Health Canada Santé Canada

Therapeutic Products Directorate

Drug Submission Performance Quarterly Report

July - September

2021

Canada

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Direction des produits thérapeutiques - Rapport trimestriel du rendement des présentations de drogue - juillet - septembre 2021

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Publication date: December 2021

Cat H167-2E-PDF
ISSN 2561-553X
Pub 210422

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OVERVIEW

The Therapeutic Products Directorate's (TPD) Quarterly Drug Submission Performance Report reflects pharmaceutical drug submission review activity over five consecutive quarters: from July - September 2020 to July - September 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.

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

- 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 and the number of applications and amendments in review under the ISAD Interim Order are included in this report. As the ISAD Interim Order expired on September 16th 2021, the Covid-19 Authorizations section of this report has been removed as zero authorizations have been issued and no new authorizations are possible.

- 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).

- The Notifiable Change (NC) section of this report has been removed since they were phased out as of April 2020 and there is no NCs received, workload or screening going forward.

- 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[2] 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[3] 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 days[5]) 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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[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, 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.

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

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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

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 .

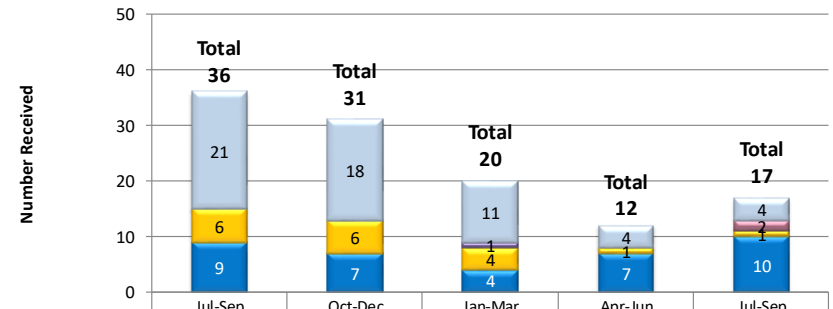
NEW DRUG SUBMISSION (NDS)

&

SUPPLEMENT TO A NEW DRUG SUBMISSION (SNDS)

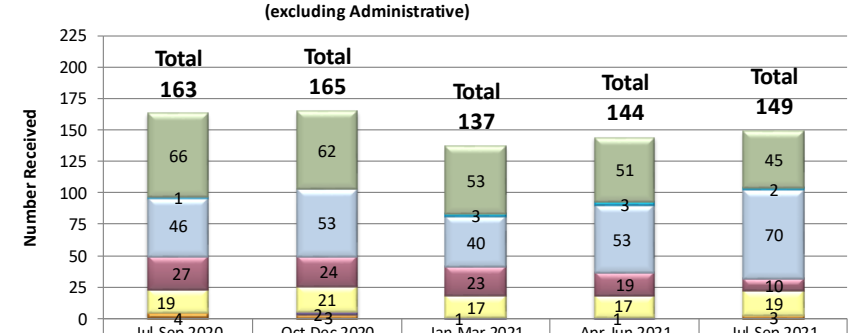
SUBMISSIONS RECEIVED [7]

NDS: Number Received by Fee Category



	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Labelling Only	21	18	11	4	4
Comparative Studies	0	0	1	0	0
Chemistry & Manufacturing	0	0	0	0	2
Clinical or Non-Clin and C&M	6	6	4	1	1
New Active Substance	9	7	4	7	10
Total	36	31	20	12	17
Priority Class	5	2	2	1	1
NOC-C Class	3	2	1	1	1
Extraordinary Use NDS	0	1	0	0	0

SNDS: Number Received by Fee Category

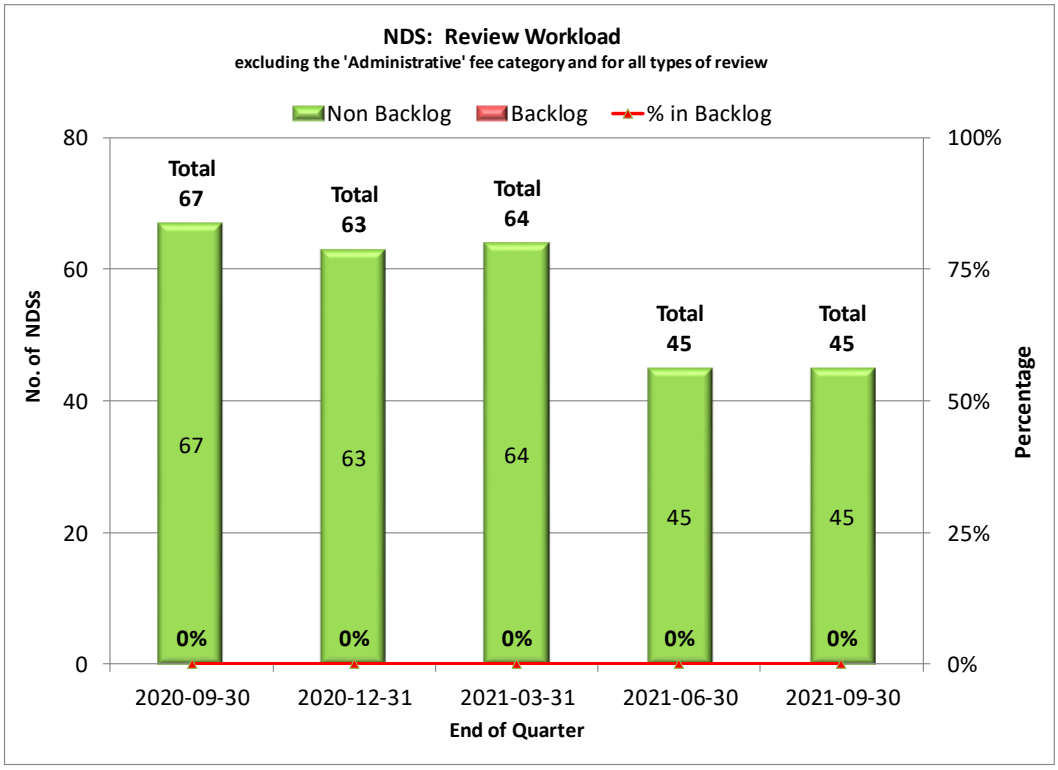


	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Safety Update Label	66	62	53	51	45
Label Update Generic	1	0	3	3	2
Labelling Only	46	53	40	53	70
Chemistry & Manufacturing	27	24	23	19	10
Clinical or Non-Clin Only	19	21	17	17	19
Published Data Only	0	0	0	0	0
Comparative Studies	0	2	1	1	0
Clinical or Non-Clin and C&M	4	3	0	0	3
Total	163	165	137	144	149
Priority Class	1	1	1	0	4
NOC-C Class	0	0	0	0	0
SNDS - Confirmatory	0	0	2	1	5

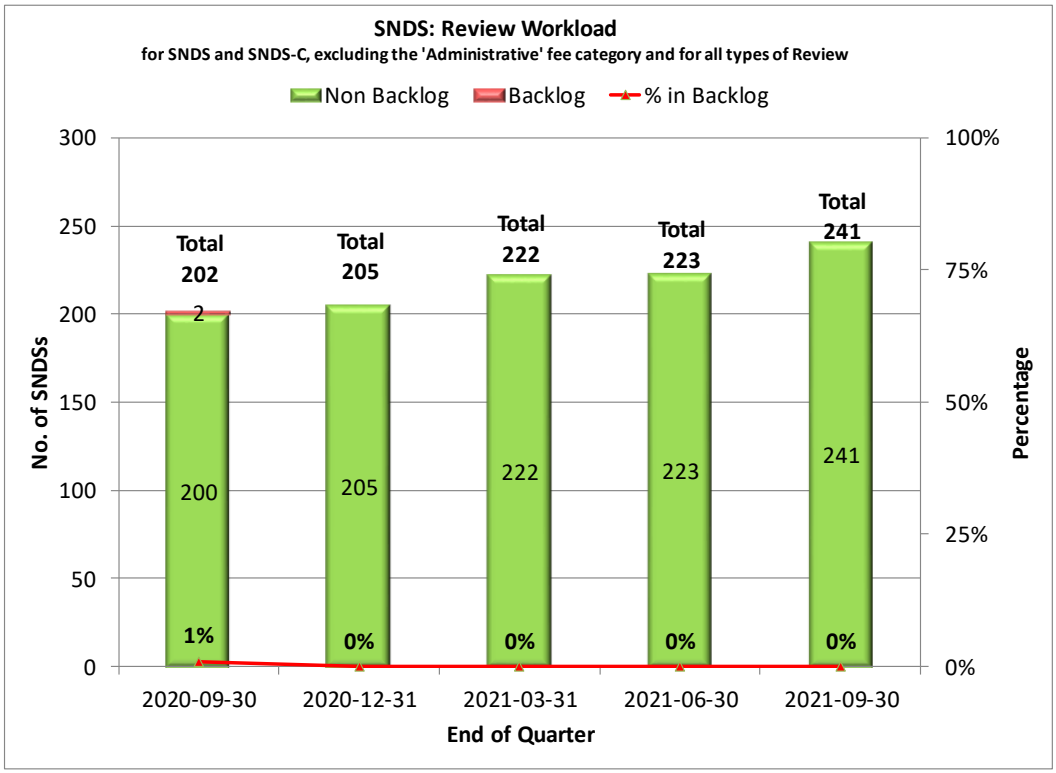
[7] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance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

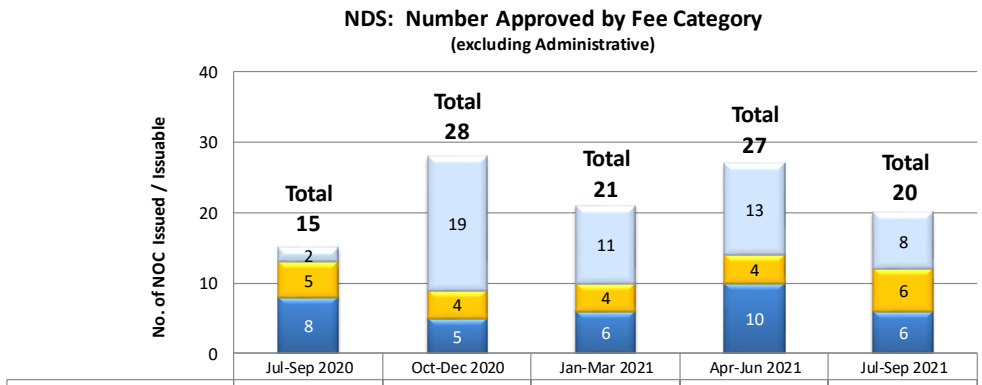
NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2020-09-30	2020-12-31	2021-03-31	2021-06-30	2021-09-30
Labelling Only	23	16	17	9	8
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	20	20	22	19	14
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	24	27	25	17	23
Backlog	*0*	*0*	*0*	*0*	*0*
Total	67	63	64	45	45
Non Backlog	67	63	64	45	45
Backlog	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%
Priority (subset)	5	7	6	2	4
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	2020-09-30	2020-12-31	2021-03-31	2021-06-30	2021-09-30
Labelling Only	48	47	49	47	73
Backlog	*1*	*0*	*0*	*0*	*0*
Comparative Studies	4	0	1	3	4
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	43	37	47	45	34
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	37	44	53	61	58
Backlog	*1*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	10	11	9	6	5
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	2	1	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Label Update Generic	0	0	2	0	1
Backlog	*0*	*0*	*0*	*0*	*0*
Safety Update Label	58	65	61	61	66
Backlog	*0*	*0*	*0*	*0*	*0*
Total	202	205	222	223	241
Non Backlog	200	205	222	223	241
Backlog	2	0	0	0	0
% in Backlog	1%	0%	0%	0%	0%
Priority (subset)	3	1	2	2	2
Backlog	*1*	*0*	*0*	*0*	*0*
SNDS-C (Confirmatory)	0	0	1	2	4
Backlog	*0*	*0*	*0*	*0*	*0*

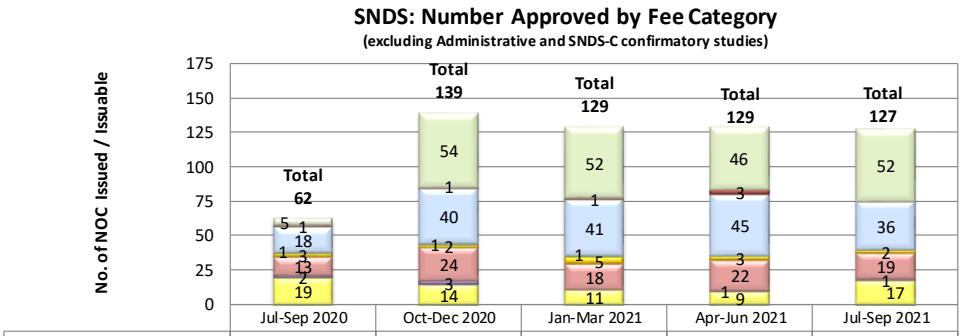
APPROVALS [8]

NDS: Number Approved by Fee Category and by NOC Type



	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Labelling Only	2	19	11	13	8
Clinical or Non-Clin and C&M	5	4	4	4	6
Comparative Studies	0	0	0	0	0
Chemistry & Manufacturing	0	0	0	0	0
New Active Substance	8	5	6	10	6
Total	15	28	21	27	20
Notice of Compliance	14	27	21	24	16
NOC with Conditions	1	0	0	3	4
NOC on Hold (Patent)	0	1	0	0	0
Priority Class	4	2	3	4	1
NOC-C Class	0	0	0	3	3

SNDS: Number Approved by Fee Category and by NOC Type



	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Safety Update Label	5	54	52	46	52
Label Update Generic	1	1	1	3	0
Labelling Only	18	40	41	45	36
Published Data Only	1	1	1	0	0
Clinical or Non-Clin and C&M	3	2	5	3	2
Chemistry & Manufacturing	13	24	18	22	19
Comparative Studies	2	3	0	1	1
Clinical or Non-Clin Only	19	14	11	9	17
Total	62	139	129	129	127
Notice of Compliance	62	138	128	129	127
NOC with Conditions	0	0	1	0	0
NOC on Hold (Patent)	0	1	0	0	0
Priority Class	1	2	1	0	2
NOC-C Class	0	0	0	0	0

[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.

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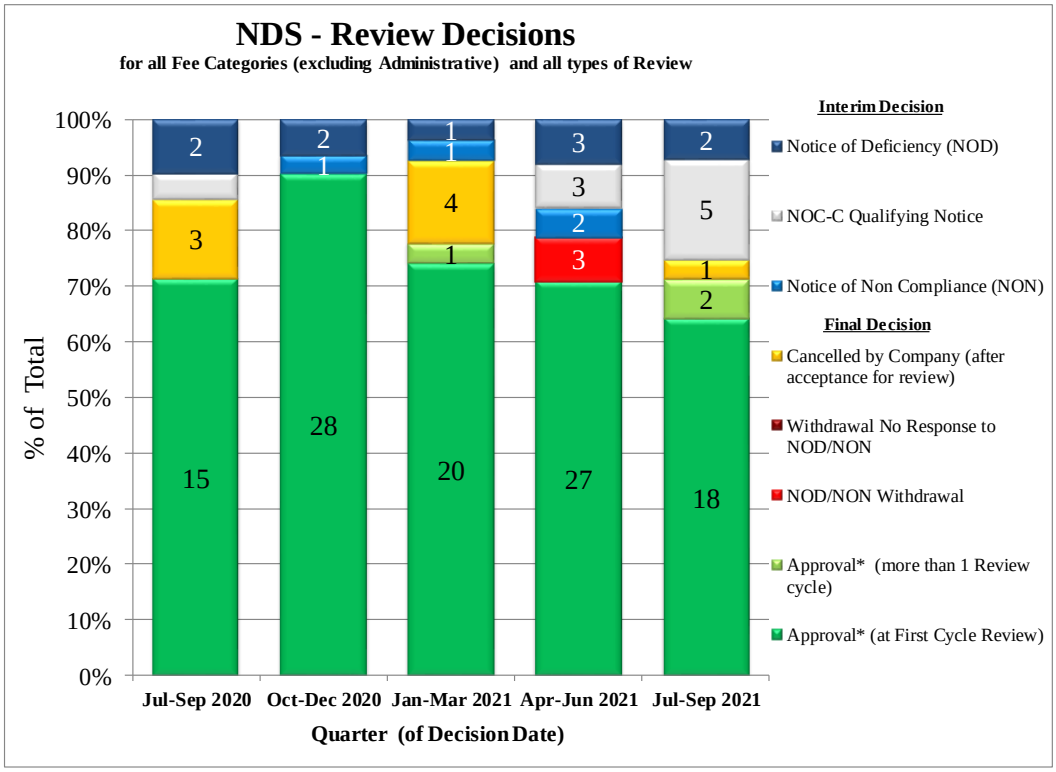
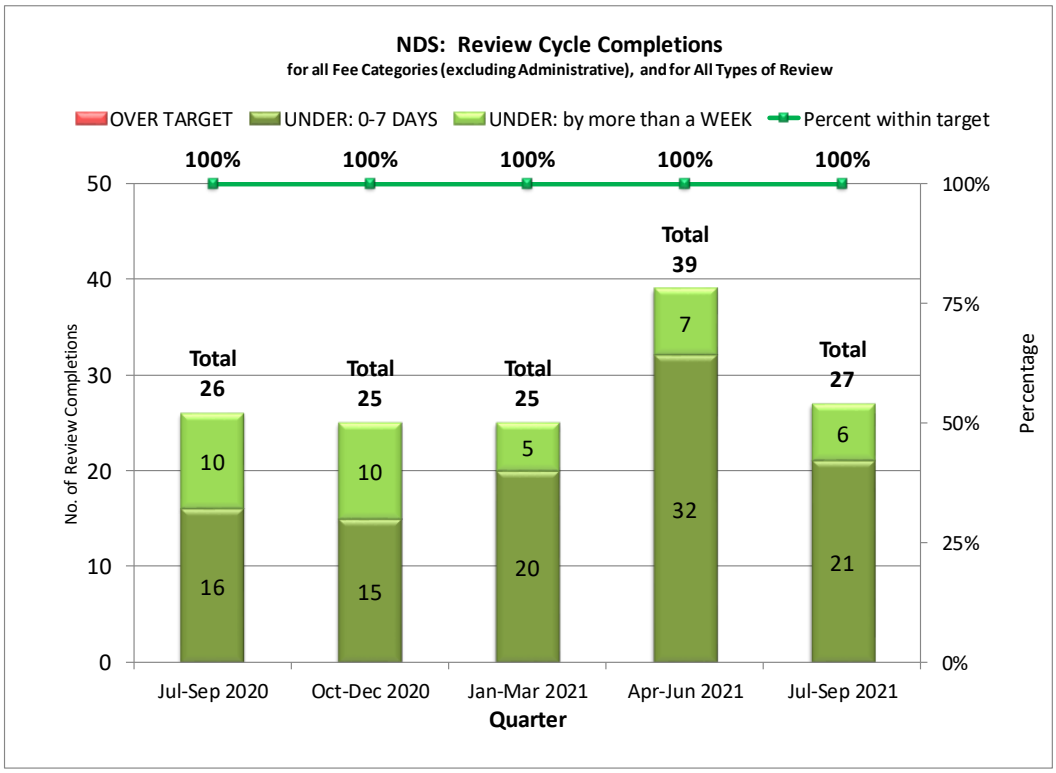
REVIEW PERFORMANCE

NDS: Review Decisions by Type

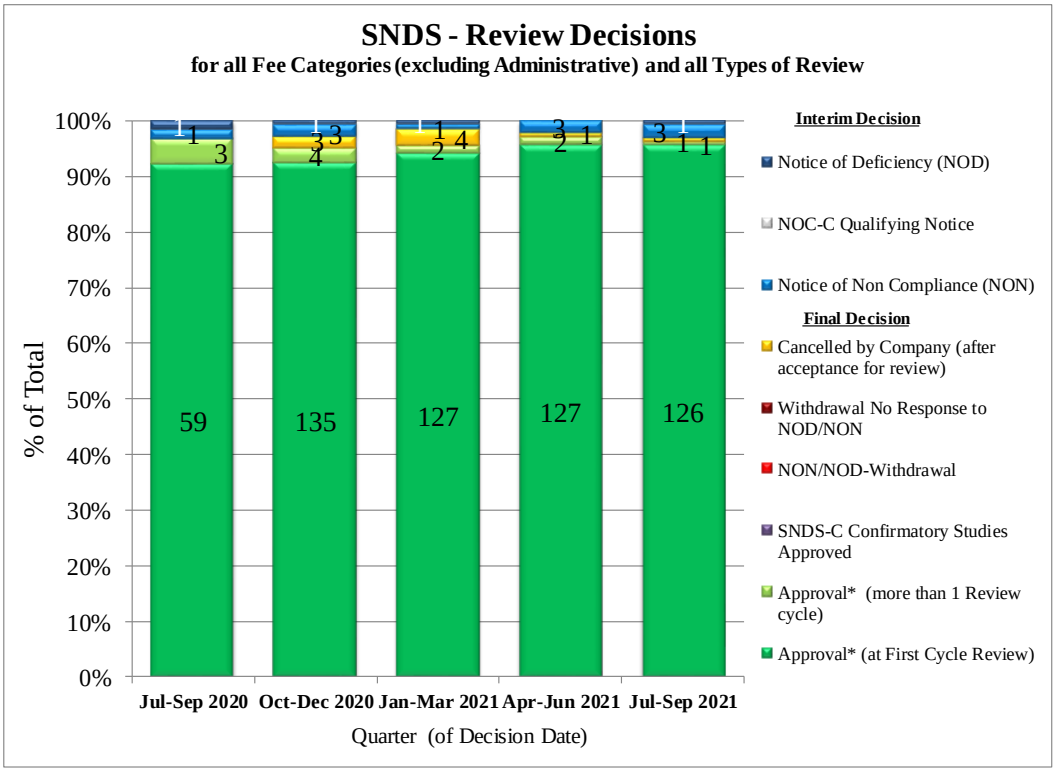


NDS: Review Cycle Completions

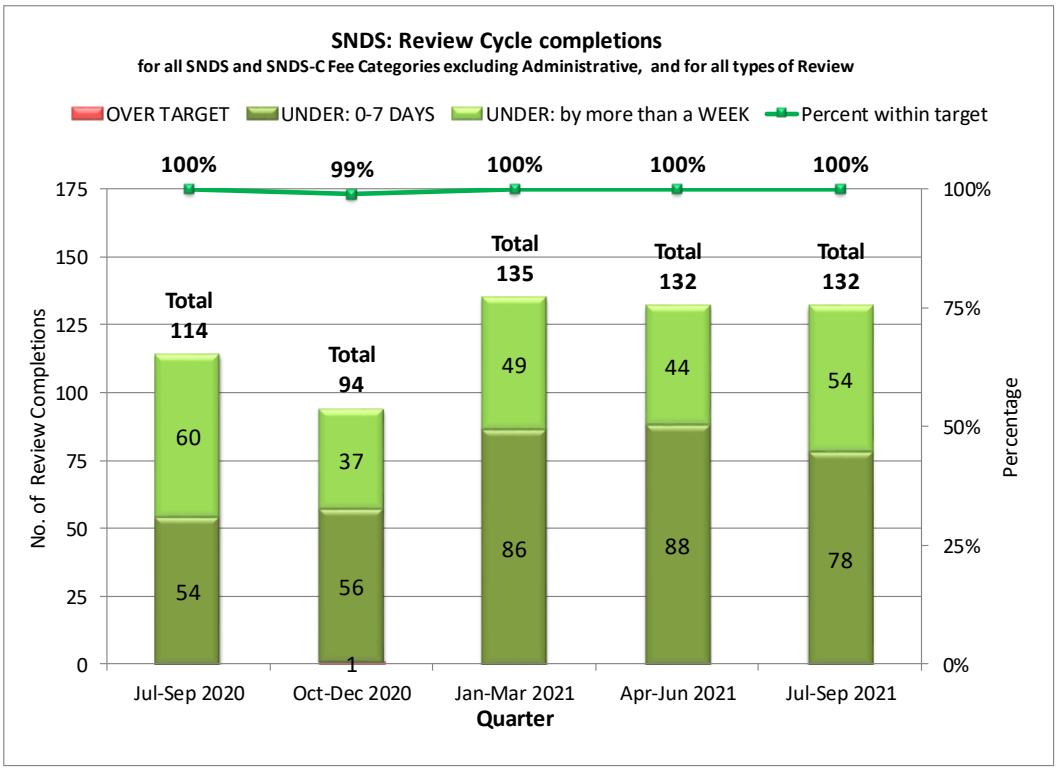


REVIEW CYCLE DECISIONS

SNDS: Review Decisions by Type

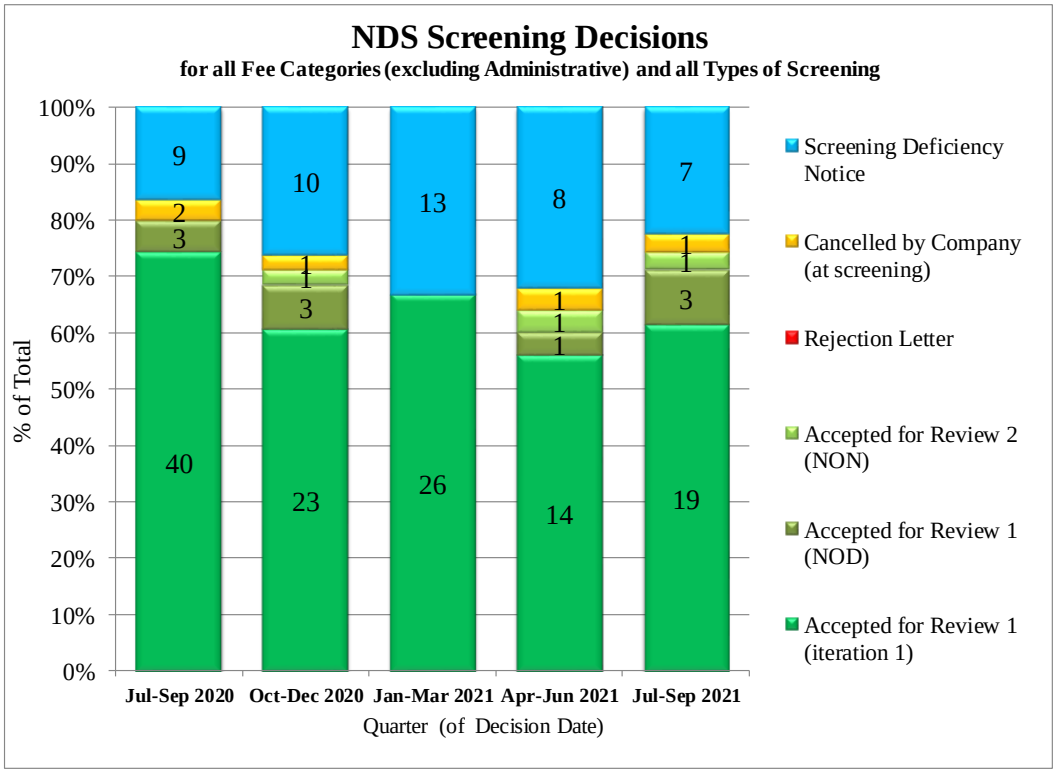


SNDS: Review Cycle Completions

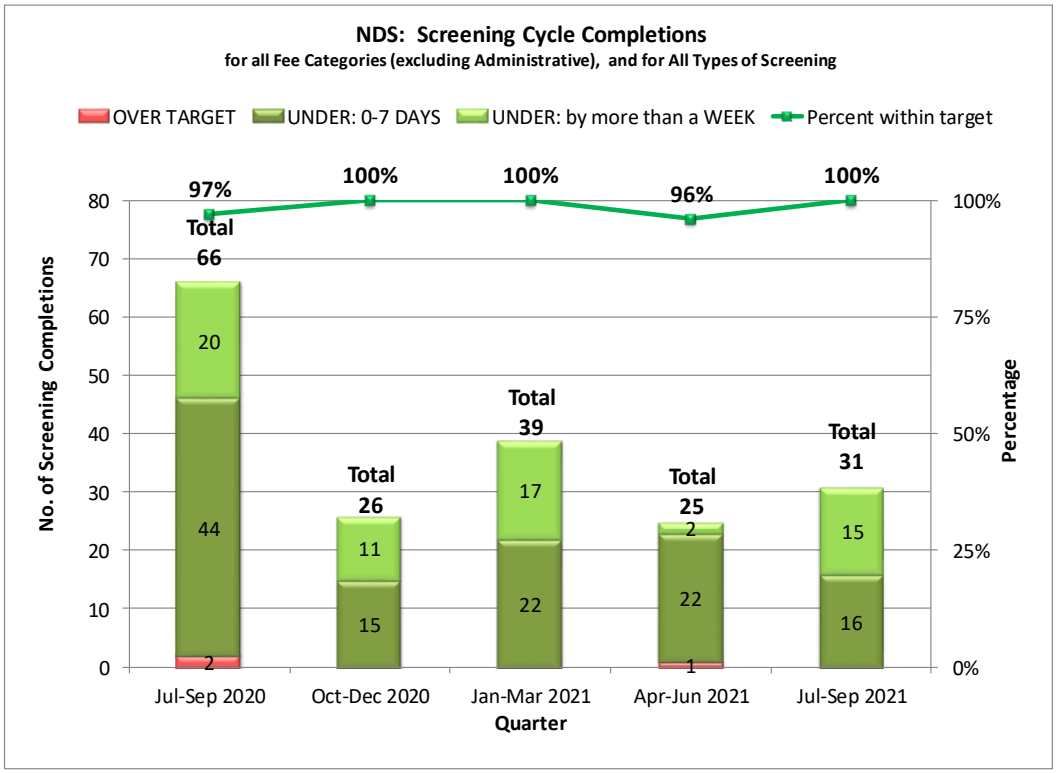


SCREENING PERFORMANCE

NDS: Screening Decisions by Type

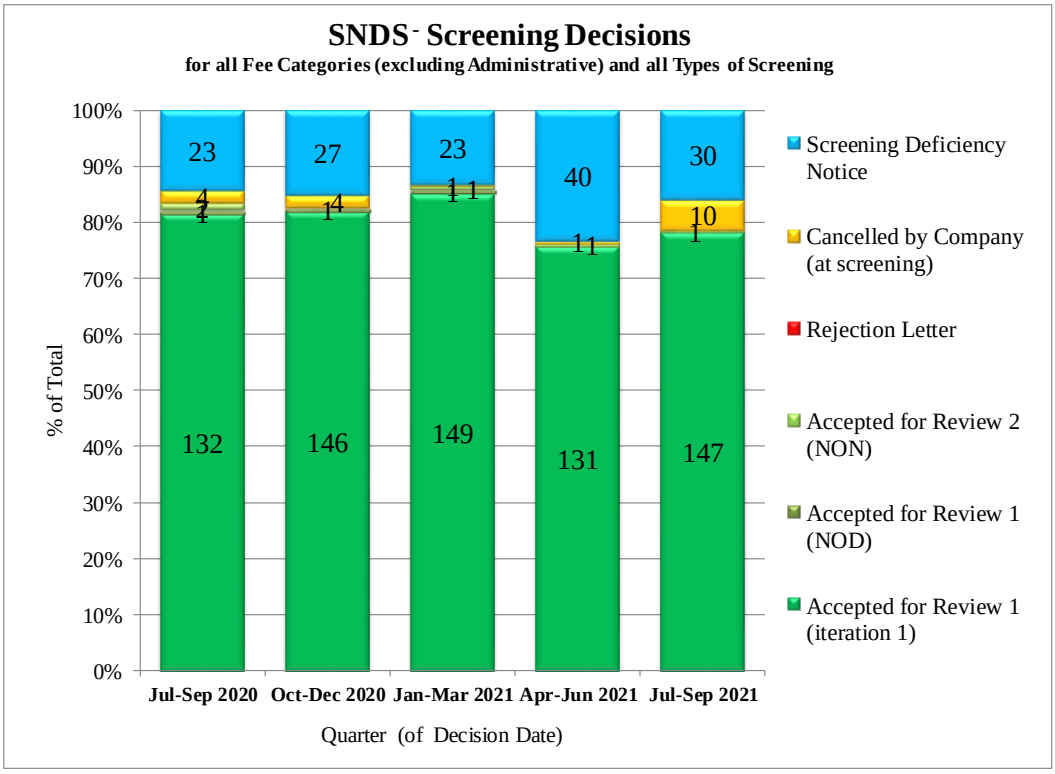


NDS: Screening Cycle Completions

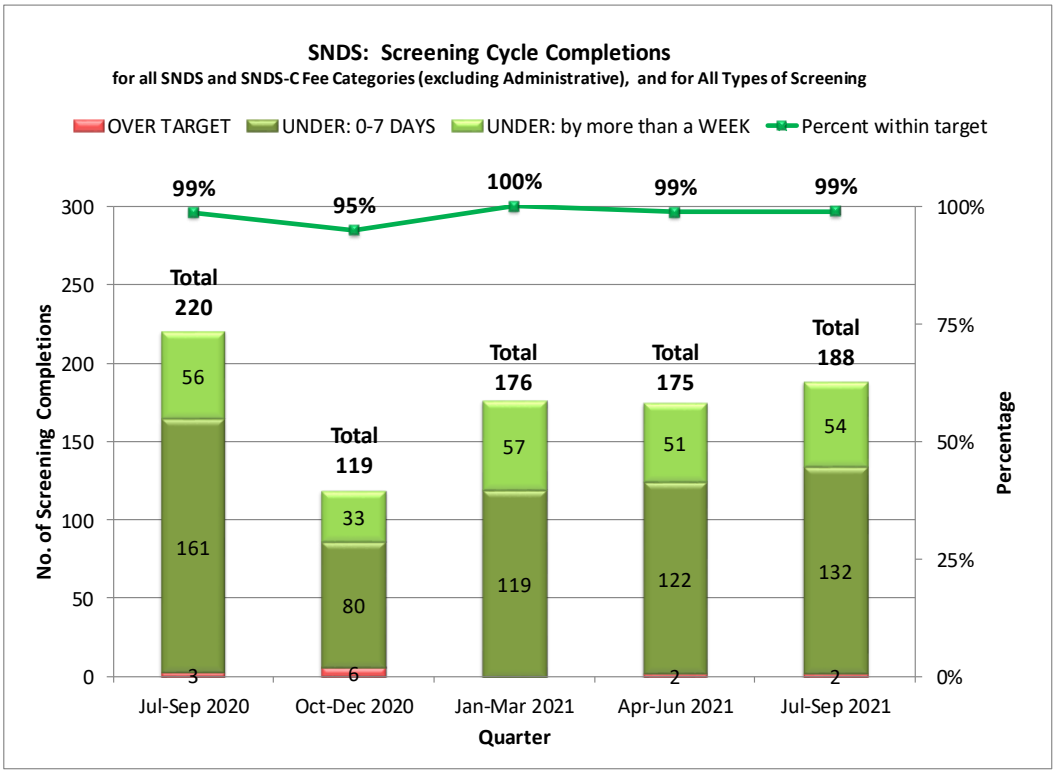


SCREENING CYCLE DECISIONS

SNDS: Screening Decisions by Type



SNDS: Screening Cycle Completions



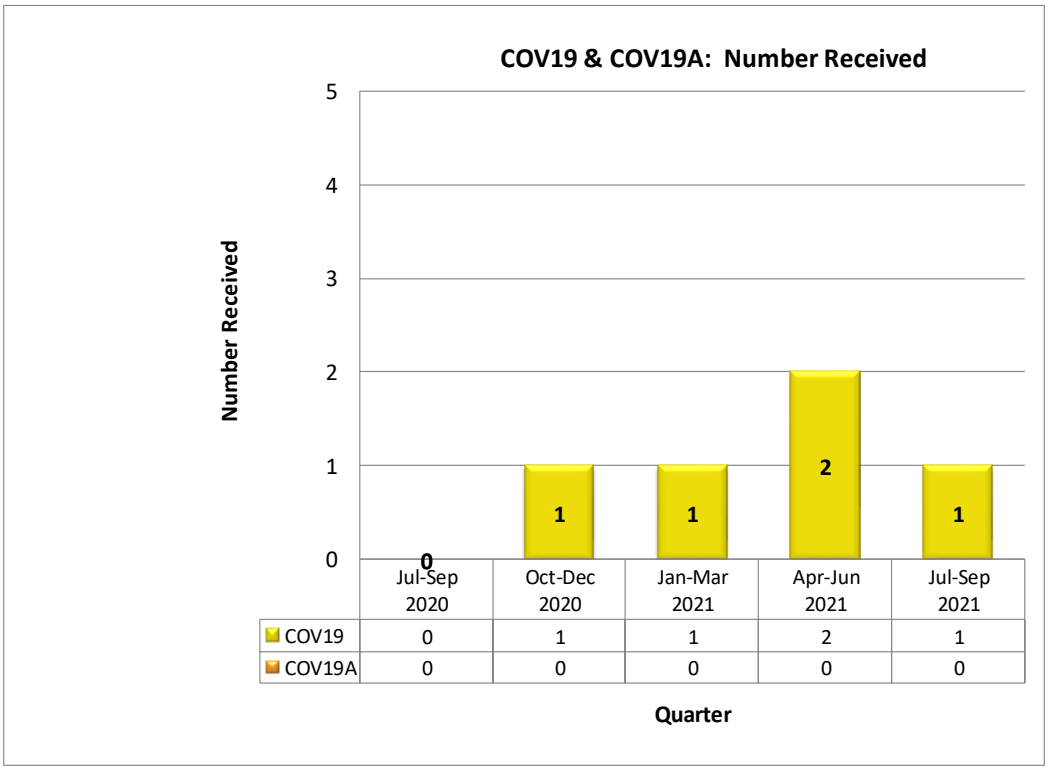
Application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (COV19)

&

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)

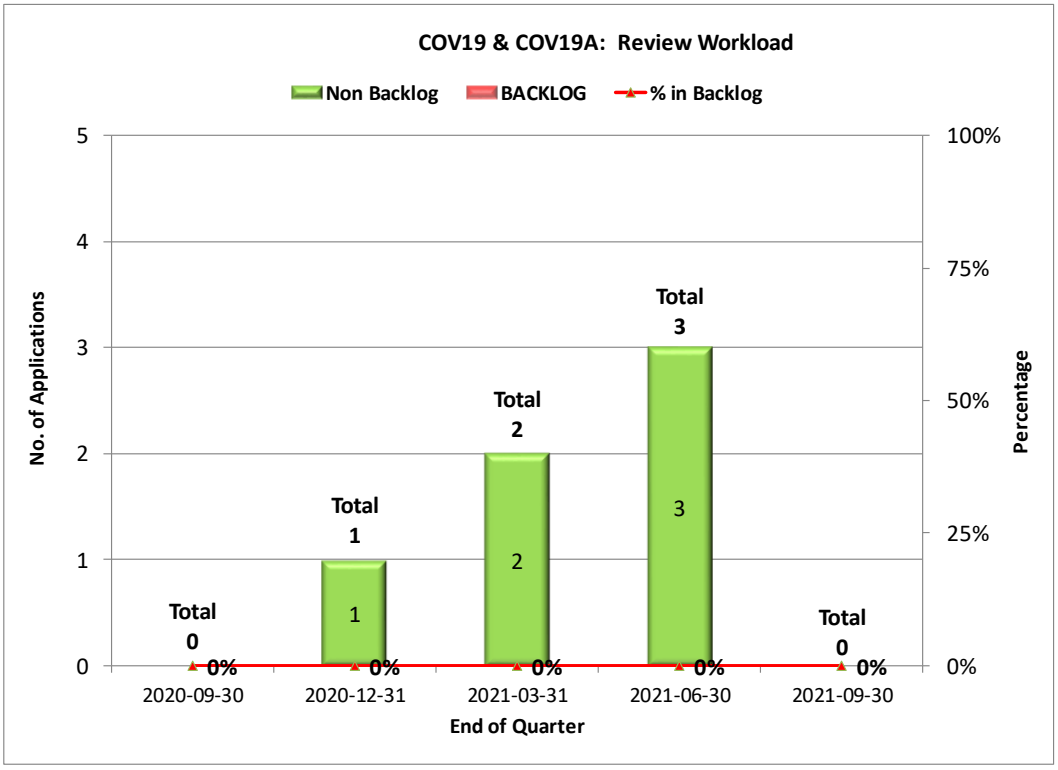
RECEIVED

COV19 & COV19A: Number Received



WORKLOAD

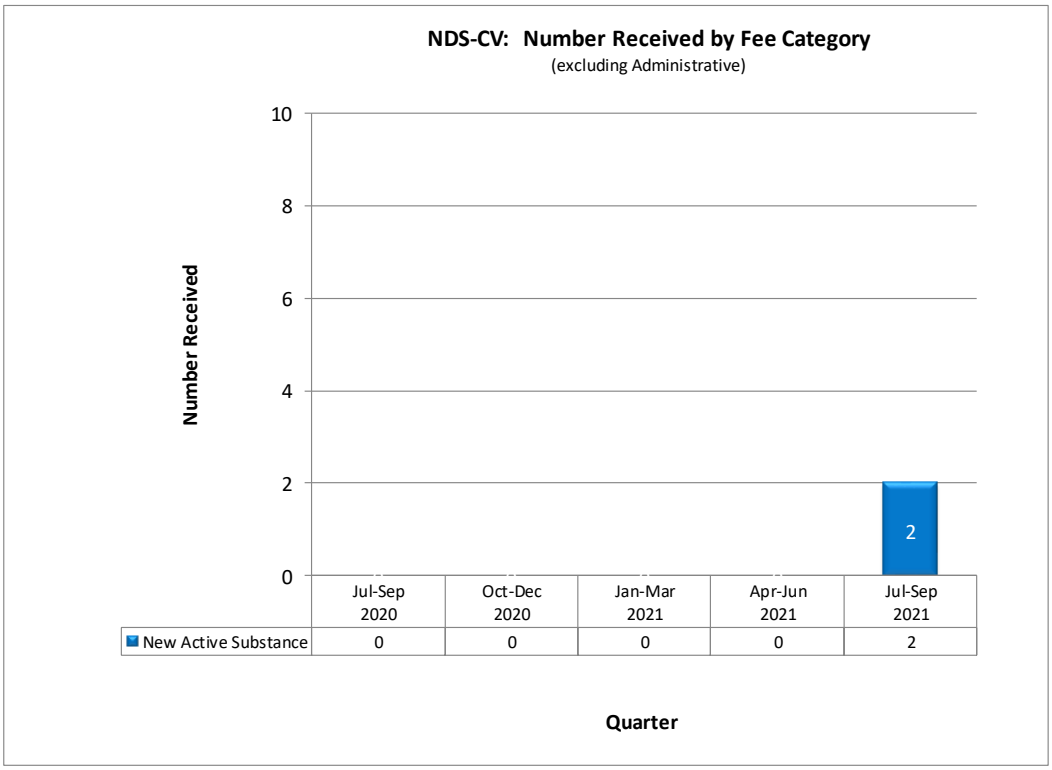
COV19 & COV19A: Review Workload



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

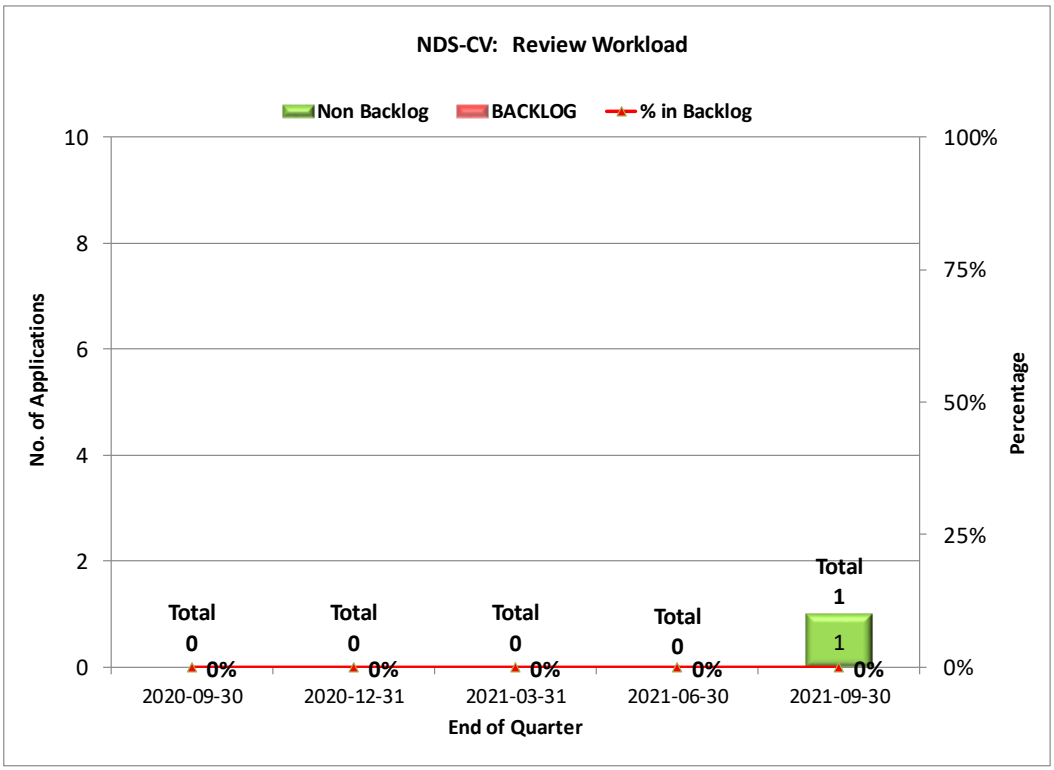
RECEIVED

NDS-CV: Number Received



WORKLOAD

NDS-CV: Review Workload



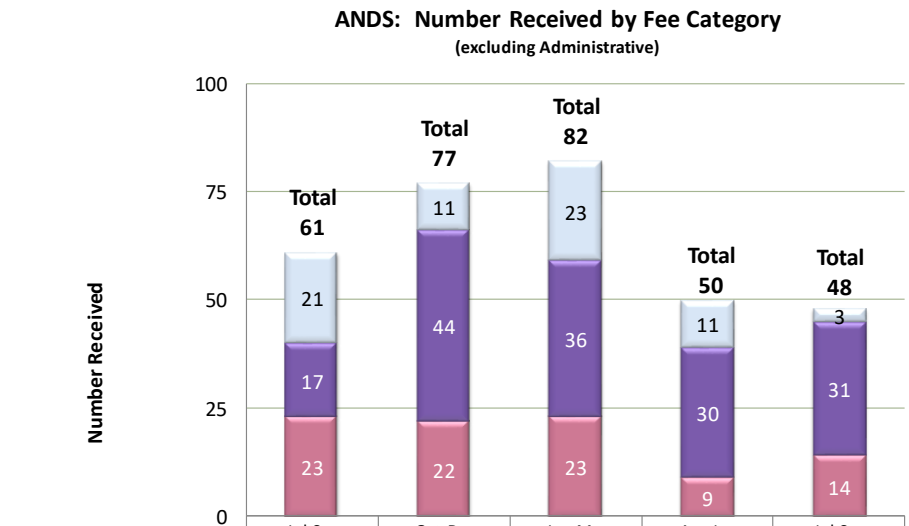
Abbreviated New Drug Submissions (ANDS)

&

Supplement to an Abbreviated New Drug Submissions (SANDS)

SUBMISSIONS RECEIVED

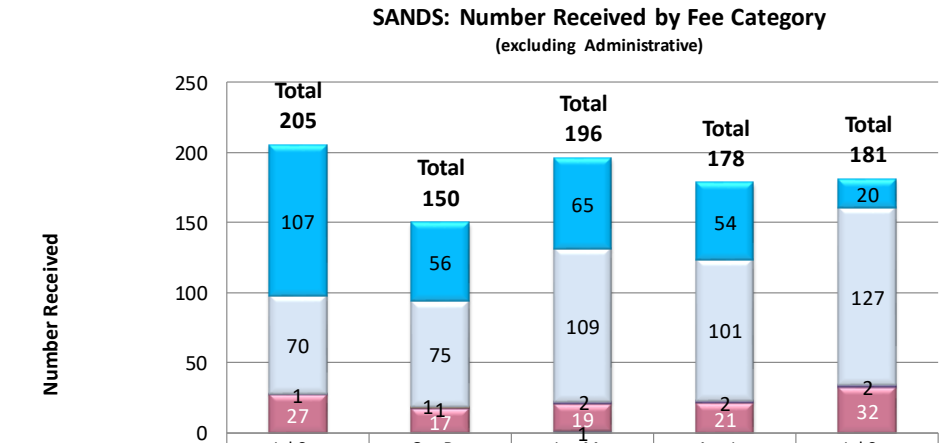
ANDS: Number Received by Fee Category



	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Labelling Only	21	11	23	11	3
Comparative Studies	17	44	36	30	31
Chemistry & Manufacturing	23	22	23	9	14
Total	61	77	82	50	48

Quarter

SANDS: Number Received by Fee Category

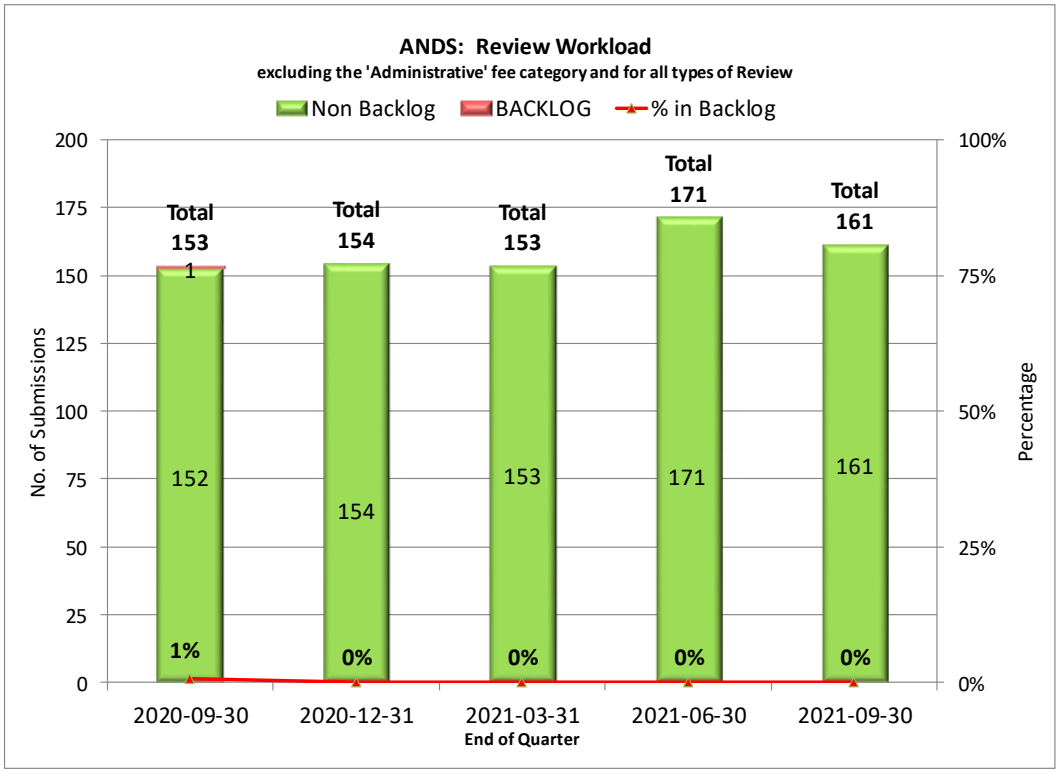


	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Label Update Generic	107	56	65	54	20
Labelling Only	70	75	109	101	127
Safety Update Label	0	1	0	0	0
Comparative Studies	1	1	2	2	2
Chemistry & Manufacturing	27	17	19	21	32
Clinical or Non-Clin Only	0	0	1	0	0
Total	205	150	196	178	181

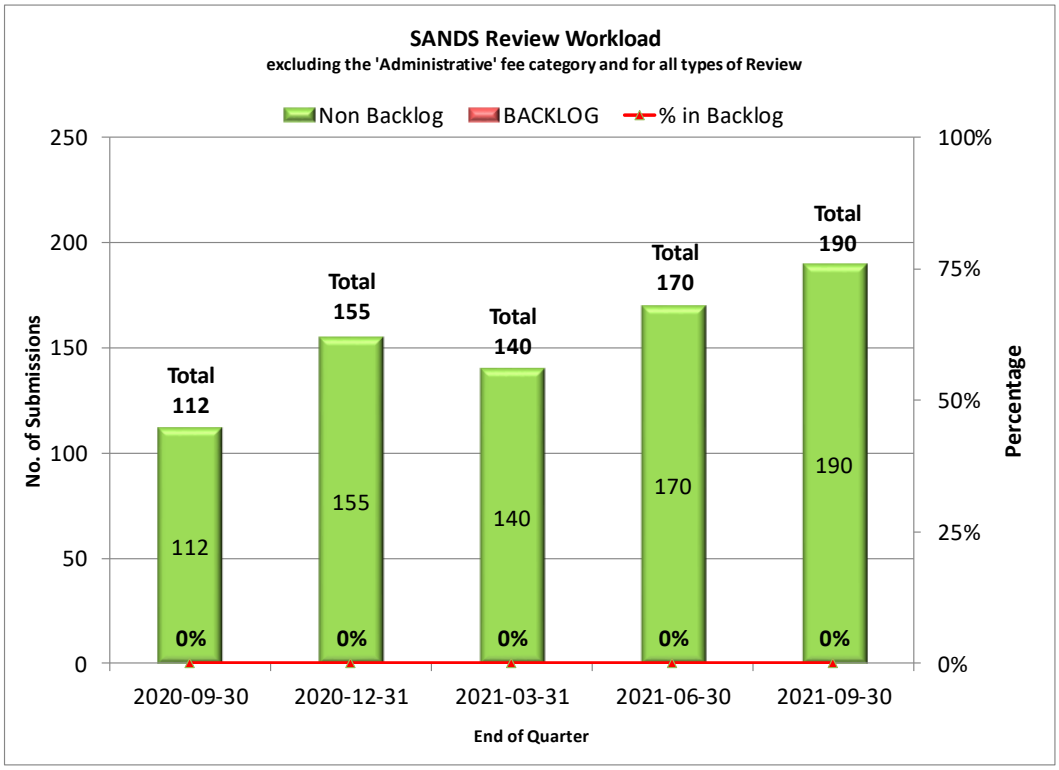
Quarter

WORKLOAD

ANDS: Review Workload



SANDS: Review Workload



WORKLOAD

ANDS: Review Workload by Fee Category

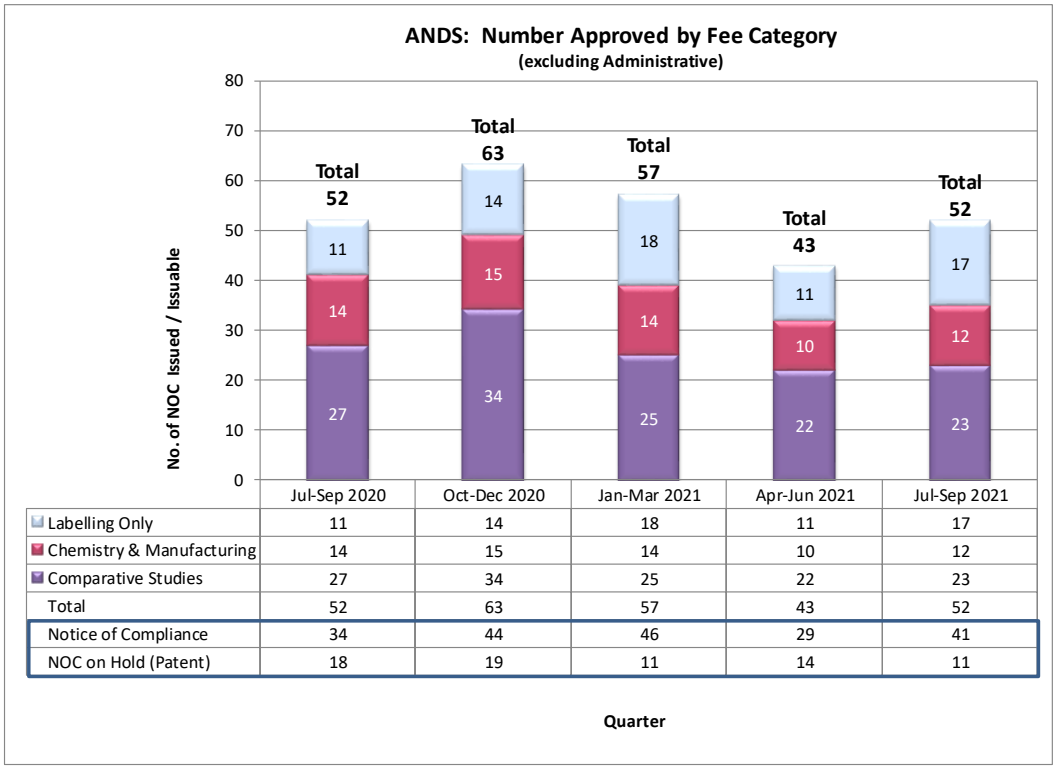
ANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2020-09-30	2020-12-31	2021-03-31	2021-06-30	2021-09-30
Chemistry & Manufacturing	51	54	53	51	52
Backlog	*1*	*0*	*0*	*0*	*0*
Comparative Studies	84	79	89	98	100
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	18	21	11	22	9
Backlog	*0*	*0*	*0*	*0*	*0*
Total	153	154	153	171	161
Non Backlog	152	154	153	171	161
BACKLOG	1	0	0	0	0
% in Backlog	1%	0%	0%	0%	0%

SANDS: Review Workload by Fee Category

SANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2020-09-30	2020-12-31	2021-03-31	2021-06-30	2021-09-30
Chemistry & Manufacturing	37	40	30	34	52
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	0	0	1	5	5
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	54	85	91	119	124
Backlog	*0*	*0*	*0*	*0*	*0*
Label Update Generic	21	29	18	12	9
Backlog	*0*	*0*	*0*	*0*	*0*
Safety Update Label	0	1	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	112	155	140	170	190
Non Backlog	112	155	140	170	190
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

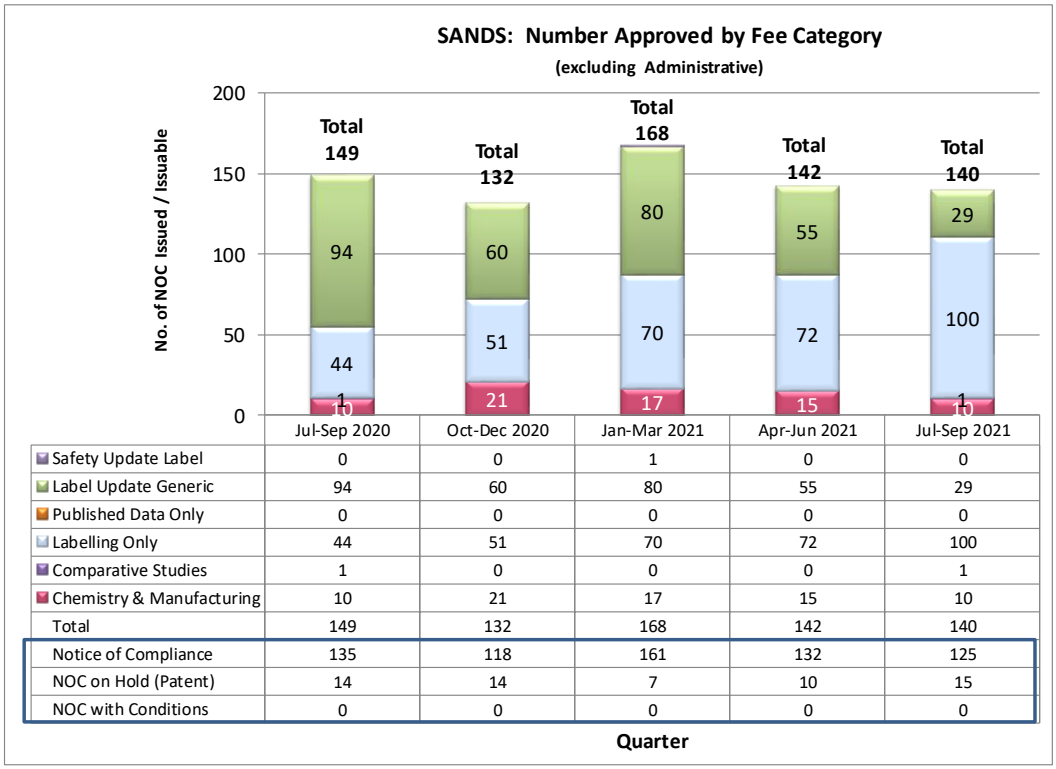
APPROVALS

ANDS: Number Approved by Fee Category and by NOC Type



	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Labelling Only	11	14	18	11	17
Chemistry & Manufacturing	14	15	14	10	12
Comparative Studies	27	34	25	22	23
Total	52	63	57	43	52
Notice of Compliance	34	44	46	29	41
NOC on Hold (Patent)	18	19	11	14	11

SANDS: Number Approved by Fee Category and by NOC Type



	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Safety Update Label	0	0	1	0	0
Label Update Generic	94	60	80	55	29
Published Data Only	0	0	0	0	0
Labelling Only	44	51	70	72	100
Comparative Studies	1	0	0	0	1
Chemistry & Manufacturing	10	21	17	15	10
Total	149	132	168	142	140
Notice of Compliance	135	118	161	132	125
NOC on Hold (Patent)	14	14	7	10	15
NOC with Conditions	0	0	0	0	0

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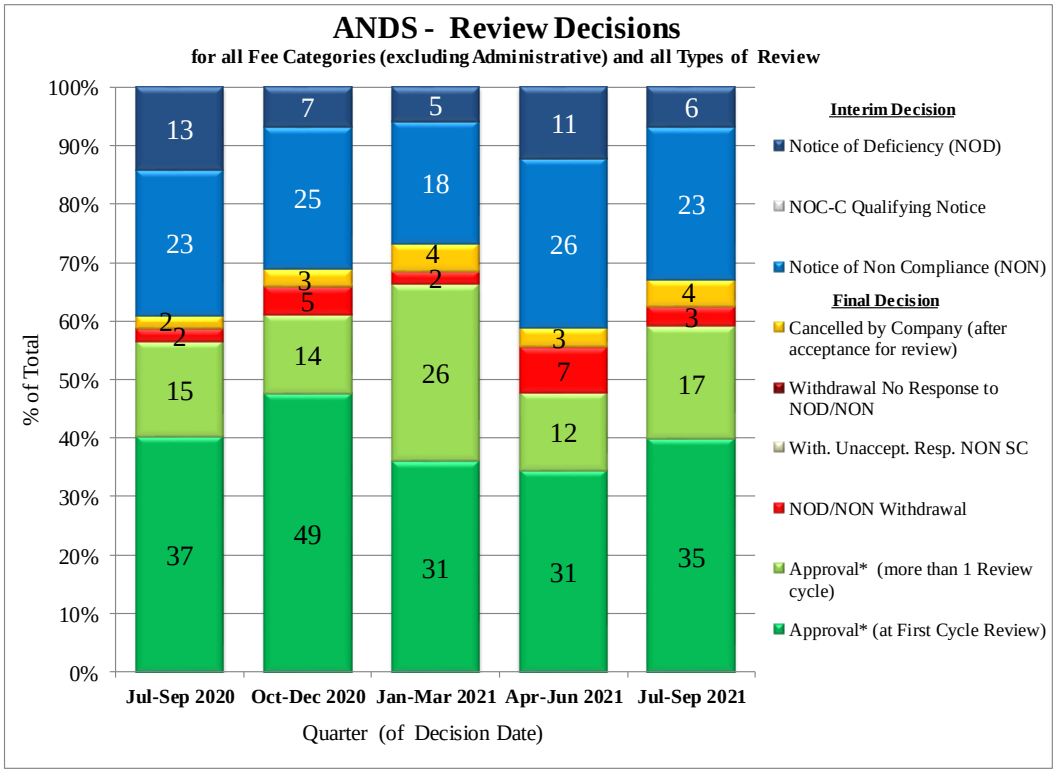
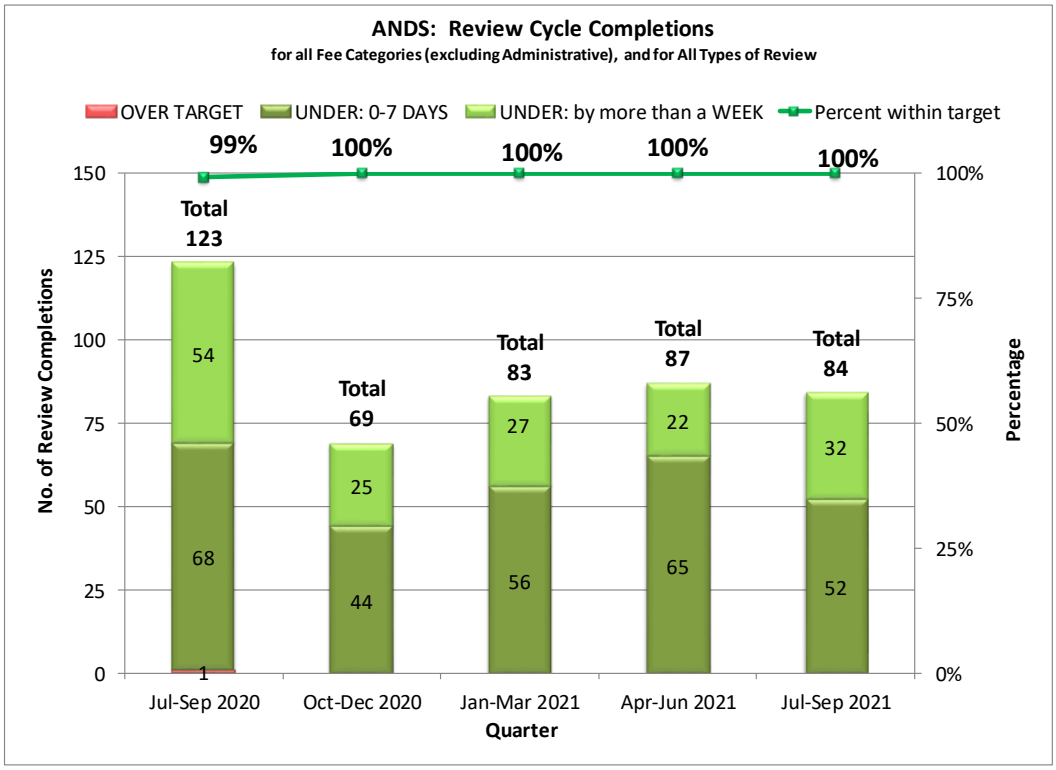
REVIEW PERFORMANCE

ANDS: Review Decisions by Type

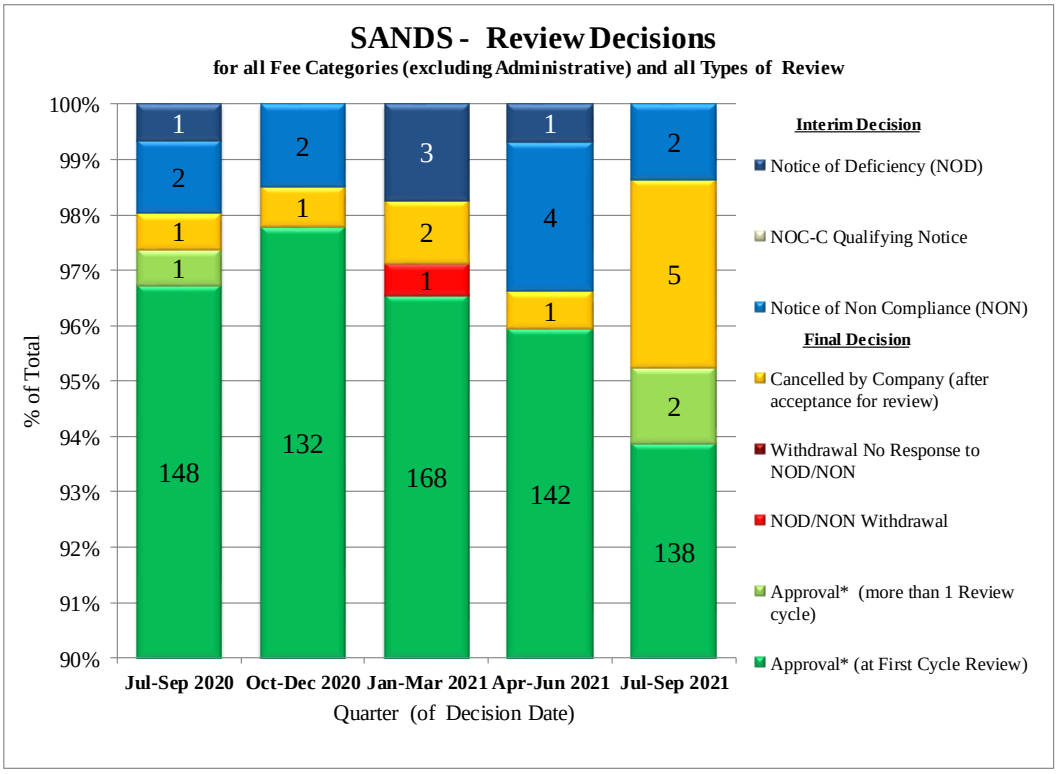


ANDS: Review Cycle Completions

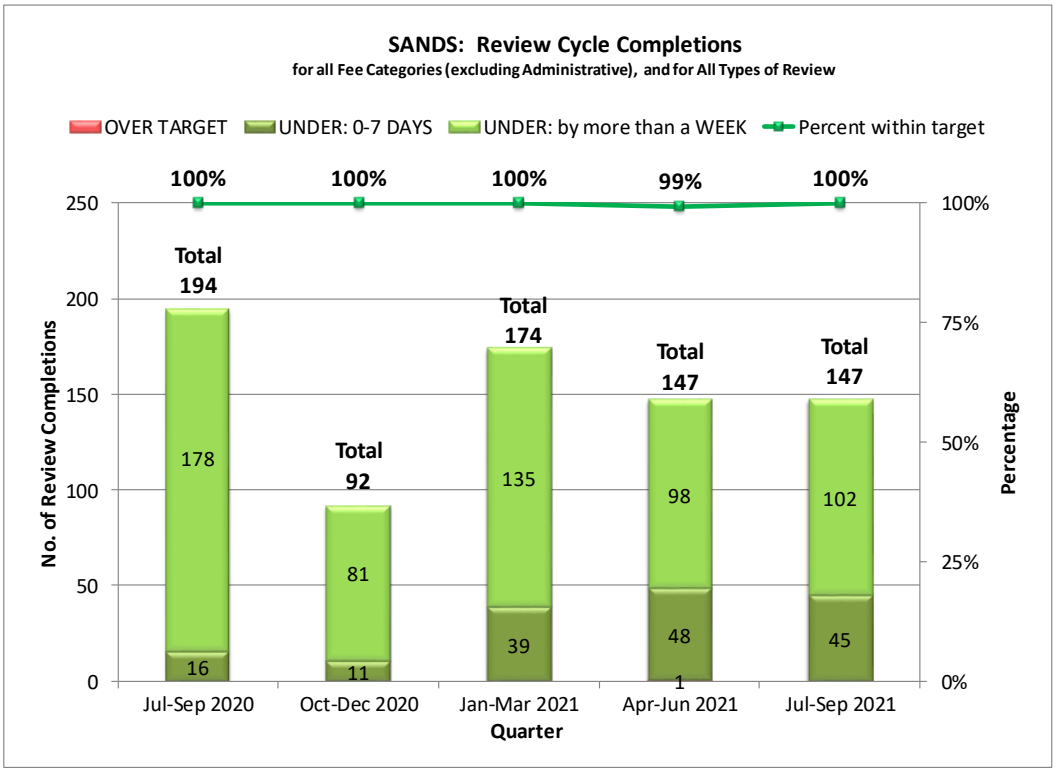


REVIEW PERFORMANCE

SANDS: Review Decisions by Type

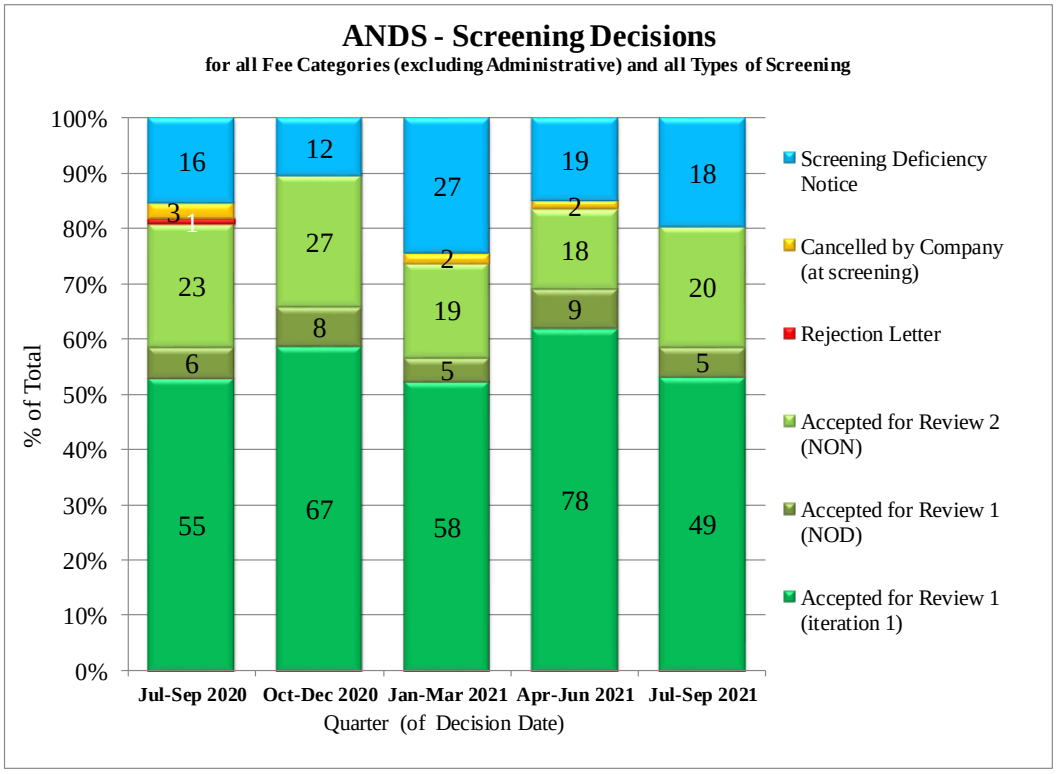


SANDS: Review Cycle Completions

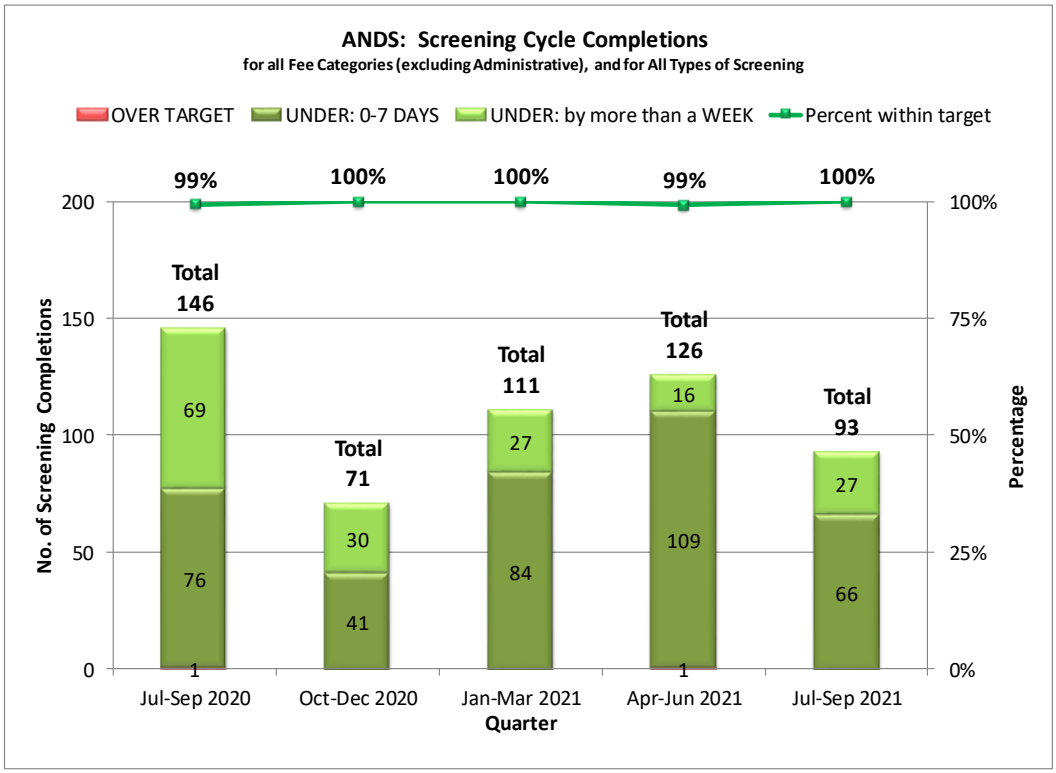


SCREENING PERFORMANCE

ANDS: Screening Decisions by Type

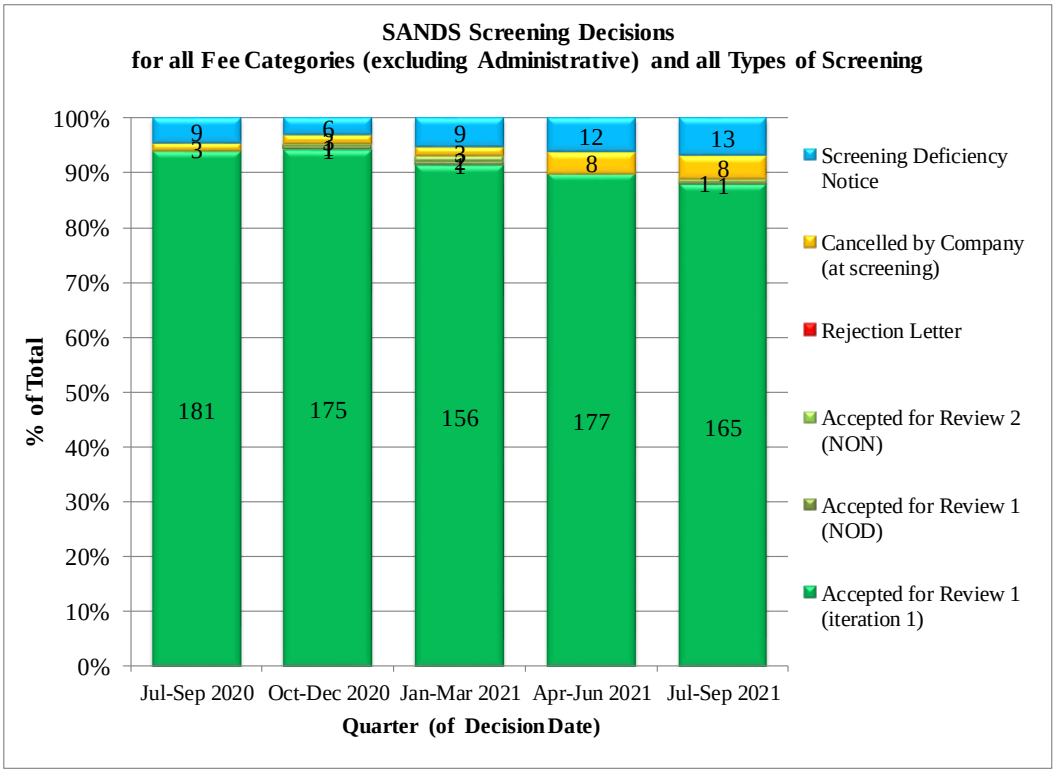


ANDS: Screening Cycle Completions

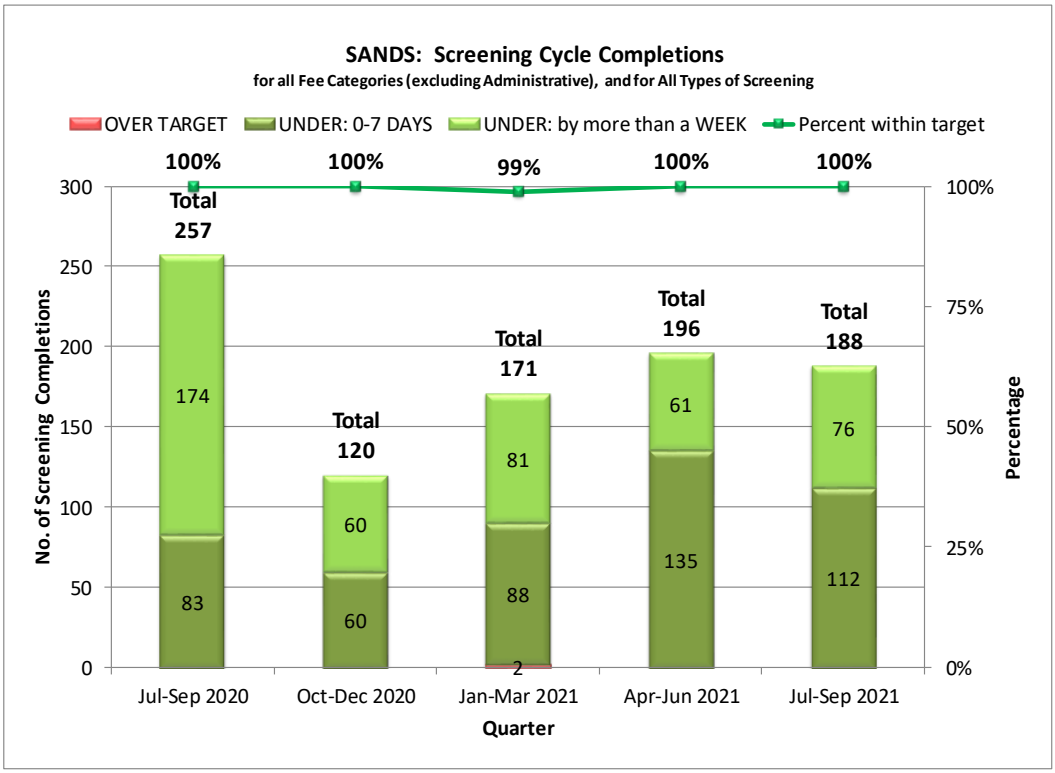


SCREENING PERFORMANCE

SANDS: Screening Decisions by Type

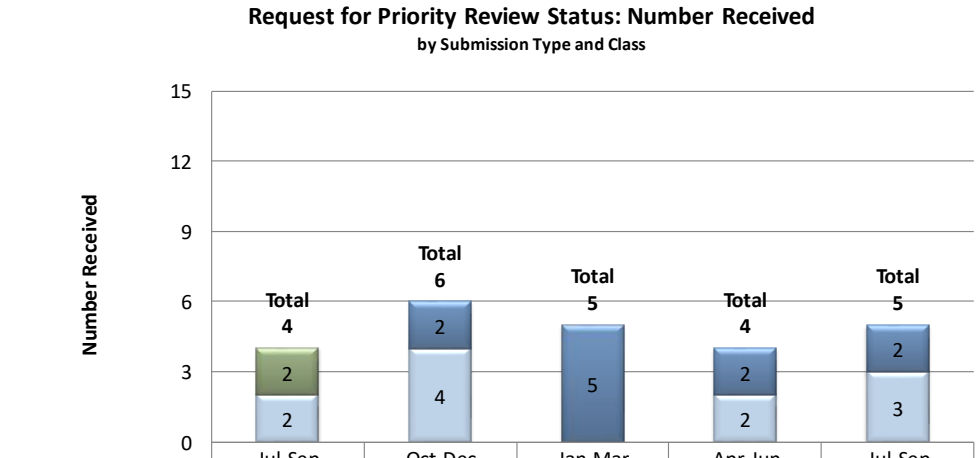


SANDS: Screening Cycle Completions



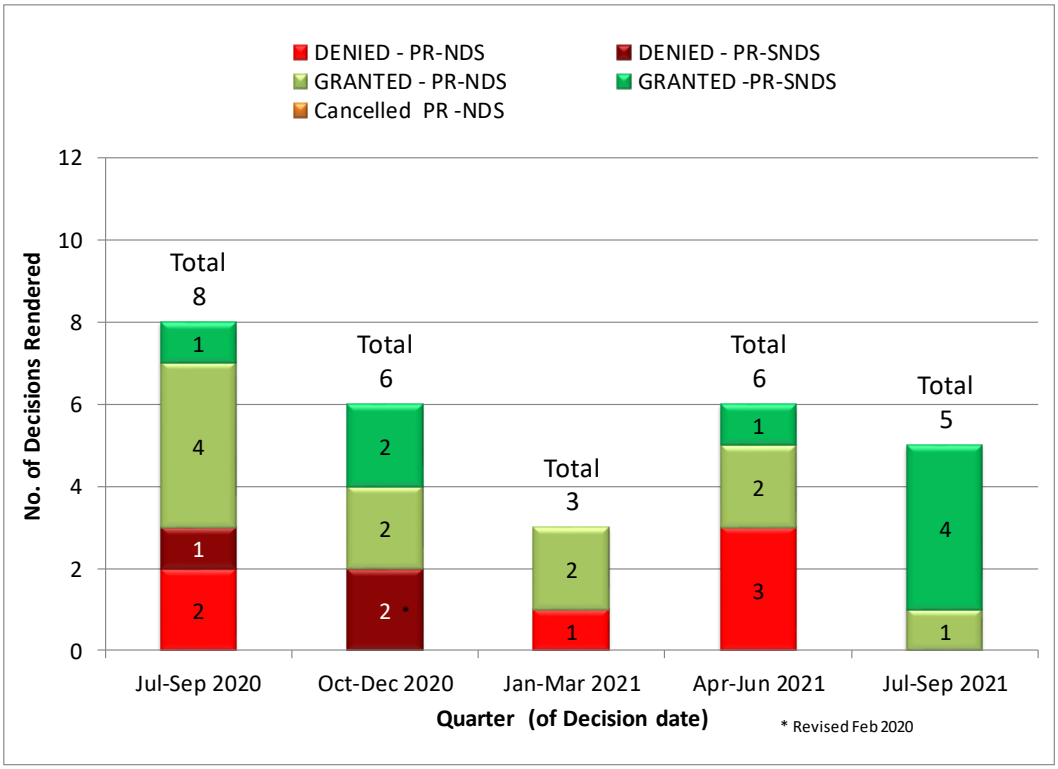
REQUEST FOR PRIORITY REVIEW STATUS (for NDS & SNDS)

Request for Priority Review Status: Number Received

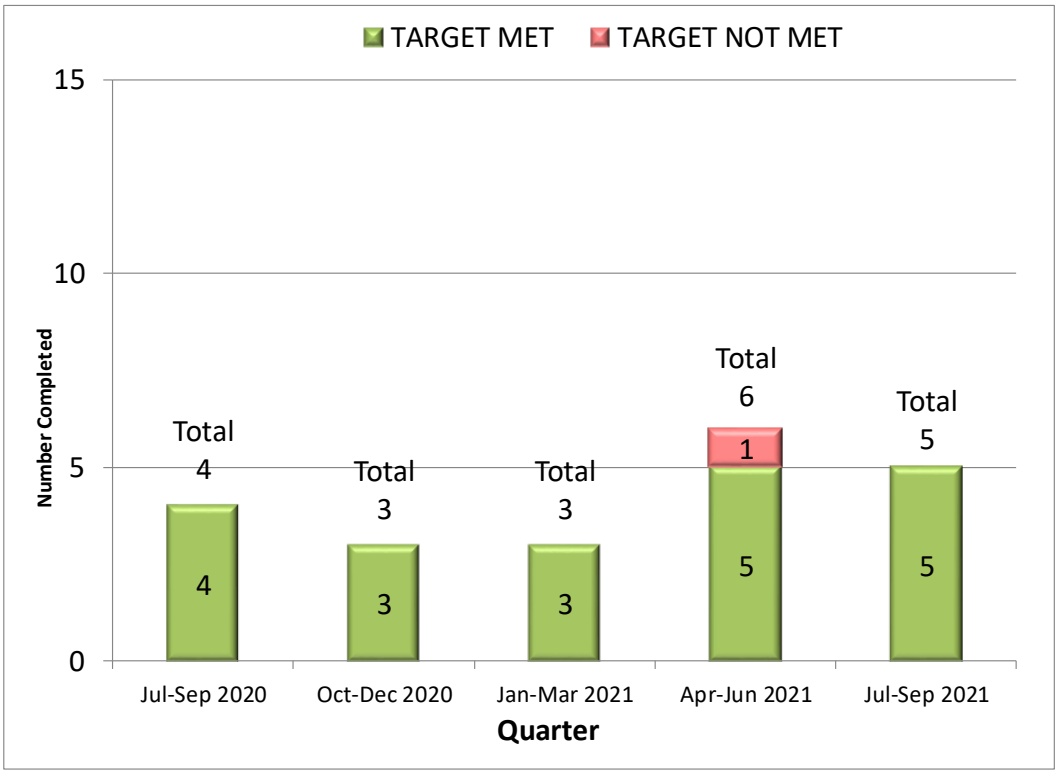


	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
PR-NDS CLIN ONLY	0	2	5	2	2
PR-NDS CLIN/C&M	2	0	0	0	0
PR-SNDS CLIN ONLY	2	4	0	2	3
PR-SNDS CLIN/C&M	0	0	0	0	0
Total	4	6	5	4	5

Request for Priority Review Status: Decisions Rendered



Request for Priority Review Status: Performance

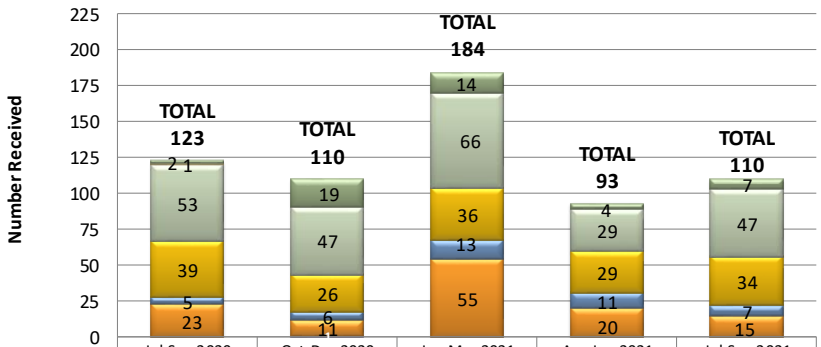


ADMINISTRATIVE SUBMISSIONS

(Manufacturer and/or Product Name Changes)[9]

RECEIVED

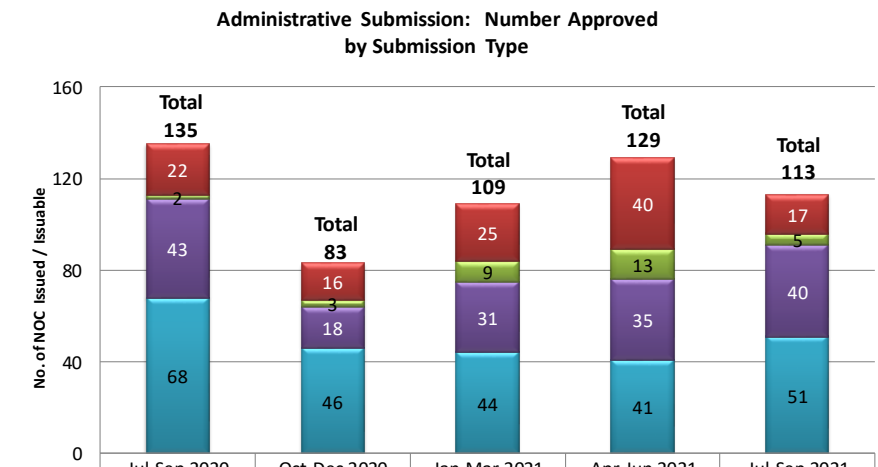
Administrative Submissions: Number Received by Submission Type



	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
DDIN	2	19	14	4	7
PDC	1	0	0	0	0
SANDS	53	47	66	29	47
ANDS	39	26	36	29	34
SNDS	5	6	13	11	7
NDS	23	11	55	20	15
NC	0	1	0	0	0
TOTAL	123	110	184	93	110

APPROVALS

Administrative Submissions: Number Approved (NDS, SNDS, ANDS and SANDS)



	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
NDS	22	16	25	40	17
SNDS	2	3	9	13	5
ANDS	43	18	31	35	40
SANDS	68	46	44	41	51
Total	135	83	109	129	113

[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	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
NOTICE OF COMPLIANCE	22	16	25	40	17
SCREENING DEFICIENCY NOTICE	0	1	1	0	2
CANCELLATION LETTER	0	0	2	2	2
PROCESSING HOLD LETTER	6	2	2	2	0
SNDS	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**
NOTICE OF COMPLIANCE	2	3	9	13	5
SCREENING DEFICIENCY NOTICE	0	0	1	1	0
CANCELLATION LETTER	2	0	0	5	2
PROCESSING HOLD LETTER	2	1	0	0	0
ANDS	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**
NOTICE OF COMPLIANCE	42	18	30	35	40
NOC ON IP HOLD	1	0	1	0	0
SCREENING DEFICIENCY NOTICE	2	0	0	0	1
CANCELLATION LETTER	5	2	1	2	1
PROCESSING HOLD LETTER	3	7	0	2	1
SANDS	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**
NOTICE OF COMPLIANCE	68	46	44	41	51
NOC ON IP HOLD	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	1	0
CANCELLATION LETTER	2	0	6	1	0
PROCESSING HOLD LETTER	4	5	1	0	1
NC	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**
NO OBJECTION LETTER	1	0	0	0	0
NC - HOLD (PATENT)	0	0	0	0	0
CANCELLATION LETTER	0	0	0	0	0
PROCESSING HOLD LETTER	0	2	0	0	0
SCREENING DEFICIENCY NOTICE	0	1	0	0	0
DINA	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**
NOTIFICATION FORM / DIN ISSUED	12	15	7	13	2
NO OBJECTION LETTER	0	0	0	0	1
SCREENING DEFICIENCY NOTICE	0	0	0	1	0
CANCELLATION LETTER	2	1	0	0	1
PROCESSING HOLD LETTER	0	0	0	0	3
PDC	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**
NO OBJECTION LETTER	0	0	0	0	0
CANCELLATION LETTER	1	0	0	0	0
PROCESSING HOLD LETTER	0	0	0	0	0

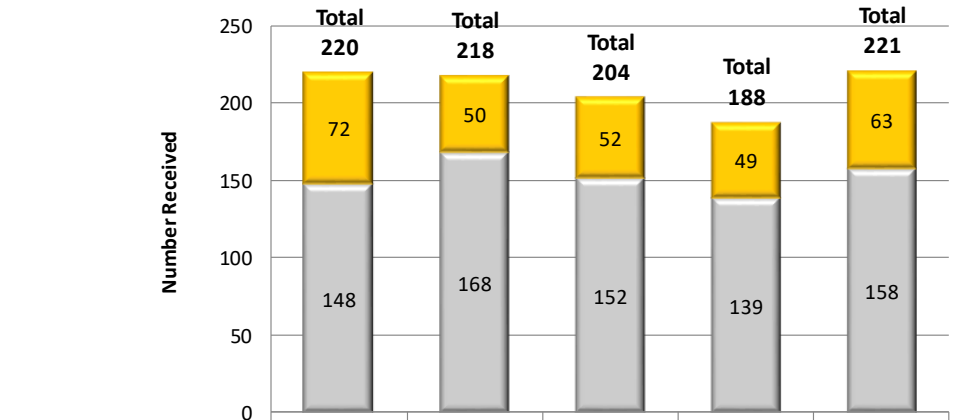
[10] The screening functions for Administrative submissions and the review functions for Labelling Only submissions with an Administrative component were moved from the Office of Submissions and Intellectual Property (OSIP) to the labelling area of the Bureau of Gastroenterology, Infection and Viral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

Clinical Trial Applications and Amendments

(CTA & CTA-A)

CTA: CLINICAL TRIAL APPLICATIONS

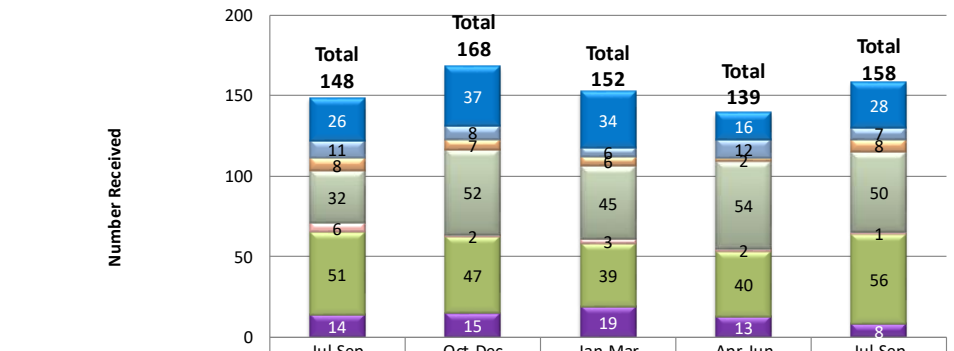
CTA: Number Received



	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Phase 1 Bioequivalence (7 day admin. Target)	72	50	52	49	63
Total (Non Bioequivalence)	148	168	152	139	158
Total	220	218	204	188	221

Quarter

CTA: Number Received by Phase



	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Phase 1 HEALTHY HUMAN	26	37	34	16	28
Phase 1 OTHER	11	8	6	12	7
Phase 1/2	8	7	6	2	8
Phase 2	32	52	45	54	50
Phase 2/3	6	2	3	2	1
Phase 3	51	47	39	40	56
Phase Other	14	15	19	13	8
Total	148	168	152	139	158

Quarter

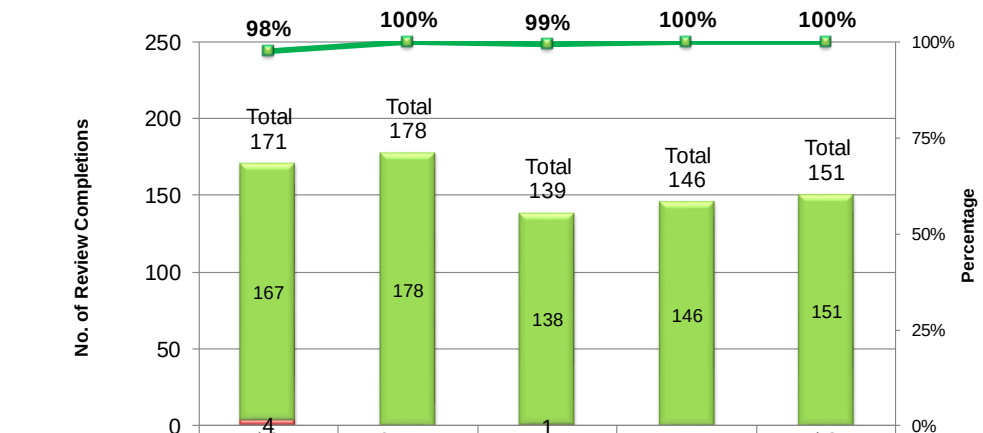
DECISION DOCUMENTS

CTA: Number of Decisions by Type

CTA					
DOCUMENT TYPE	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**
NO OBJECTION LETTER	185	217	186	188	165
NO OBJECTION LETTER WITH COMMITMENTS	0	0	0	0	44
CANCELLED BY COMPANY DURING REVIEW	8	14	7	9	5
CANCELLED BY COMPANY AT PROCESSING	4	1	2	6	4
NOTICE OF AUTHORIZATION	2	6	0	1	0

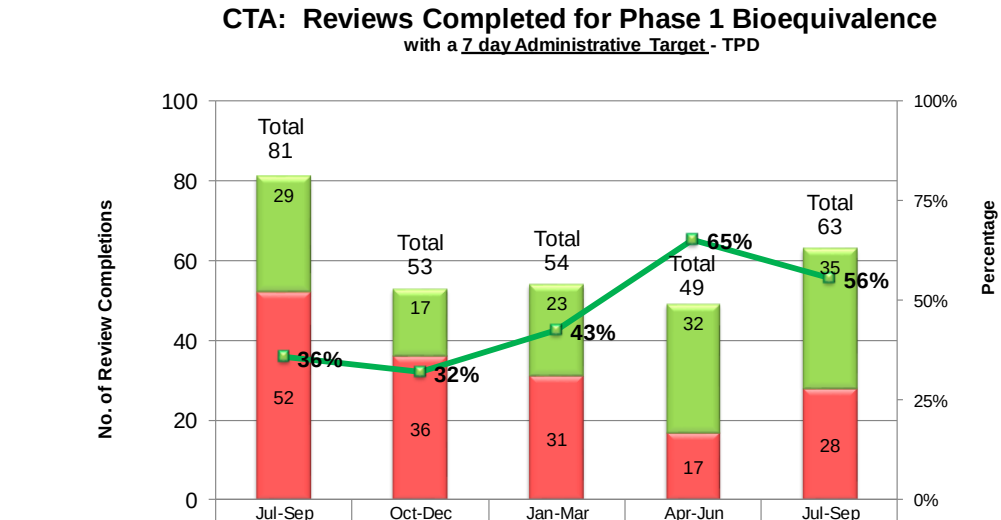
PERFORMANCE

CTA: Reviews Completed (excluding Phase 1 Bioequivalence)



	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Target MET	167	178	138	146	151
Target Not Met	4	0	1	0	0
Total	171	178	139	146	151
Percent within target	98%	100%	99%	100%	100%
Average days	30	33	25	26	27
Median days	29	38	27	28	28

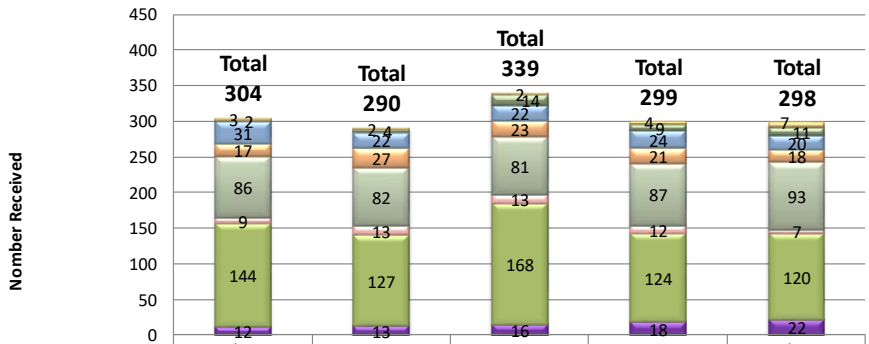
CTA: Reviews Completed for Phases with a 7 Day Administrative Target



	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Target MET	29	17	23	32	35
Target Not Met	52	36	31	17	28
Total	81	53	54	49	63
Percent within target	36%	32%	43%	65%	56%
Average days	10	11	9	8	9
Median days	8	10	8	7	7

CTA-A: CLINICAL TRIAL APPLICATION-AMENDMENTS

CTA-A: Number Received by Phase



	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Phase 1 BIOEQUIVALENCE-7	3	2	2	4	7
Phase 1 HEALTHY HUMAN	2	4	14	9	11
Phase 1 OTHER	31	22	22	24	20
Phase 1/2	17	27	23	21	18
Phase 2	86	82	81	87	93
Phase 2/3	9	13	13	12	7
Phase 3	144	127	168	124	120
Phase Other	12	13	16	18	22
Total	304	290	339	299	298

Quarter

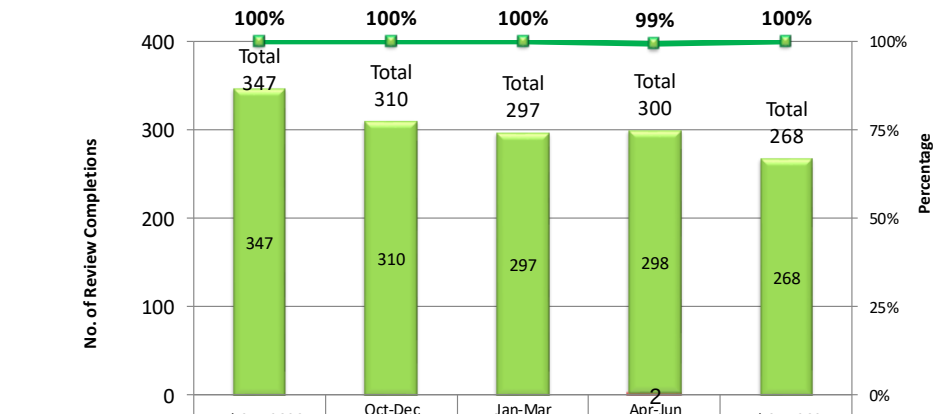
DECISIONS

CTA-A: Number of Decisions by Type

CTA-A (excluding administrative)					
DOCUMENT TYPE	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**
NO OBJECTION LETTER	259	301	293	303	262
NO OBJECTION LETTER WITH COMMITMENTS	0	0	0	0	9
CANCELLED BY COMPANY DURING REVIEW	2	7	2	2	2
CANCELLED BY COMPANY AT PROCESSING	14	8	21	9	14
NOT SATISFACTORY NOTICE	0	0	0	0	0
NOTICE OF AUTHORIZATION	0	2	4	2	1
NOTICE OF AUTHORIZA AMEND	0	0	0	2	1

PERFORMANCE

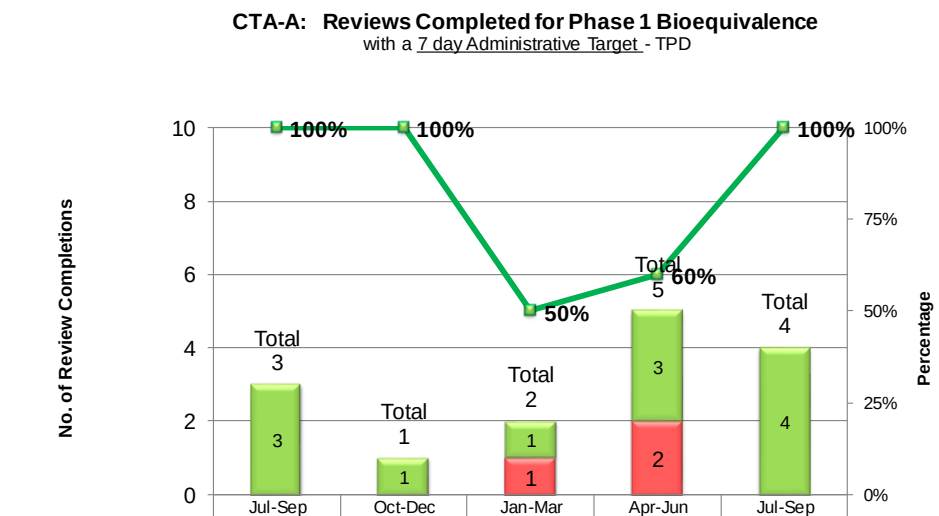
CTA-A: Reviews Completed (excluding Phase 1 Bioequivalence)



	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Target MET	347	310	297	298	268
Target Not Met	0	0	0	2	0
Total	347	310	297	300	268
Percent within target	100%	100%	100%	99%	100%
Average days	23	28	20	21	22
Median days	23	28	22	23	25

Quarter (decision date)

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

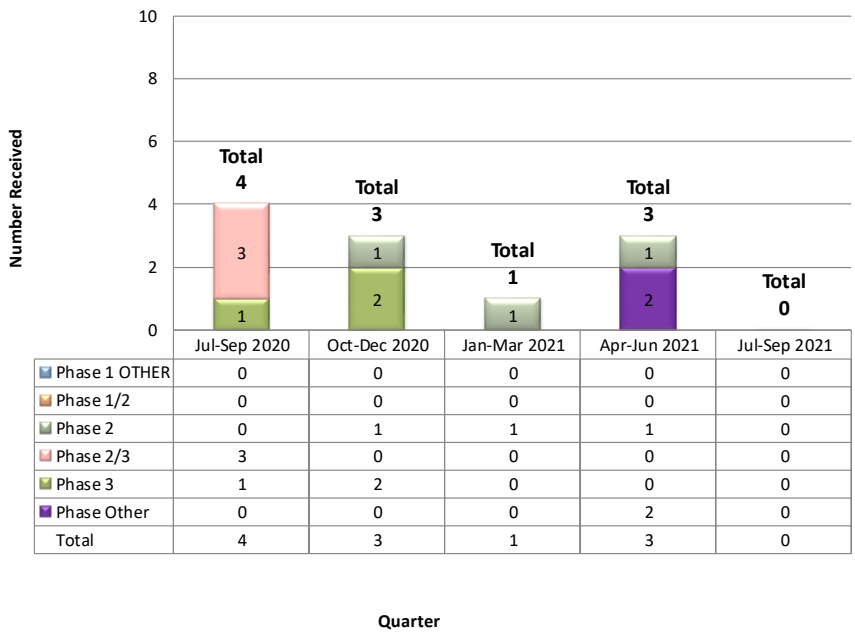


	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Target MET	3	1	1	3	4
Target Not Met	0	0	1	2	0
Total	3	1	2	5	4
Percent within target	100%	100%	50%	60%	100%
Average days	6	5	10	9	4
Median days	6	5	10	7	4

Quarter (decision date)

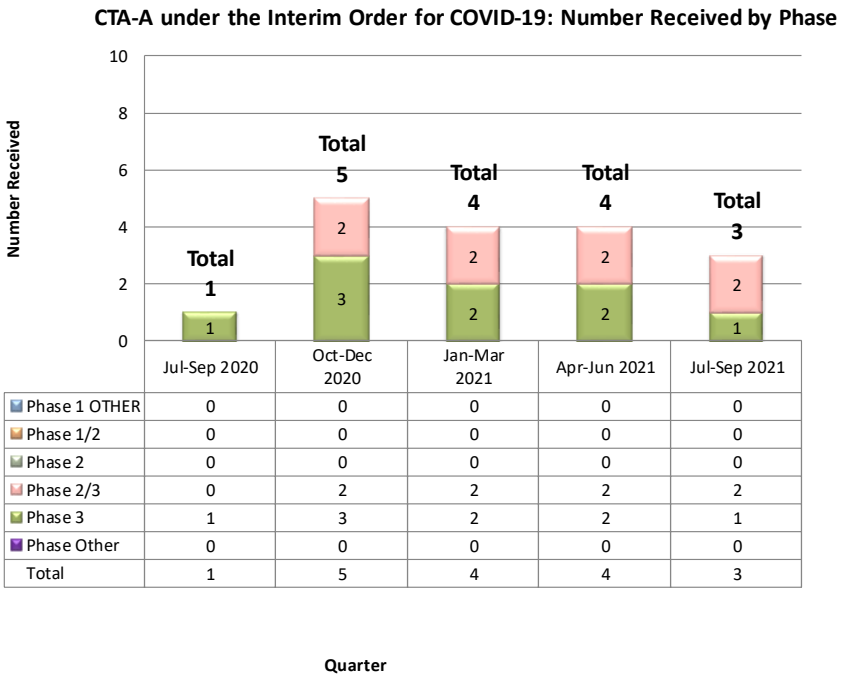
CTA & CTA-A RECEIVED UNDER THE INTERIM ORDER COVID 19

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



	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Phase 1 OTHER	0	0	0	0	0
Phase 1/2	0	0	0	0	0
Phase 2	0	1	1	1	0
Phase 2/3	3	0	0	0	0
Phase 3	1	2	0	0	0
Phase Other	0	0	0	2	0
Total	4	3	1	3	0

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



	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Phase 1 OTHER	0	0	0	0	0
Phase 1/2	0	0	0	0	0
Phase 2	0	0	0	0	0
Phase 2/3	0	2	2	2	2
Phase 3	1	3	2	2	1
Phase Other	0	0	0	0	0
Total	1	5	4	4	3

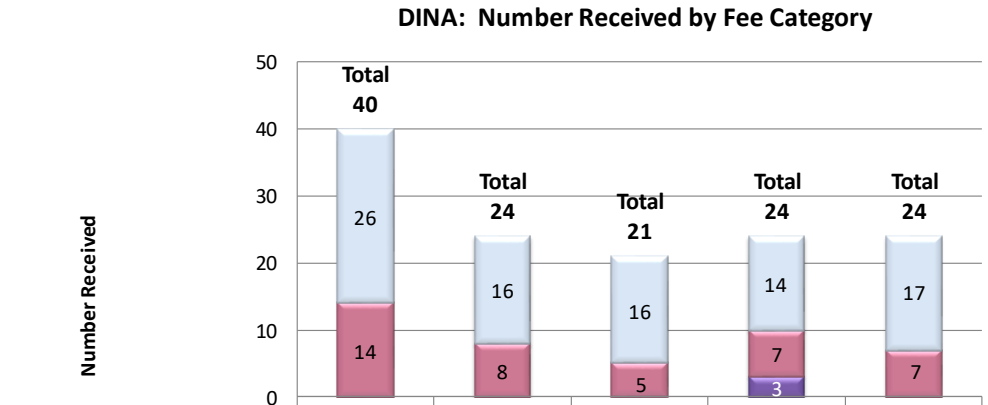
These figures are a subset of the total CTA and CTA-A received.

DINA

Application for a Drug Identification Number

DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER [11]

DINA: Number Received by Fee Category



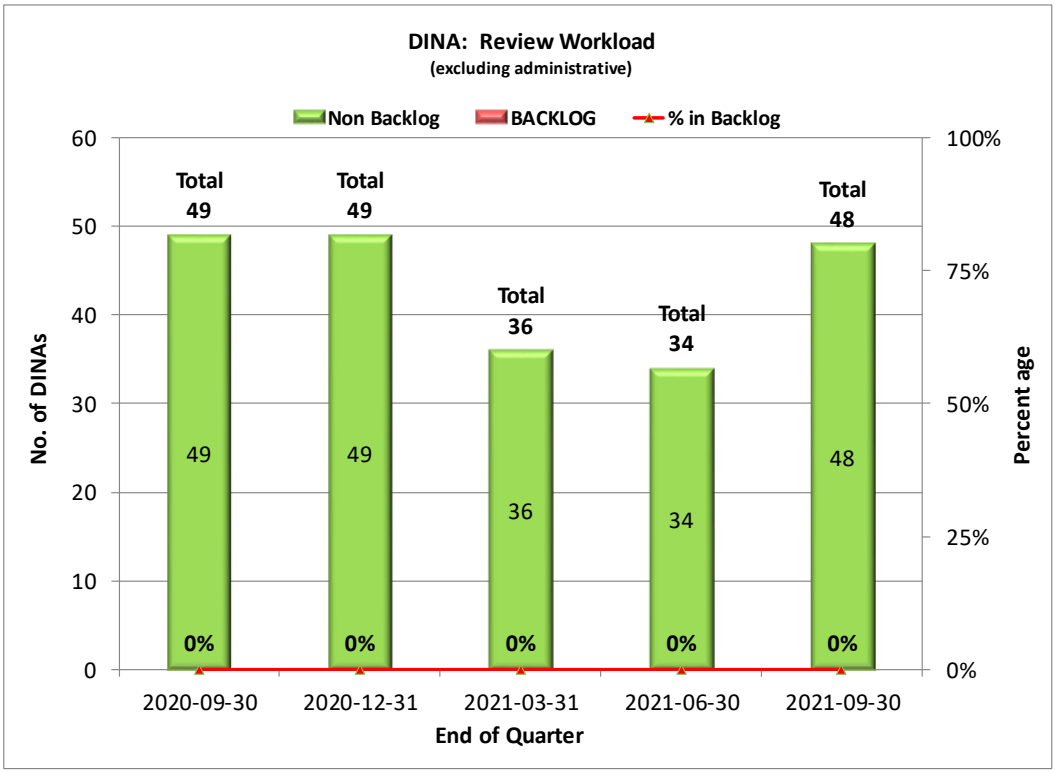
	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
Labelling Only	26	16	16	14	17
Labelling Standard	0	0	0	0	0
Chemistry & Manufacturing	14	8	5	7	7
Clinical or Non-Clin and C&M	0	0	0	0	0
Comparative Studies	0	0	0	3	0
Published Data Only	0	0	0	0	0
Total	40	24	21	24	24

Quarter

[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

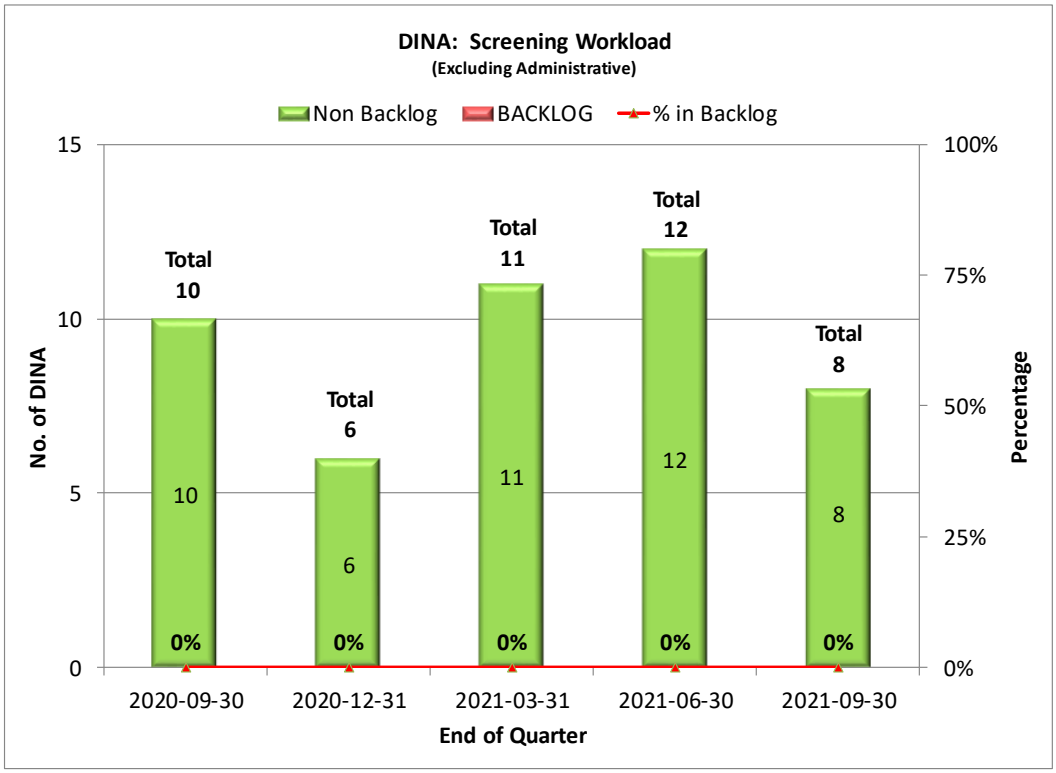


DINA: Review Workload by Fee Category

DINA: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2020-09-30	2020-12-31	2021-03-31	2021-06-30	2021-09-30
Labelling Only	36	29	16	14	22
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	11	18	19	18	24
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	0	1	1	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	2	1	0	2	2
Backlog	*0*	*0*	*0*	*0*	*0*
Total	49	49	36	34	48
Non Backlog	49	49	36	34	48
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	**2020-09-30**	**2020-12-31**	**2021-03-31**	**2021-06-30**	**2021-09-30**
Labelling Only	**2**	**3**	**7**	**6**	**5**
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Standard	**2**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**6**	**3**	**4**	**4**	**3**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**0**	**0**	**0**	**2**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**10**	**6**	**11**	**12**	**8**
Non Backlog	**10**	**6**	**11**	**12**	**8**
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	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
NOTIFICATION FORM/DIN ISSUED	5	2	8	1	2
NO OBJECTION LETTER	22	19	17	13	7
CANCELLED BY COMPANY	3	0	1	0	3
NEW DRUG LETTER SCREEN	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	1
NOTICE OF NON-COMPLIANCE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	1	0	2

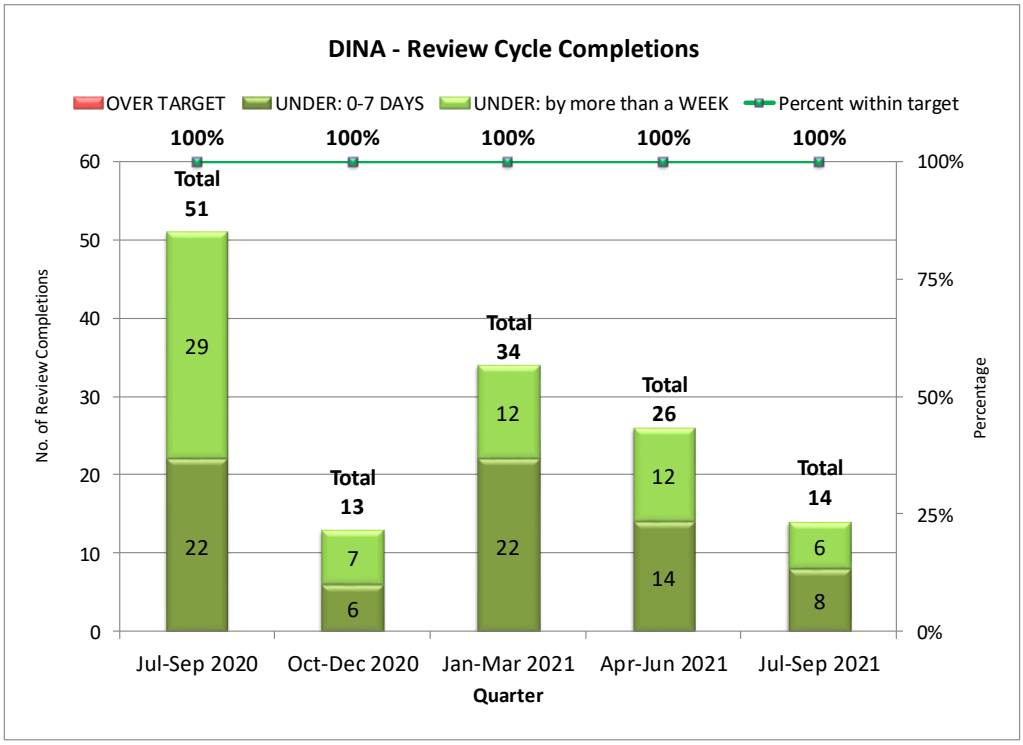
DINA - CHEMISTRY AND MANUFACTURING					
DOCUMENT TYPE	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
NOTIFICATION FORM/DIN ISSUED	4	0	3	6	0
NO OBJECTION LETTER	5	4	5	1	3
NOD WITHDRAWAL LETTER	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	1	0
NOTICE OF NON-COMPLIANCE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

DINA - COMPARATIVE STUDIES					
DOCUMENT TYPE	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
NOTIFICATION FORM/DIN ISSUED	0	0	1	0	0
NOTICE OF DEFICIENCY	0	1	0	0	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

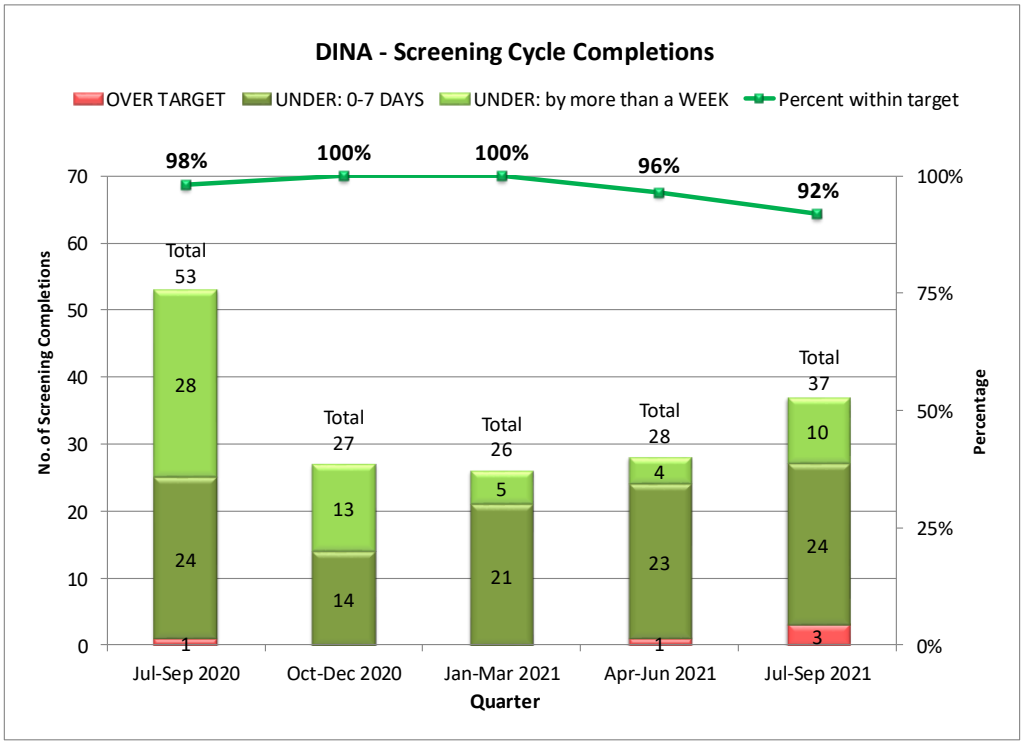
DINA - CLINICAL OR NON CLINICAL DATA AND C&M					
DOCUMENT TYPE	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021
CANCELLED BY COMPANY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	0	0	0	0	0
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	1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

PERFORMANCE

DINA: Review Cycle Completions

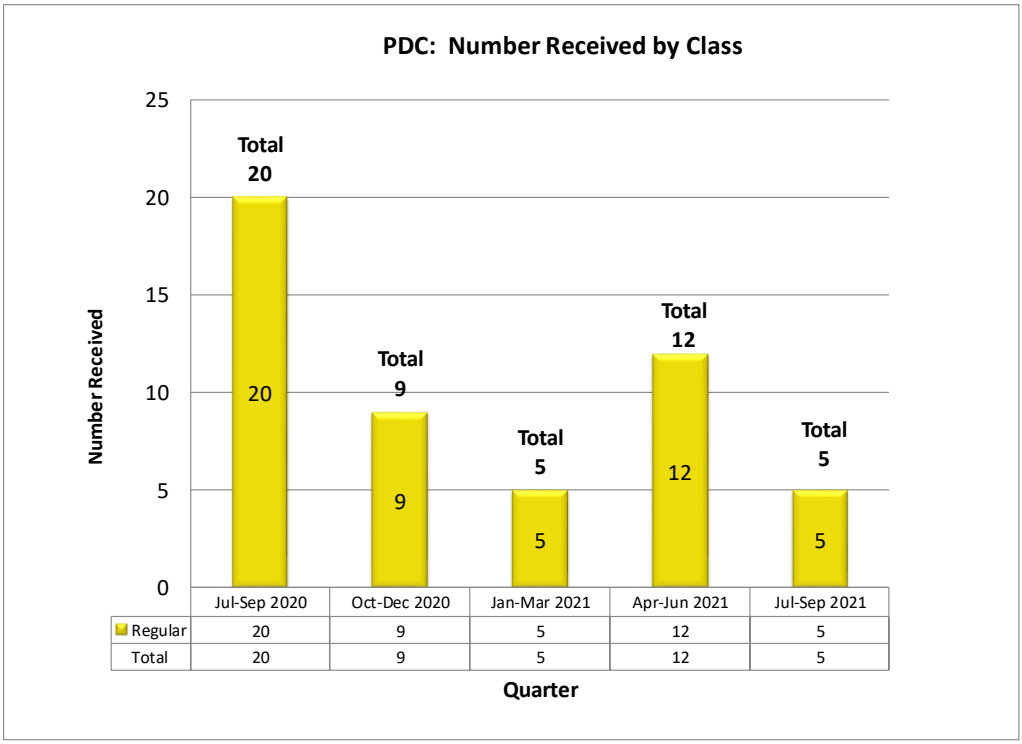


DINA: Screening Cycle Completions



PDC: POST-AUTHORIZATION DIVISION 1 CHANGE

PDC: Number Received

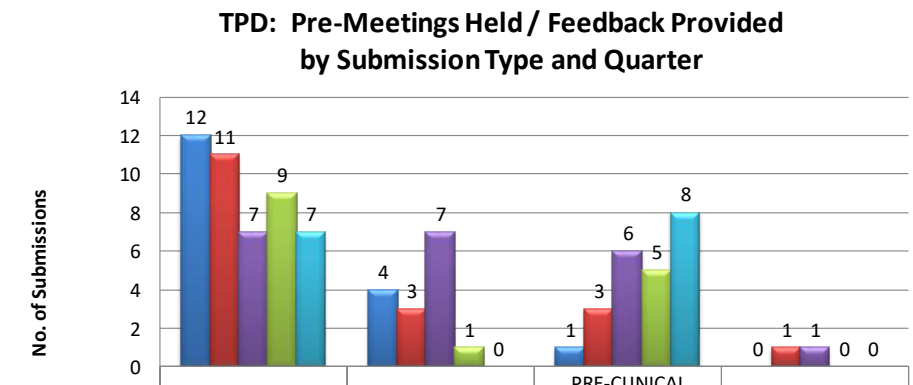


PDC: Number of Decisions by Type

PDC					
DOCUMENT TYPE	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**
REGULAR					
CANCELLED BY COMPANY	8	3	4	6	5
NO OBJECTION LETTER	7	11	4	1	3
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0

APPENDIX A: PRE-SUBMISSION MEETINGS [12]

Pre-submission Meetings Held / Feedback Provided



	PRE-NDS MEETING MPNDS	PRE-SNDS MEETING MPSNDS	PRE-CLINICAL TRIAL APPLICATION MEETING PRECTA	PRE-DIN MEETING MPDIN
JUL-SEP 2020	12	4	1	0
OCT-DEC 2020	11	3	3	1
JAN-MAR 2021	7	7	6	1
APR-JUN 2021	9	1	5	0
JUL-SEP 2021	7	0	8	0

[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.