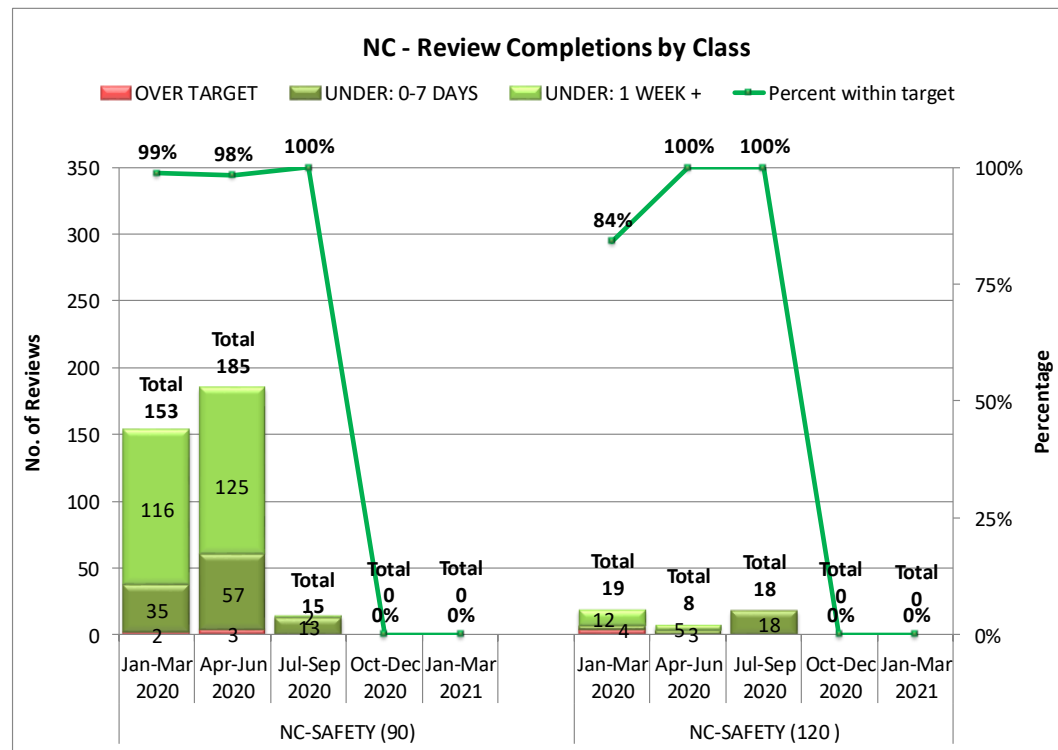


NC-SAFETY: Review Workload by Class

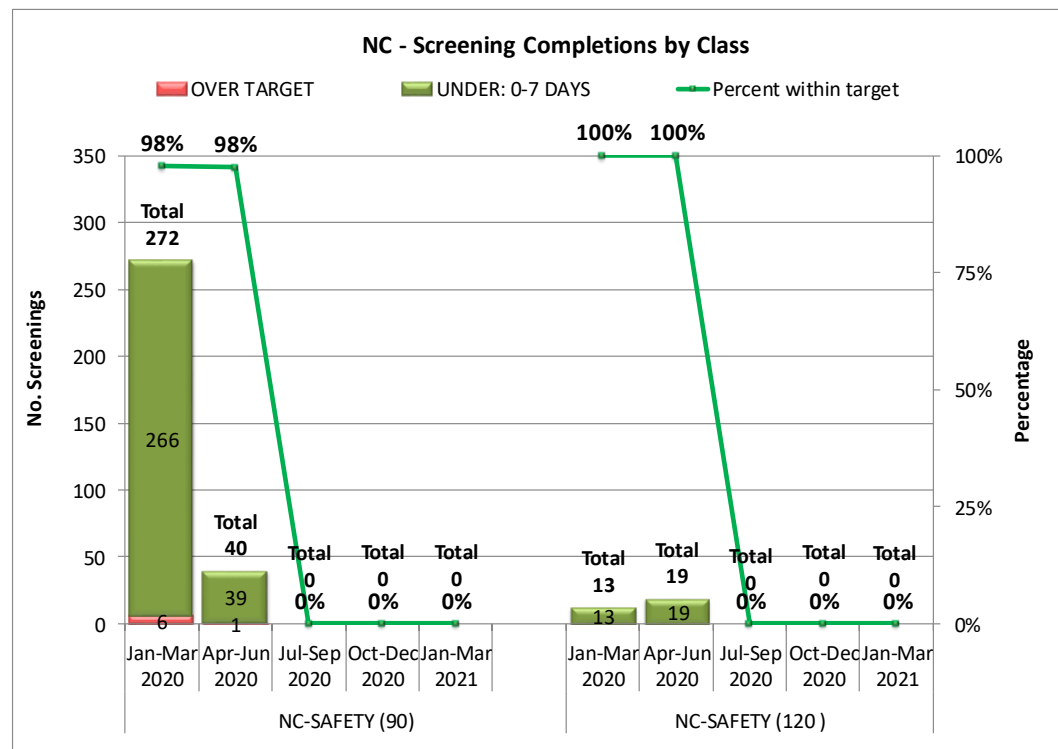
TPD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
Class	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
SAFETY - 90 day	166	15	0	0	0
Backlog	0	0	0	0	0
SAFETY - 120 day	10	18	0	0	0
Backlog	0	0	0	0	0
Total	176	33	0	0	0
Non Backlog	176	33	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

PERFORMANCE

NC-SAFETY: Review Completions by Class



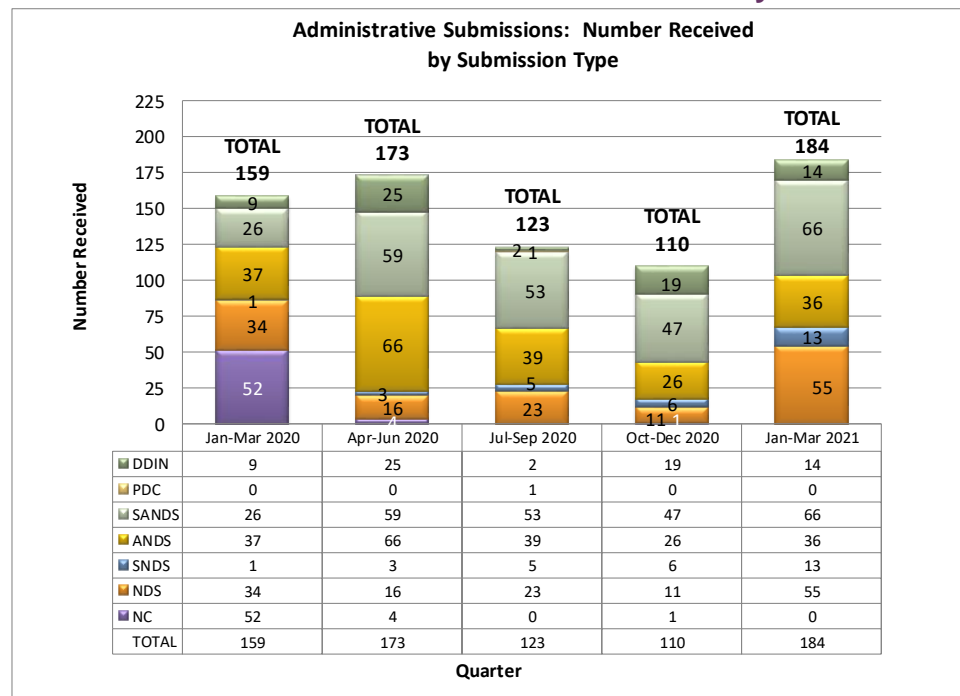
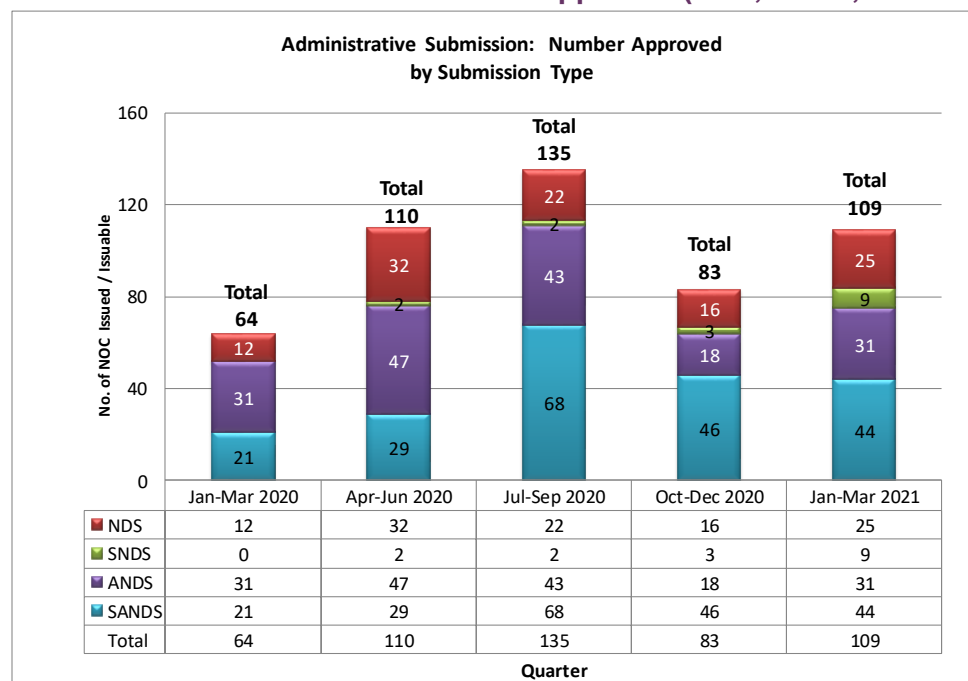
NC-SAFETY: Screening Completions by Class



NC–SAFETY: Number of Decisions by Class

NC - SAFETY (90)					
DOCUMENT TYPE	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
NO OBJECTION LETTER	153	181	15	1	4
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	22	5	0	0	0
CANCELLED BY COMPANY	6	6	0	0	0
NC - HOLD (PATENT)	5	1	0	0	0

NC - SAFETY (120)					
DOCUMENT TYPE	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
NO OBJECTION LETTER	18	8	18	0	0
NOT SATISFACTORY NOTICE	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	1	2	0	0	0
CANCELLED BY COMPANY	5	1	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
NC - HOLD (PATENT)	0	0	0	0	0

ADMINISTRATIVE SUBMISSIONS(Manufacturer and/or Product Name Changes)⁹**RECEIVED****Administrative Submissions: Number Received by Submission Type****APPROVALS****Administrative Submissions: Number Approved (NDS, SNDS, ANDS and SANDS)**

⁹ The screening functions for Administrative submissions and the review functions for Labelling Only submissions with an Administrative component were moved from the Office of Submissions and Intellectual Property (OSIP) to the labelling area of the Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD) at TPD in December 2018.

ADMINISTRATIVE SUBMISSIONS

(Manufacturer and/or Product Name Changes) ¹⁰

DECISIONS

Administrative Submissions/Applications: Number of Decisions by Submission Type

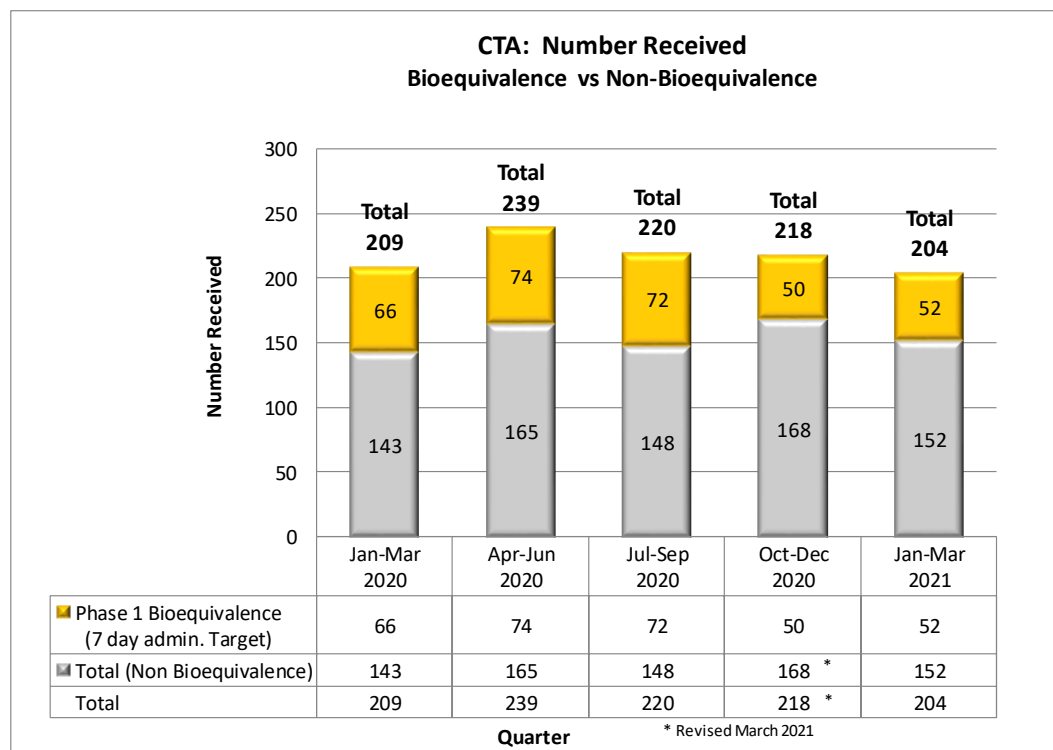
NDS	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
NOTICE OF COMPLIANCE	12	32	22	16	25
SCREENING DEFICIENCY NOTICE	0	0	0	1	1
CANCELLATION LETTER	0	1	0	0	2
PROCESSING HOLD LETTER	8	6	6	2	2
SNDS	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
NOTICE OF COMPLIANCE	0	2	2	3	9
SCREENING DEFICIENCY NOTICE	0	0	0	0	1
CANCELLATION LETTER	1	0	2	0	0
PROCESSING HOLD LETTER	1	0	2	1	0
ANDS	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
NOTICE OF COMPLIANCE	30	47	42	18	30
NOC ON IP HOLD	1	0	1	0	1
SCREENING DEFICIENCY NOTICE	0	1	2	0	0
CANCELLATION LETTER	4	6	5	2	1
PROCESSING HOLD LETTER	11	13	3	7	0
SANDS	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
NOTICE OF COMPLIANCE	21	29	68	46	44
NOC ON IP HOLD	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLATION LETTER	3	4	2	0	6
PROCESSING HOLD LETTER	2	10	4	5	1
NC	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
NO OBJECTION LETTER	49	1	1	0	0
NC - HOLD (PATENT)	0	0	0	0	0
CANCELLATION LETTER	12	4	0	0	0
PROCESSING HOLD LETTER	1	0	0	2	0
SCREENING DEFICIENCY NOTICE	0	0	0	1	0
DINA	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
NOTIFICATION FORM / DIN ISSUED	1	12	12	15	7
NO OBJECTION LETTER	0	1	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLATION LETTER	0	8	2	1	0
PROCESSING HOLD LETTER	1	4	0	0	0
PDC	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
NO OBJECTION LETTER	0	0	0	0	0
CANCELLATION LETTER	0	0	1	0	0
PROCESSING HOLD LETTER	0	0	0	0	0

¹⁰ The screening functions for Administrative submissions and the review functions for Labelling Only submissions with an Administrative component were moved from the Office of Submissions and Intellectual Property (OSIP) to the labelling area of the Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD) at TPD in December 2018.

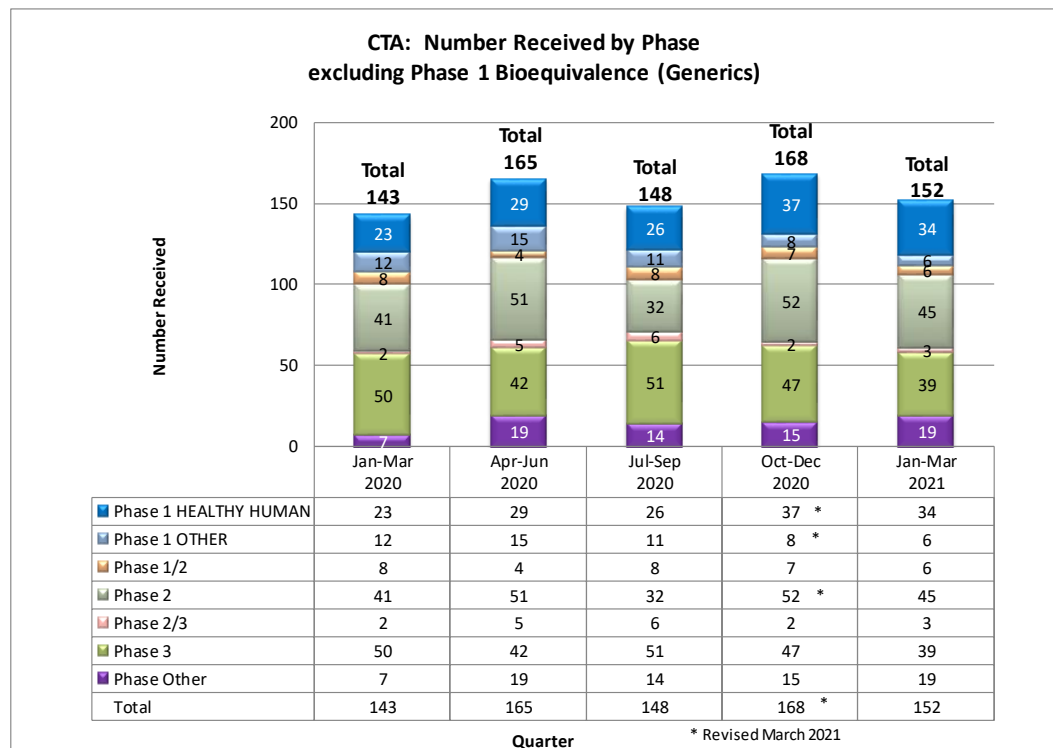
Clinical Trial Applications and Amendments (CTA & CTA-A)

CTA: CLINICAL TRIAL APPLICATIONS

CTA: Number Received



CTA: Number Received by Phase

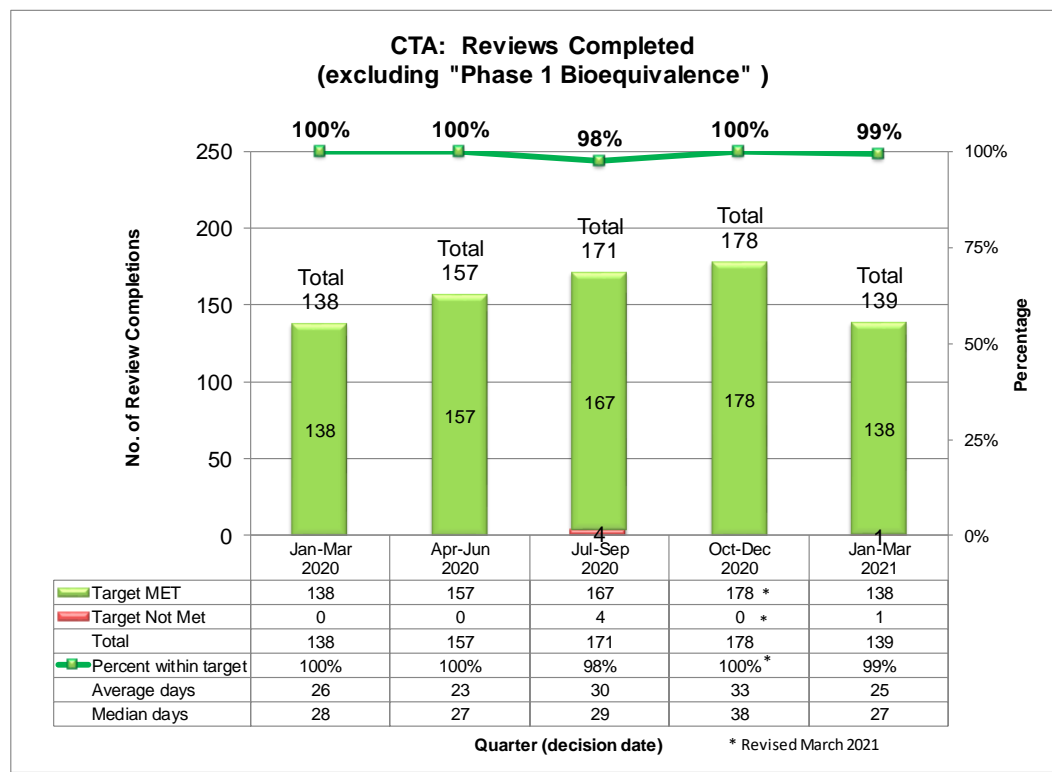


DECISION DOCUMENTS**CTA: Number of Decisions by Type**

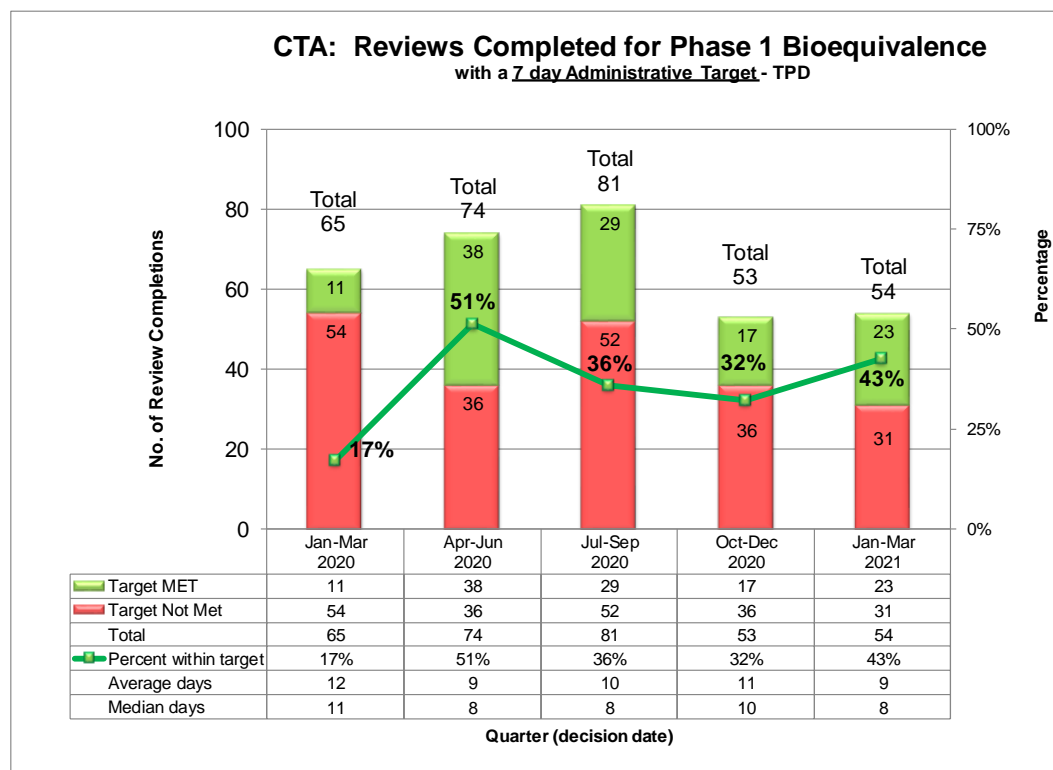
CTA					
DOCUMENT TYPE	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
NO OBJECTION LETTER	186	215	185	217	186
CANCELLED BY COMPANY DURING REVIEW	17	18	8	14	7
CANCELLED BY COMPANY AT PROCESSING	9	5	4	1	2
NOTICE OF AUTHORIZATION	0	1	2	6	0

PERFORMANCE

CTA: Reviews Completed (excluding Phase 1 Bioequivalence)

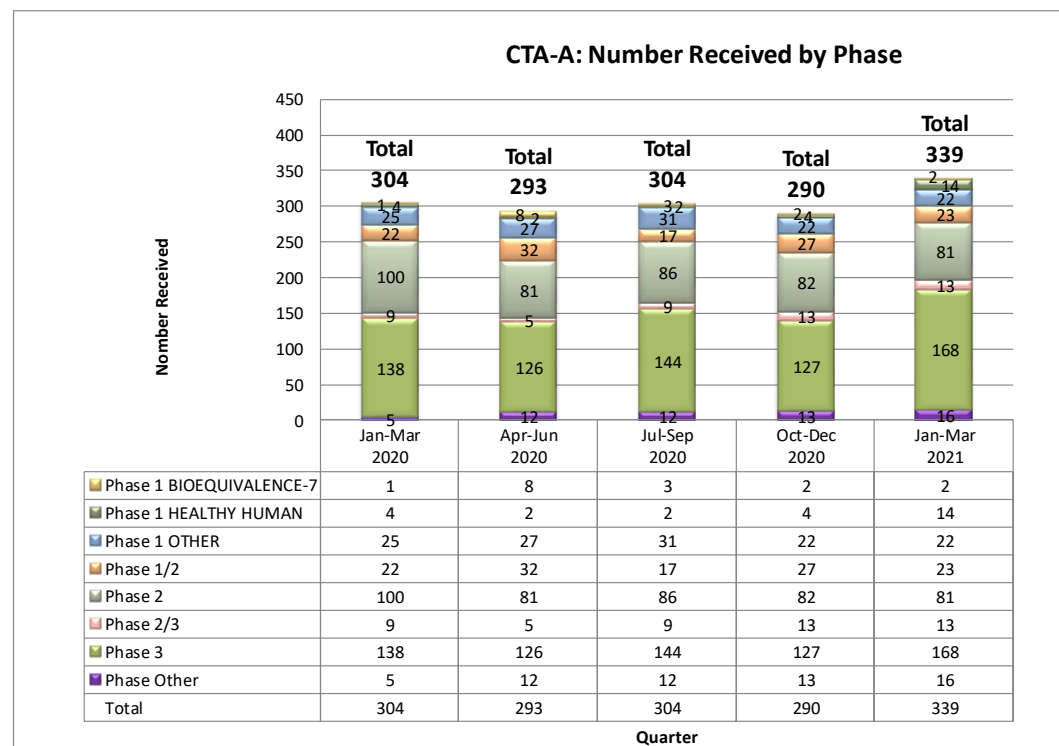


CTA: Reviews Completed for Phases with a 7 Day Administrative Target



CTA-A: CLINICAL TRIAL APPLICATION-AMENDMENTS

CTA-A: Number Received by Phase



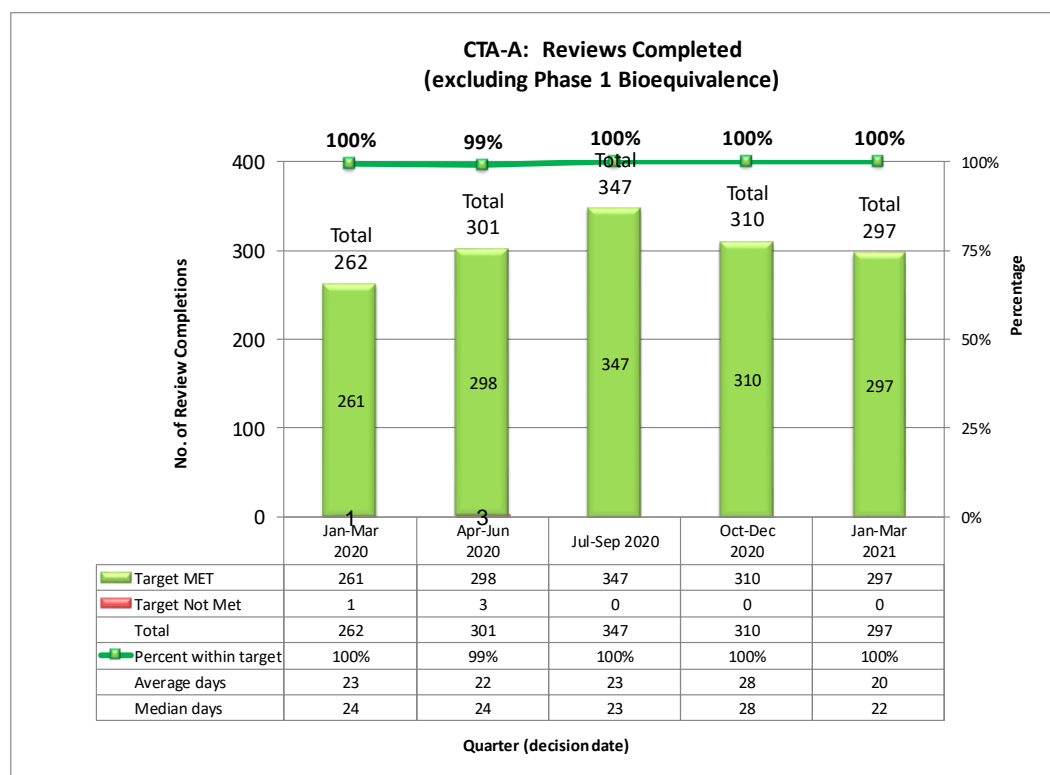
DECISIONS

CTA-A: Number of Decisions by Type

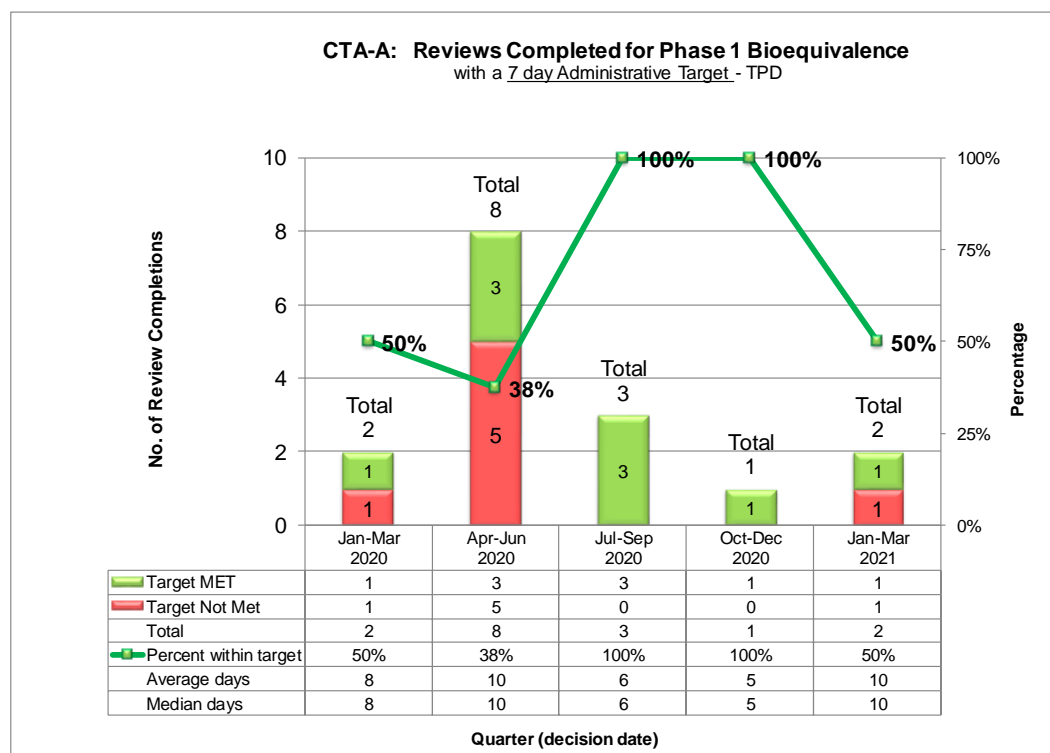
CTA-A (excluding administrative)					
DOCUMENT TYPE	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
NO OBJECTION LETTER	252	307	259	301	293
CANCELLED BY COMPANY DURING REVIEW	12	5	2	7	2
CANCELLED BY COMPANY AT PROCESSING	15	7	14	8	21
NOT SATISFACTORY NOTICE	1	0	0	0	0
NOTICE OF AUTHORIZATION	0	0	0	2	4

PERFORMANCE

CTA-A: Reviews Completed (excluding Phase 1 Bioequivalence)

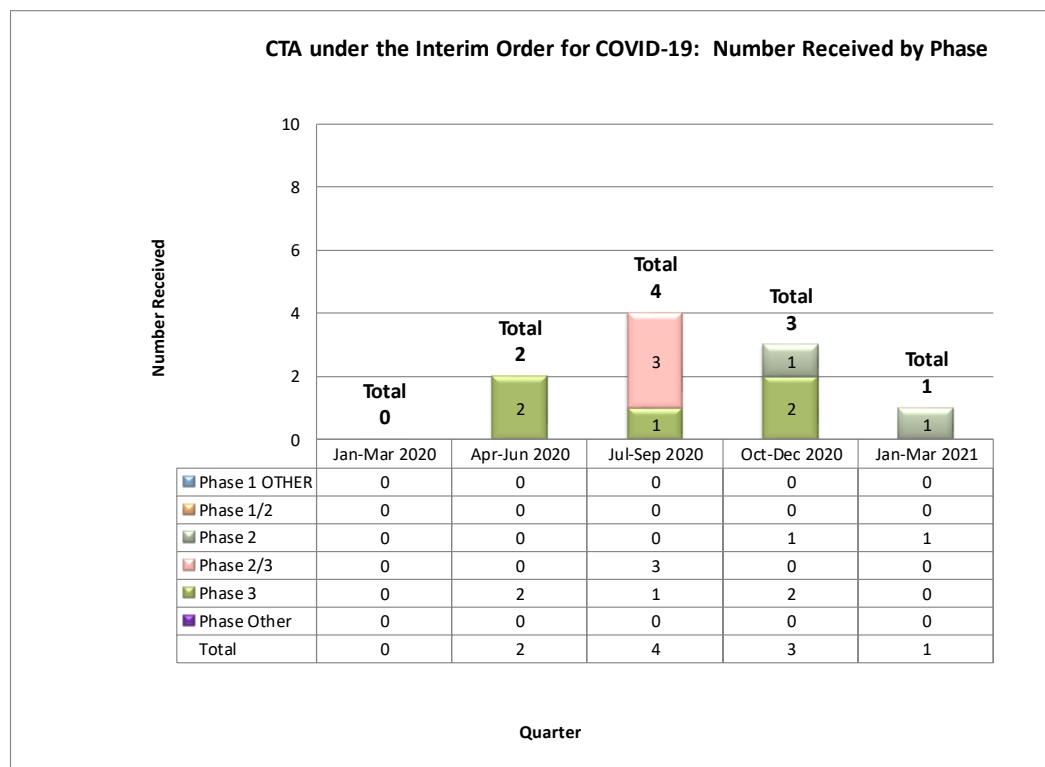


CTA-A: Reviews Completed for Phases with a 7 Day Administrative Target

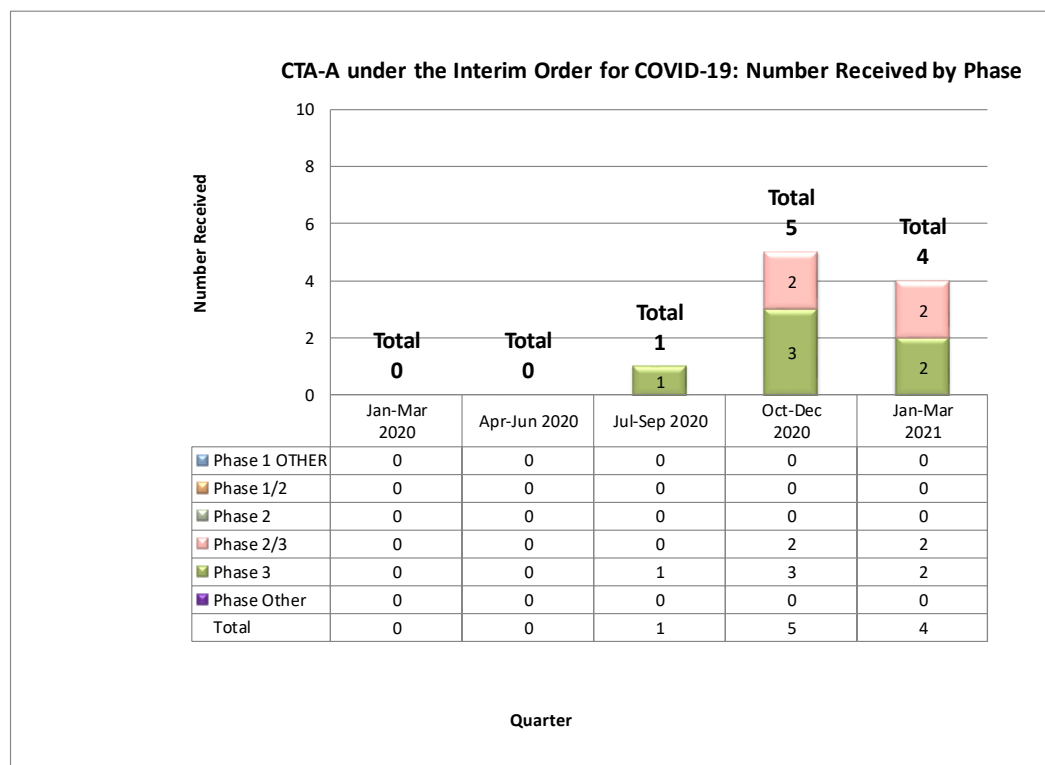


CTA & CTA-A RECEIVED UNDER THE INTERIM ORDER COVID 19

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



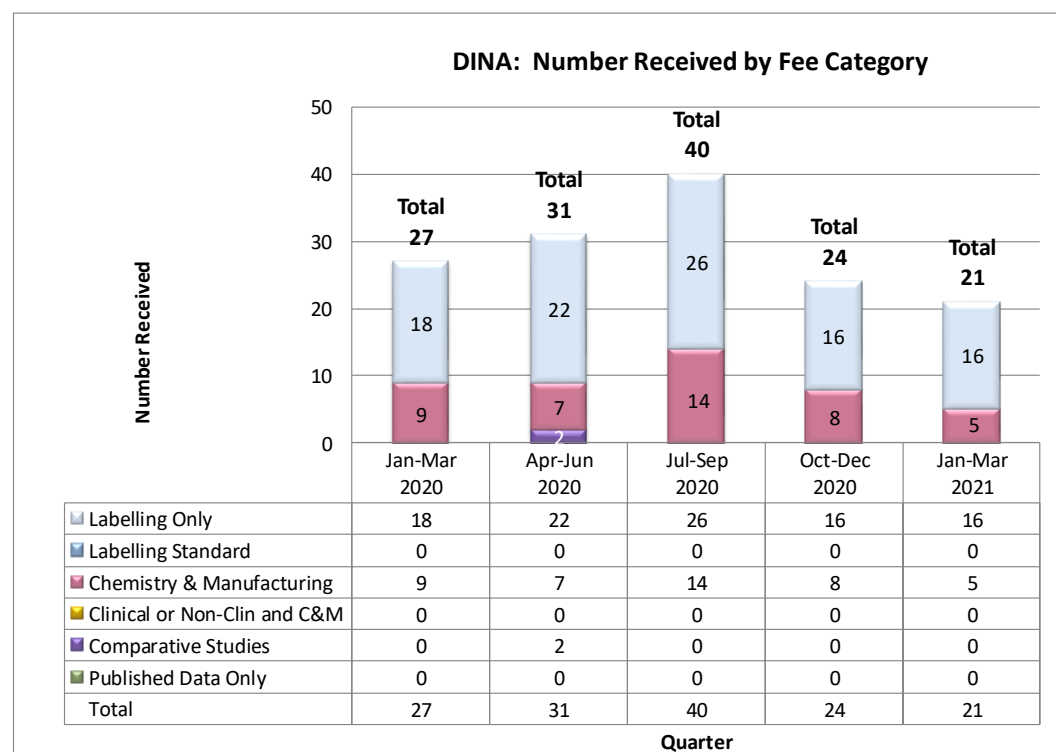
CTA-A: Number Received under the Interim Order Covid-19 by phase



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

DINA

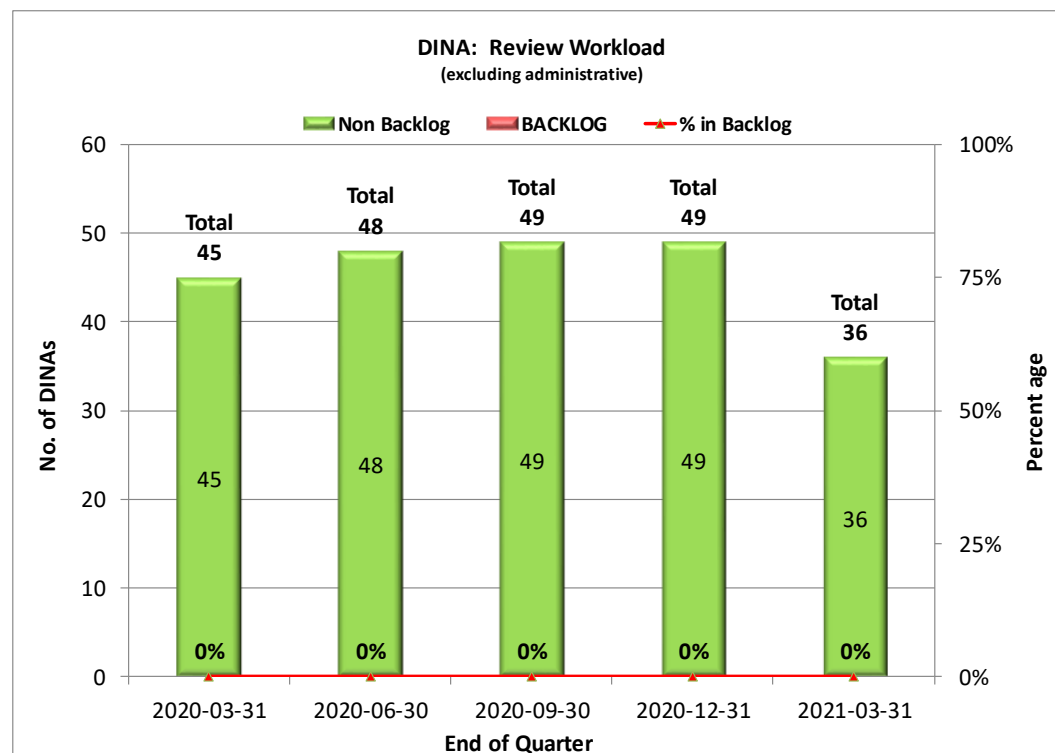
Application for a Drug Identification Number

DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER ¹¹**DINA: Number Received by Fee Category**

¹¹ 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 in a separate NNHPD Drug Submission Performance Report as of October 1, 2015.

REVIEW WORKLOAD

DINA: Review Workload

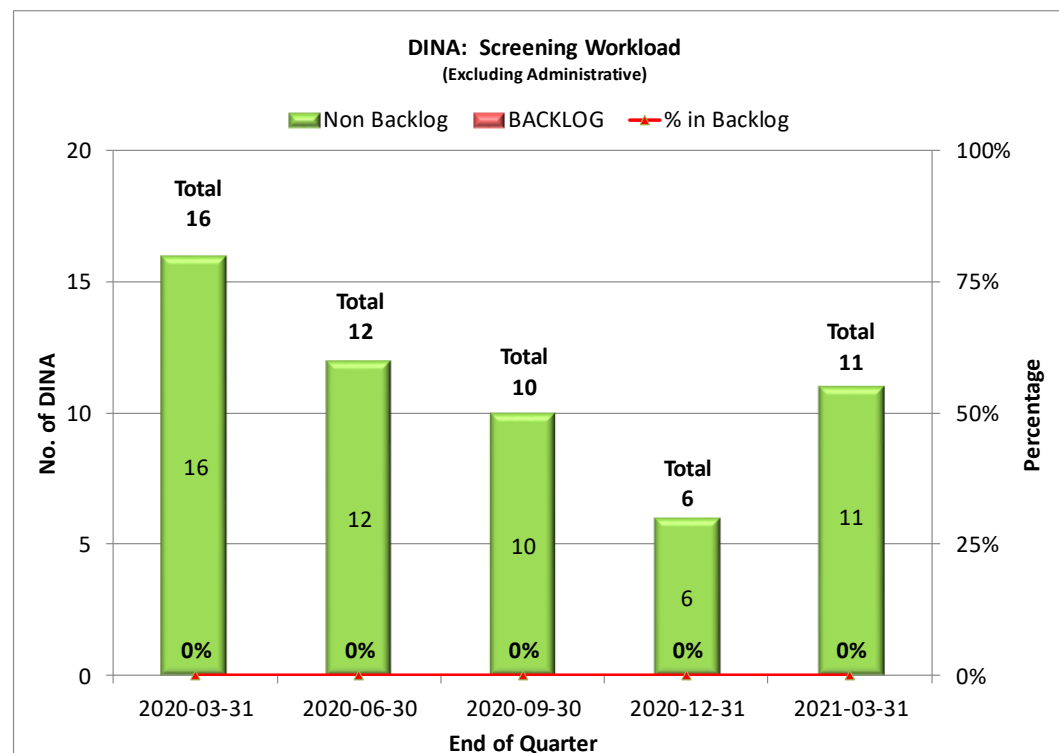


DINA: Review Workload by Fee Category

DINA: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Labelling Only	29	35	36	29	16
<i>Backlog</i>	0	0	0	0	0
Chemistry & Manufacturing	15	12	11	18	19
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clin and C&M	1	0	0	1	1
<i>Backlog</i>	0	0	0	0	0
Comparative Studies	0	1	2	1	0
<i>Backlog</i>	0	0	0	0	0
Total	45	48	49	49	36
Non Backlog	45	48	49	49	36
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

SCREENING WORKLOAD

DINA: Screening Workload



DINA: Screening Workload by Fee Category

DINA: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Labelling Only	10	8	2	3	7
Backlog	0	0	0	0	0
Labelling Standard	0	0	2	0	0
Backlog	0	0	0	0	0
Chemistry & Manufacturing	6	3	6	3	4
Backlog	0	0	0	0	0
Comparative Studies	0	1	0	0	0
Backlog	0	0	0	0	0
Total	16	12	10	6	11
Non Backlog	16	12	10	6	11
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DECISIONS

DINA: Number of Decisions by Fee Category

DINA - LABELLING ONLY					
DOCUMENT TYPE	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
NOTIFICATION FORM/DIN ISSUED	0	4	5	2	8
NO OBJECTION LETTER	12	13	22	19	17
CANCELLED BY COMPANY	0	2	3	0	1
NEW DRUG LETTER SCREEN	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	0
NOTICE OF DEFICIENCY	0	1	0	0	0
NOTICE OF NON-COMPLIANCE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	1	2	0	0	1

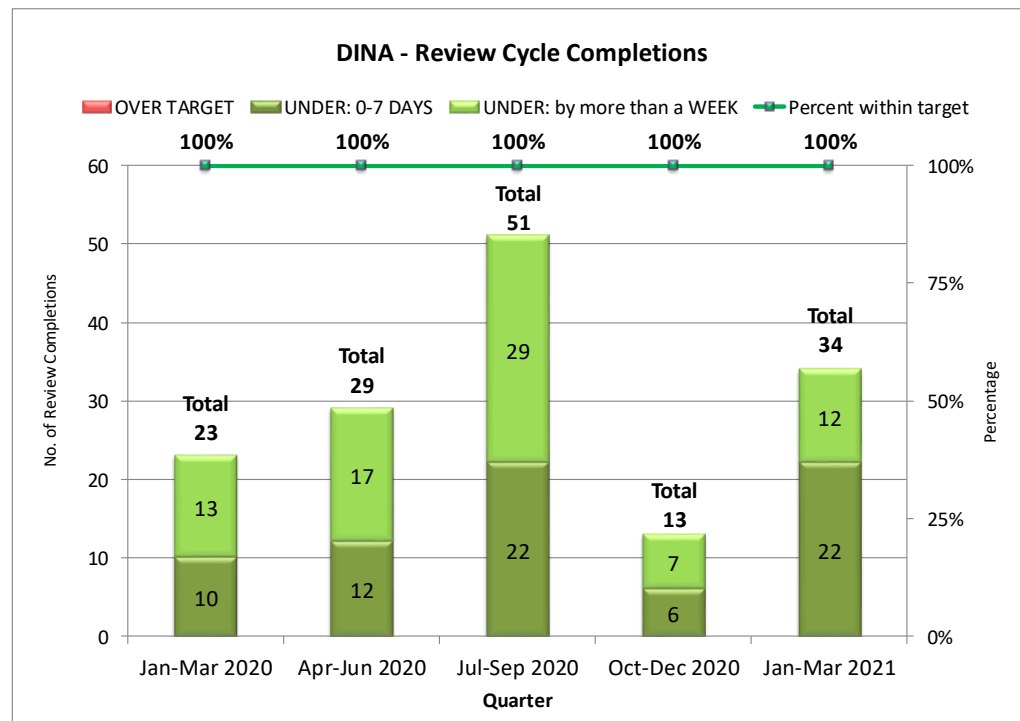
DINA - CHEMISTRY AND MANUFACTURING					
DOCUMENT TYPE	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
NOTIFICATION FORM/DIN ISSUED	7	6	4	0	3
NO OBJECTION LETTER	4	3	5	4	5
NOD WITHDRAWAL LETTER	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	0	0	0	2	0
NEW DRUG LETTER REVIEW	0	0	0	0	0
NEW DRUG LETTER SCREEN	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	2	5	5	7	3
CANCELLED BY COMPANY	0	0	1	0	0

DINA - COMPARATIVE STUDIES					
DOCUMENT TYPE	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	1
NOTICE OF DEFICIENCY	0	0	0	1	0
NOTICE OF NON-COMPLIANCE	0	0	0	0	0
NO OBJECTION LETTER	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

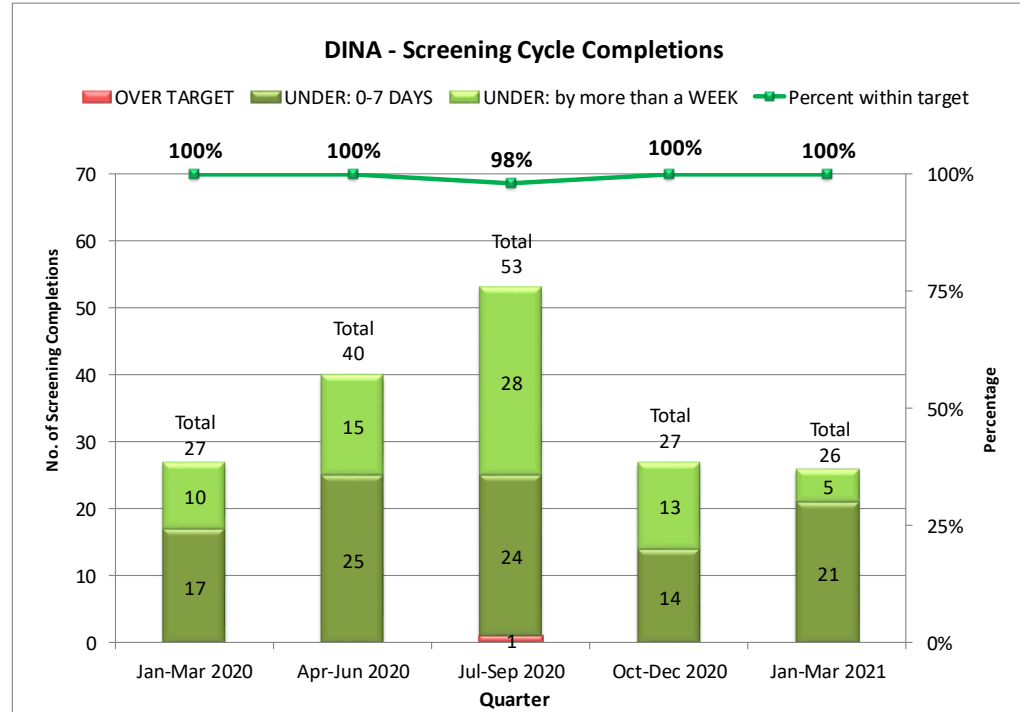
DINA - CLINICAL OR NON CLINICAL DATA AND C&M					
DOCUMENT TYPE	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
CANCELLED BY COMPANY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	0	1	0	0	0
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0

PERFORMANCE

DINA: Review Cycle Completions

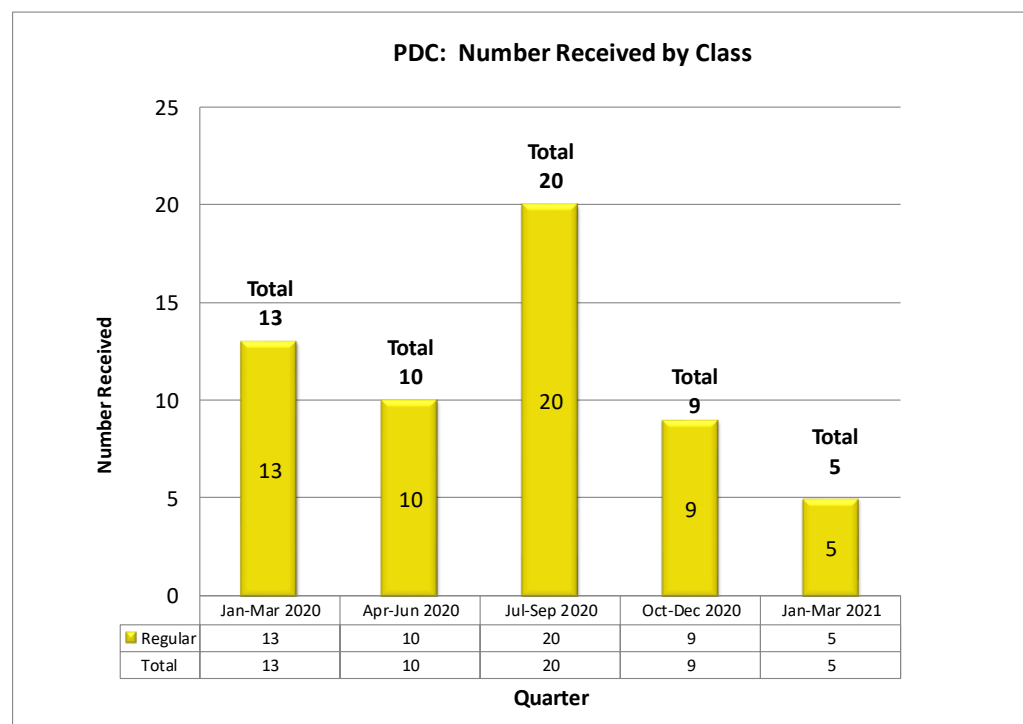


DINA: Screening Cycle Completions



PDC: POST-AUTHORIZATION DIVISION 1 CHANGE

PDC: Number Received

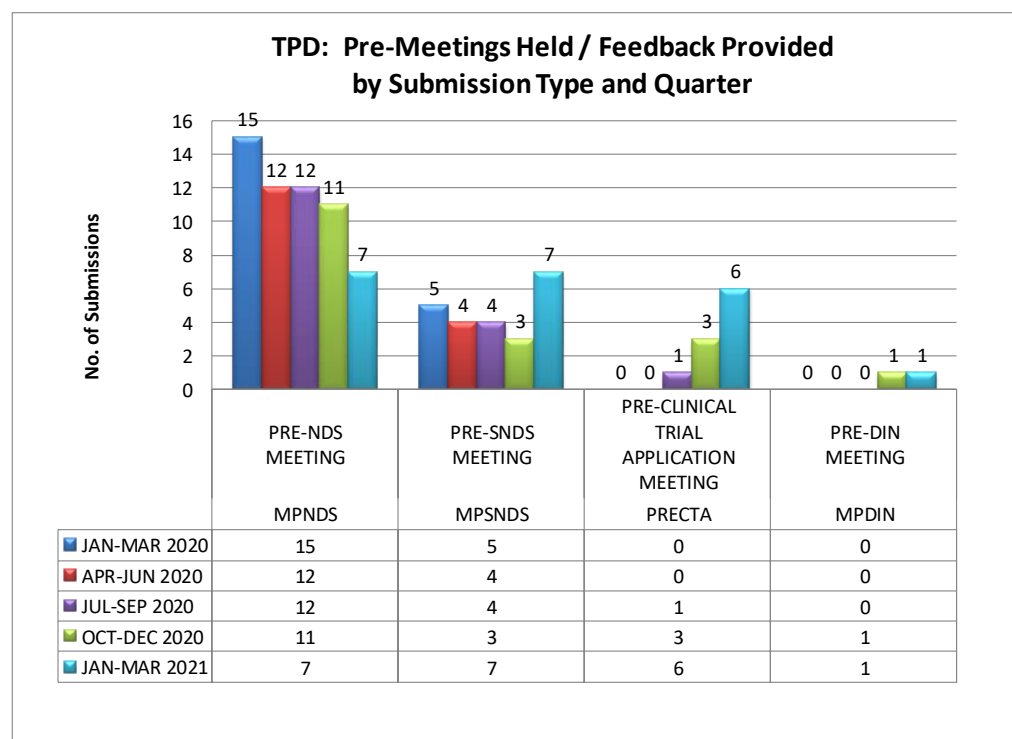


PDC: Number of Decisions by Type

PDC					
DOCUMENT TYPE	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
REGULAR					
CANCELLED BY COMPANY	1	2	8	3	4
NO OBJECTION LETTER	11	9	7	11	4
NOT SATISFACTORY NOTICE	0	1	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0

APPENDIX A: PRE-SUBMISSION MEETINGS ¹²

Pre-submission Meetings Held / Feedback Provided



¹² 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 [Management of Drug Submissions Guidance](#).