Health Canada Santé Canada

Therapeutic Products Directorate

Drug Submission Performance Quarterly Report

October - December

2020

Canada

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Direction des produits thérapeutiques - Rapport trimestriel du rendement des présentations de drogue - octobre - décembre 2020

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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 October - December 2019 to October - December 2020. 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 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.

[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,
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Finance Building, A.L. # 0202A1
101 Tunney's Pasture Driveway, Tunney's Pasture
Ottawa, Ontario, K1A 0K9

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

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

[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 .

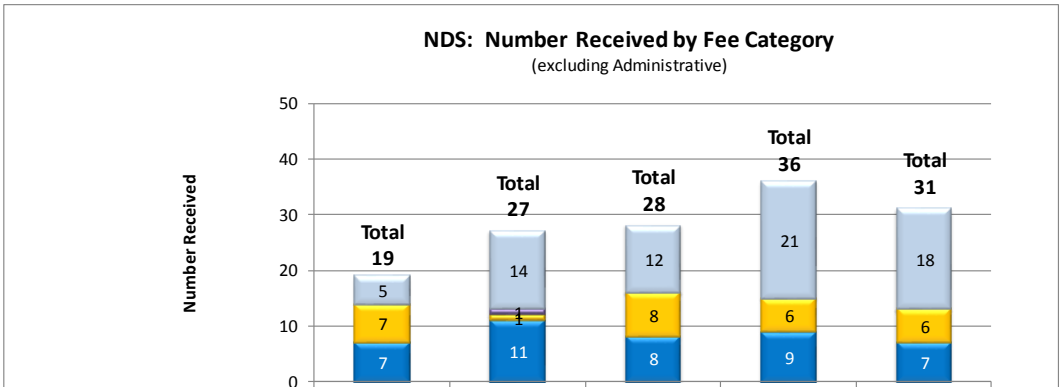
NEW DRUG SUBMISSION (NDS)

&

SUPPLEMENT TO A NEW DRUG SUBMISSION (SNDS)

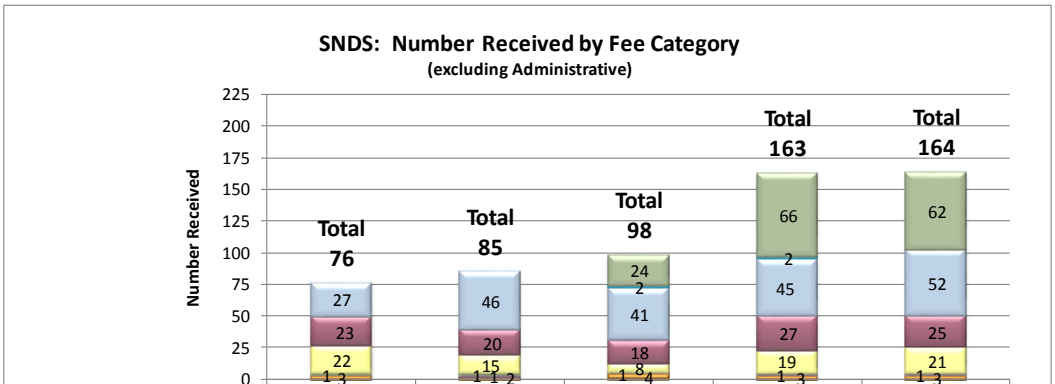
SUBMISSIONS RECEIVED [7]

NDS: Number Received by Fee Category



	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Unassigned	0	0	0	0	0
Labelling Only	5	14	12	21	18
Comparative Studies	0	1	0	0	0
Chemistry & Manufacturing	0	0	0	0	0
Clinical or Non-Clin Only	0	0	0	0	0
Clinical or Non-Clin and C&M	7	1	8	6	6
New Active Substance	7	11	8	9	7
Total	19	27	28	36	31
Priority Class	6	2	2	5	2
NOC-C Class	0	0	0	3	2
Extraordinary Use NDS	0	0	0	0	1

SNDS: Number Received by Fee Category

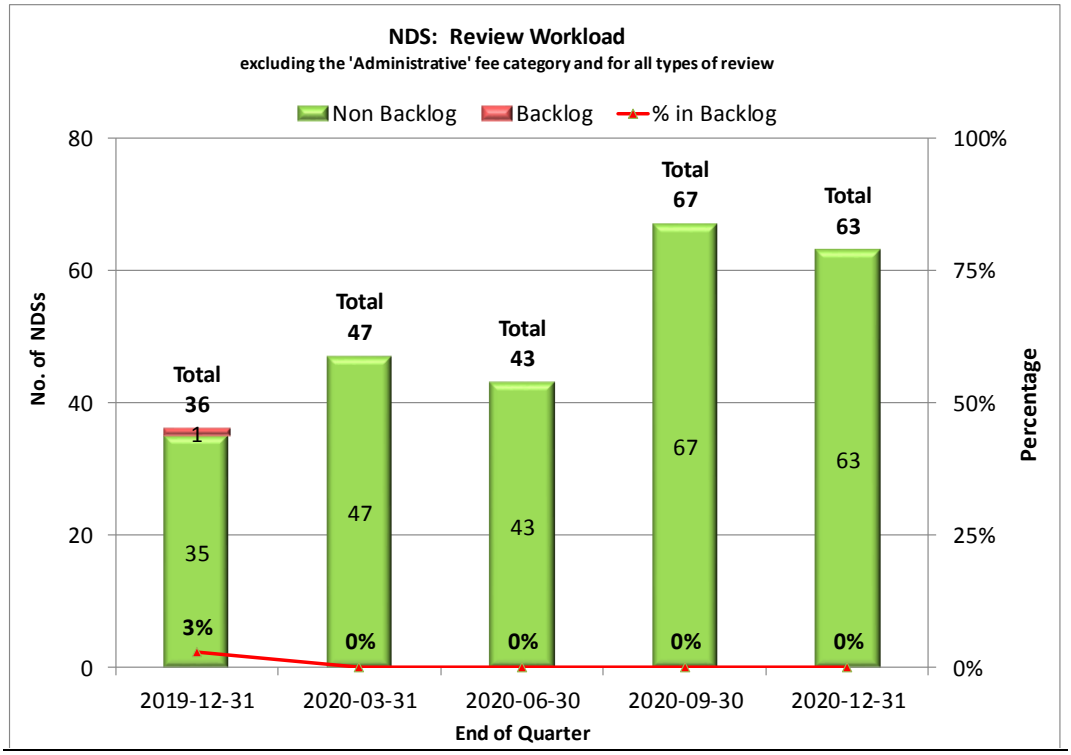


	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Safety Update Label	0	0	24	66	62
Label Update Generic	0	0	2	2	0
Labelling Only	27	46	41	45	52
Chemistry & Manufacturing	23	20	18	27	25
Clinical or Non-Clin Only	22	15	8	19	21
Published Data Only	1	1	0	0	0
Comparative Studies	0	1	1	1	1
Clinical or Non-Clin and C&M	3	2	4	3	3
Total	76	85	98	163	164
Priority Class	4	2	0	3	1
NOC-C Class	0	0	0	0	0
SNDS - Confirmatory	0	0	0	0	0

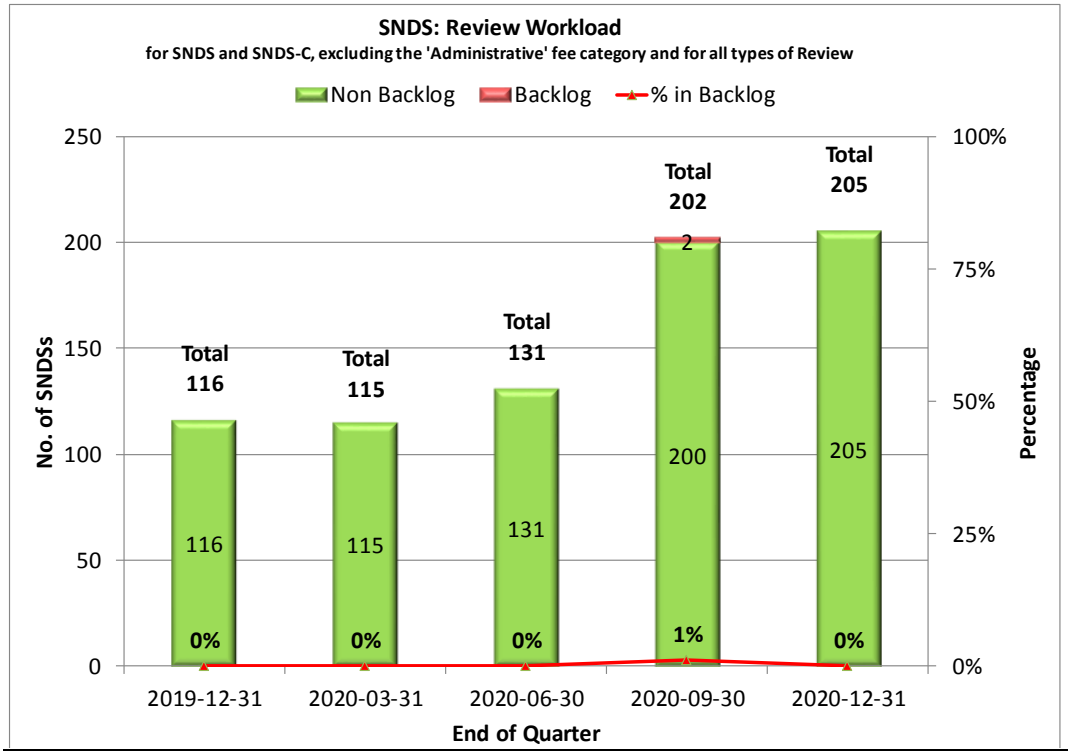
[7] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance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

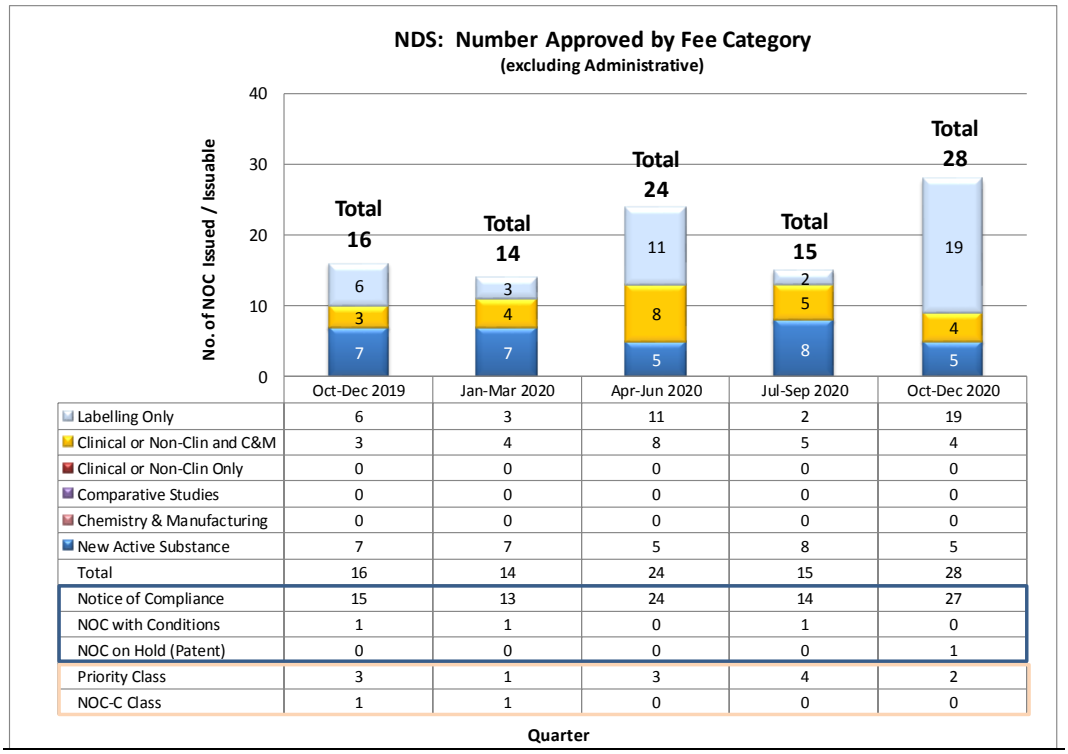
NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	**2019-12-31**	**2020-03-31**	**2020-06-30**	**2020-09-30**	**2020-12-31**
Labelling Only	**2**	**4**	**4**	**23**	**16**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**0**	**0**	**1**	**0**	**0**
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**	**24**	**16**	**20**	**20**
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	**14**	**19**	**22**	**24**	**27**
Backlog	*1*	*0*	*0*	*0*	*0*
Total	**36**	**47**	**43**	**67**	**63**
Non Backlog	**35**	**47**	**43**	**67**	**63**
Backlog	**1**	**0**	**0**	**0**	**0**
% in Backlog	**3%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**2**	**8**	**6**	**5**	**7**
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	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Labelling Only	**18**	**24**	**19**	**48**	**47**
Backlog	*0*	*0*	*0*	*1*	*0*
Comparative Studies	**2**	**5**	**5**	**4**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**26**	**26**	**35**	**43**	**37**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	**55**	**49**	**47**	**37**	**44**
Backlog	*0*	*0*	*0*	*1*	*0*
Clinical or Non-Clin and C&M	**5**	**8**	**9**	**10**	**11**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	**10**	**3**	**3**	**2**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Label Update Generic	**0**	**0**	**1**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Safety Update Label	**0**	**0**	**12**	**58**	**65**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**116**	**115**	**131**	**202**	**205**
Non Backlog	**116**	**115**	**131**	**200**	**205**
Backlog	**0**	**0**	**0**	**2**	**0**
% in Backlog	**0%**	**0%**	**0%**	**1%**	**0%**
Priority (subset)	**4**	**4**	**3**	**3**	**1**
Backlog	*0*	*0*	*0*	*1*	*0*
SNDS-C (Confirmatory)	**3**	**1**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*

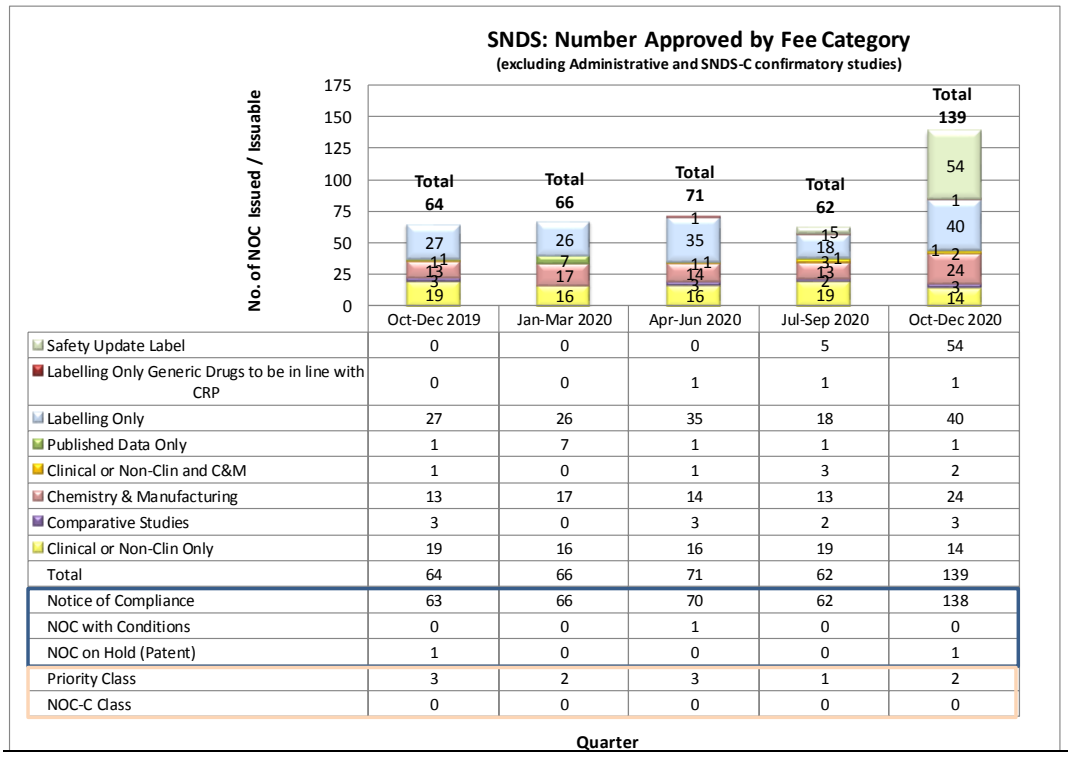
APPROVALS [8]

NDS: Number Approved by Fee Category and by NOC Type



	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Labelling Only	6	3	11	2	19
Clinical or Non-Clin and C&M	3	4	8	5	4
Clinical or Non-Clin Only	0	0	0	0	0
Comparative Studies	0	0	0	0	0
Chemistry & Manufacturing	0	0	0	0	0
New Active Substance	7	7	5	8	5
Total	16	14	24	15	28
Notice of Compliance	15	13	24	14	27
NOC with Conditions	1	1	0	1	0
NOC on Hold (Patent)	0	0	0	0	1
Priority Class	3	1	3	4	2
NOC-C Class	1	1	0	0	0

SNDS: Number Approved by Fee Category and by NOC Type



	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Safety Update Label	0	0	0	5	54
Labelling Only Generic Drugs to be in line with CRP	0	0	1	1	1
Labelling Only	27	26	35	18	40
Published Data Only	1	7	1	1	1
Clinical or Non-Clin and C&M	1	0	1	3	2
Chemistry & Manufacturing	13	17	14	13	24
Comparative Studies	3	0	3	2	3
Clinical or Non-Clin Only	19	16	16	19	14
Total	64	66	71	62	139
Notice of Compliance	63	66	70	62	138
NOC with Conditions	0	0	1	0	0
NOC on Hold (Patent)	1	0	0	0	1
Priority Class	3	2	3	1	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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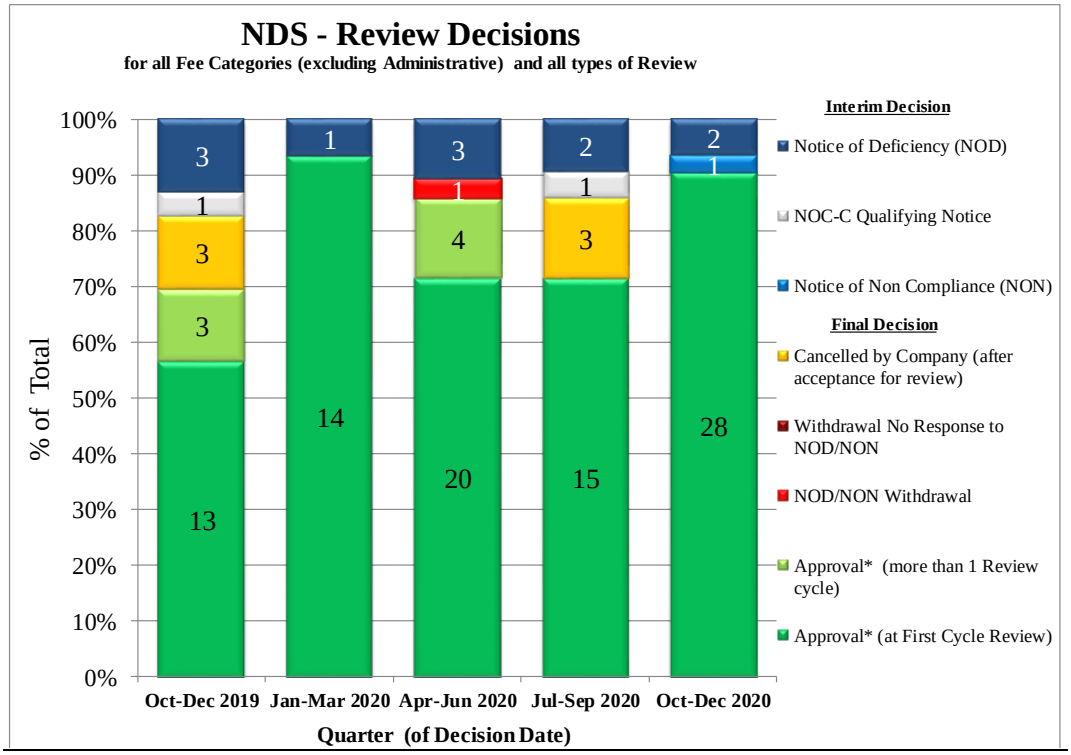
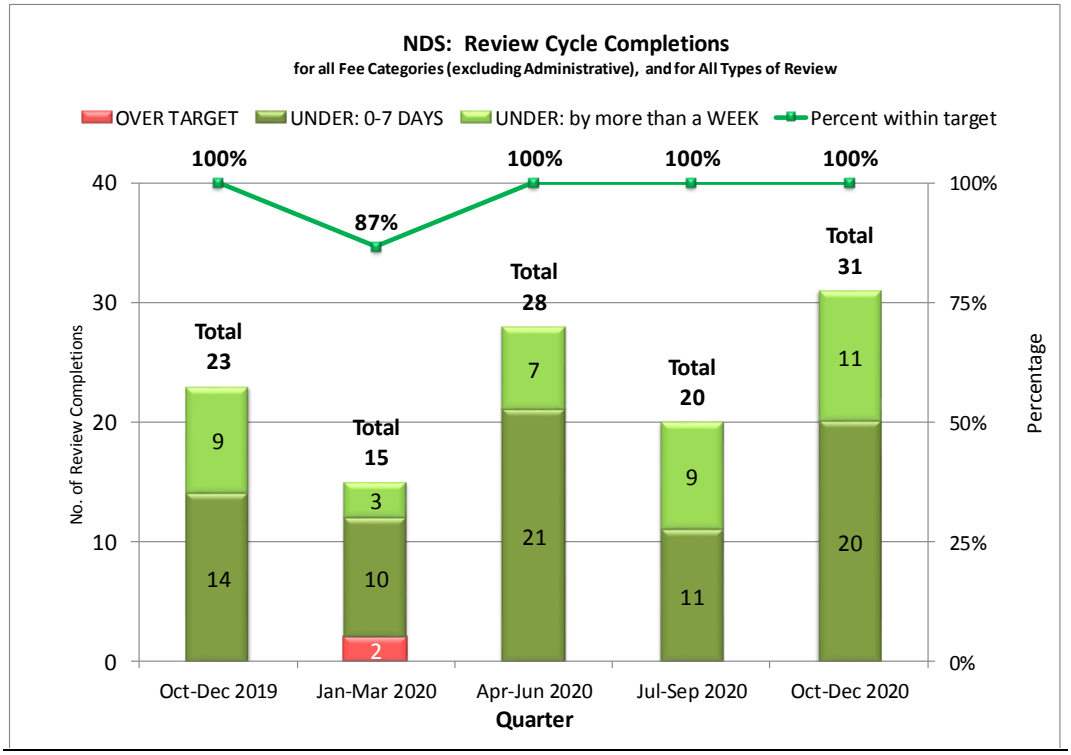
REVIEW PERFORMANCE

NDS: Review Decisions by Type

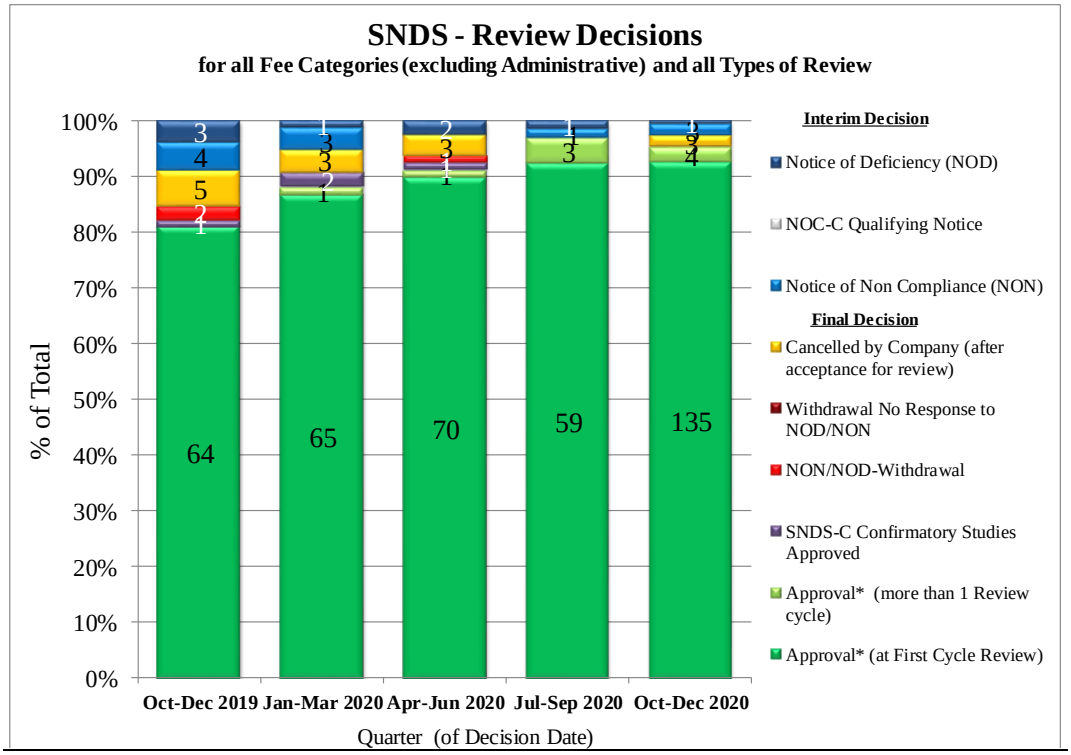


NDS: Review Cycle Completions

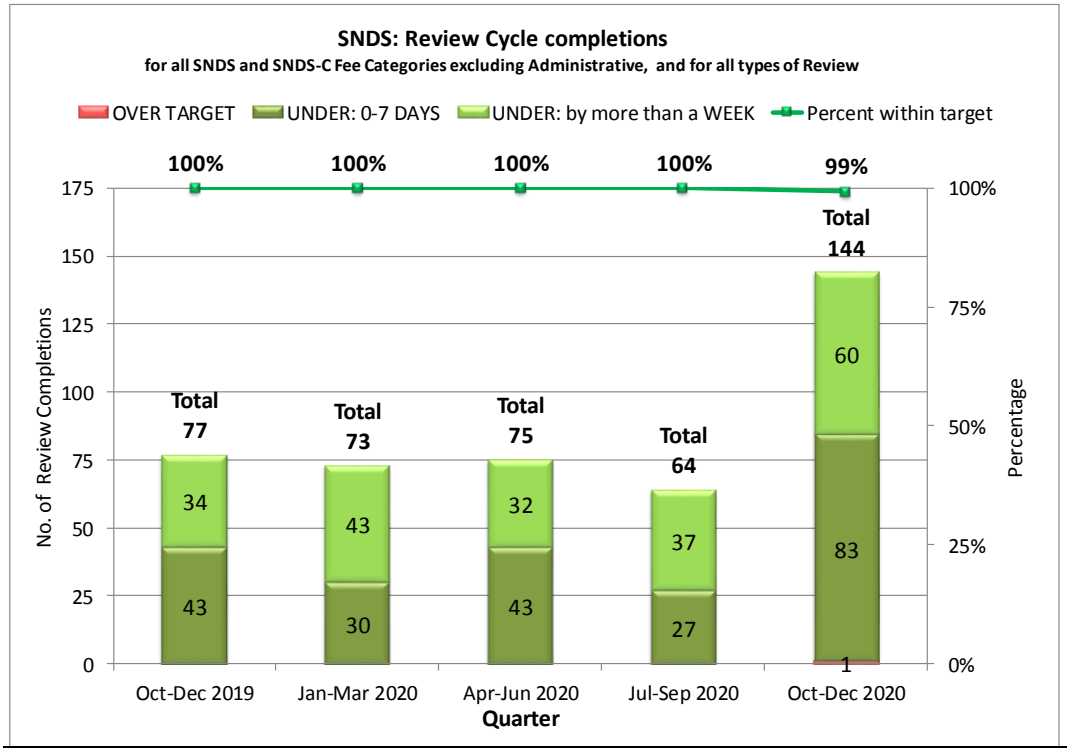


REVIEW CYCLE DECISIONS

SNDS: Review Decisions by Type

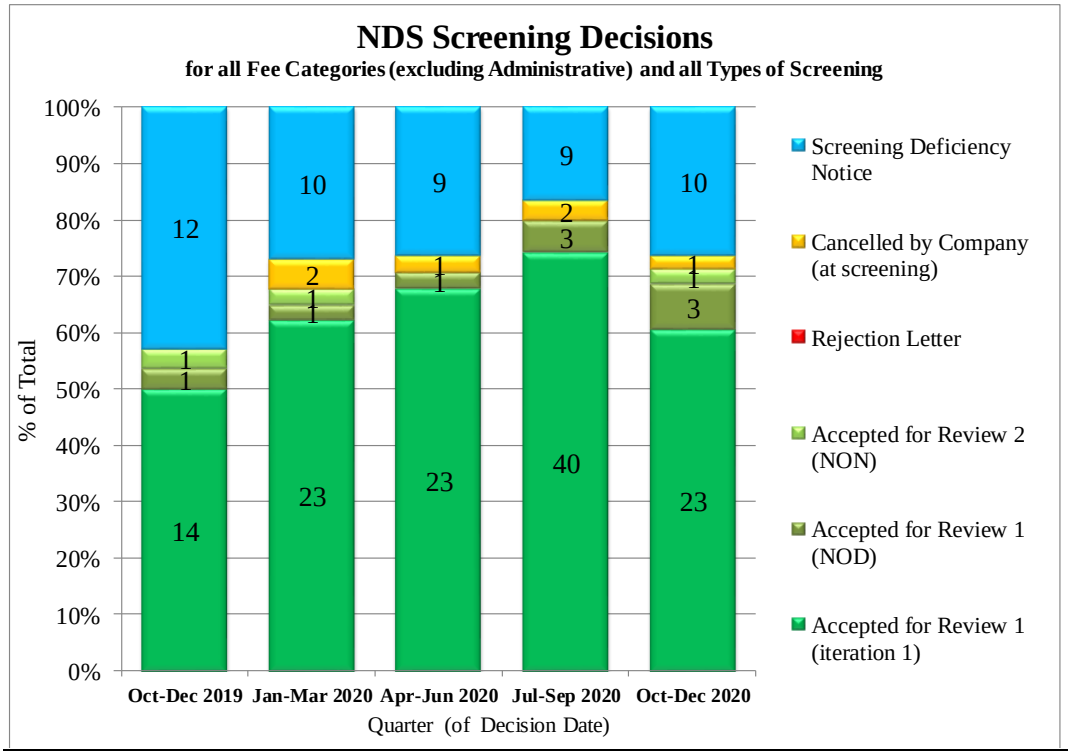


SNDS: Review Cycle Completions

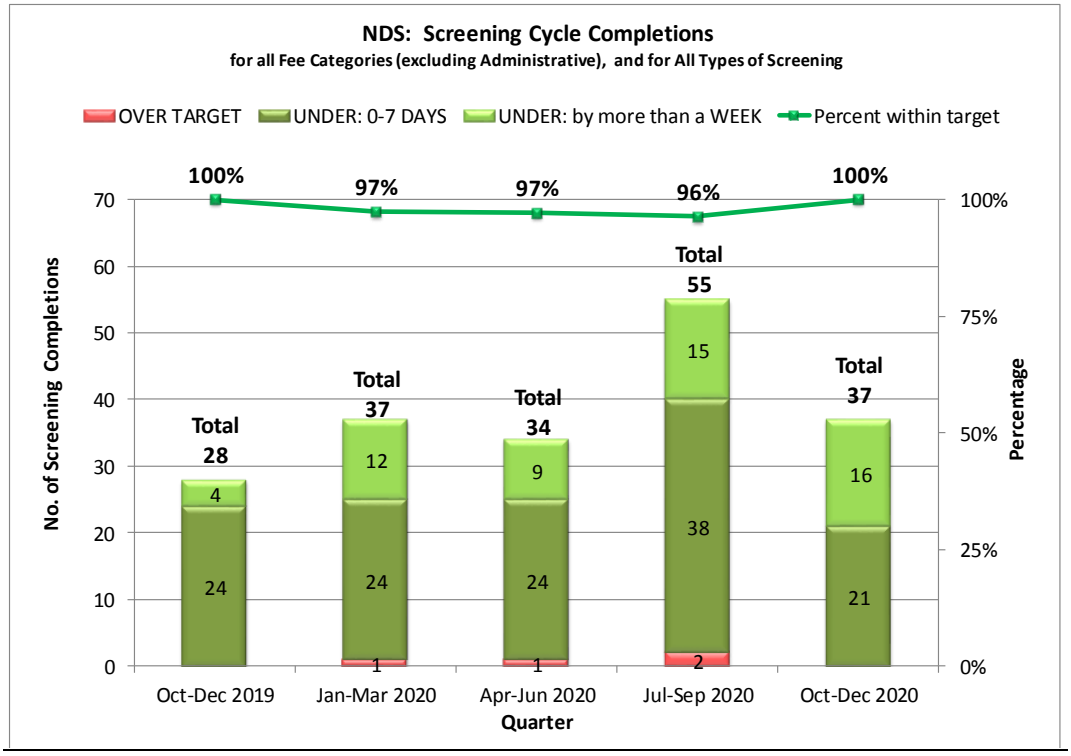


SCREENING PERFORMANCE

NDS: Screening Decisions by Type

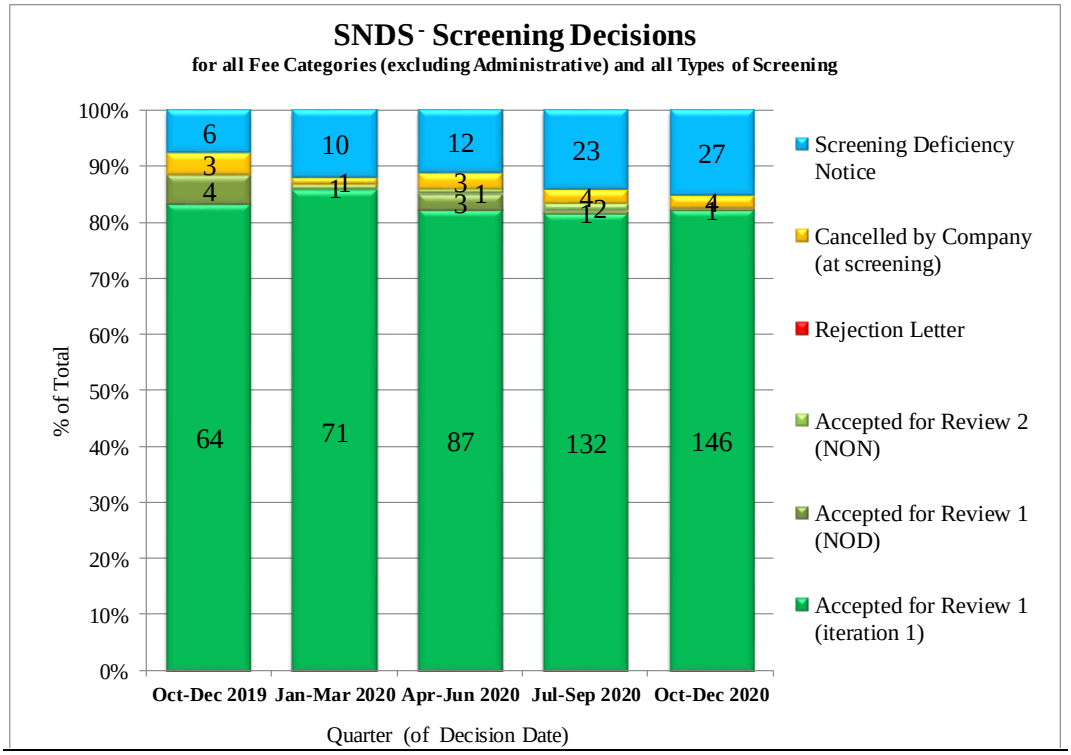


NDS: Screening Cycle Completions

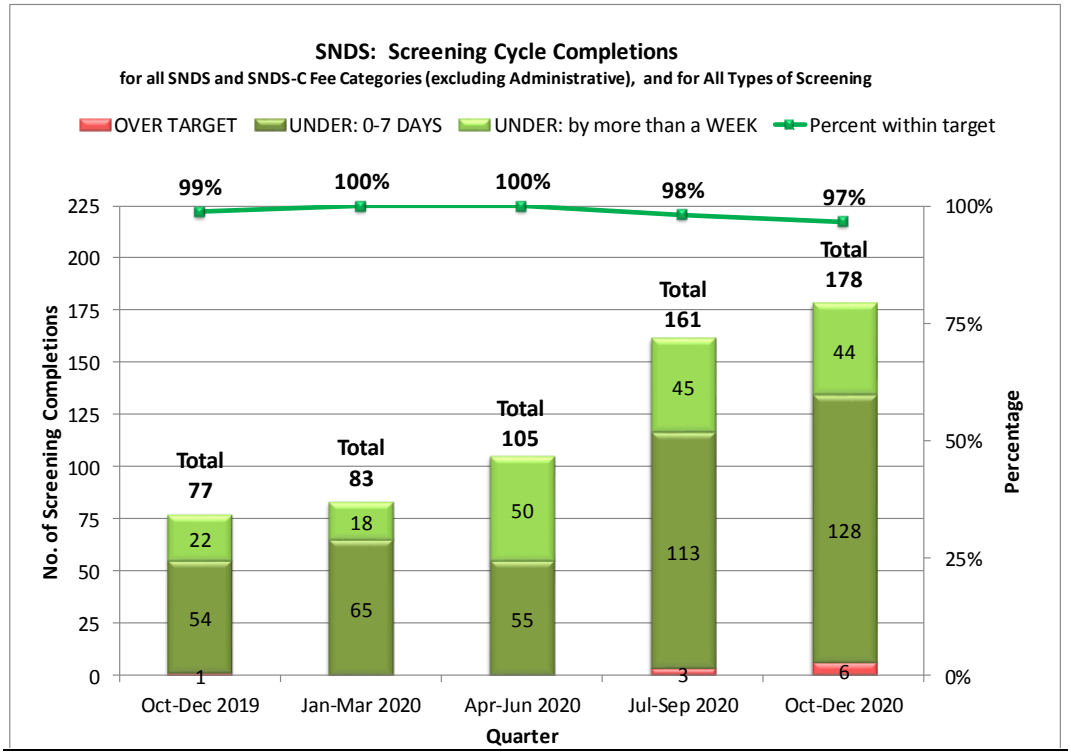


SCREENING CYCLE DECISIONS

SNDS: Screening Decisions by Type



SNDS: Screening Cycle Completions



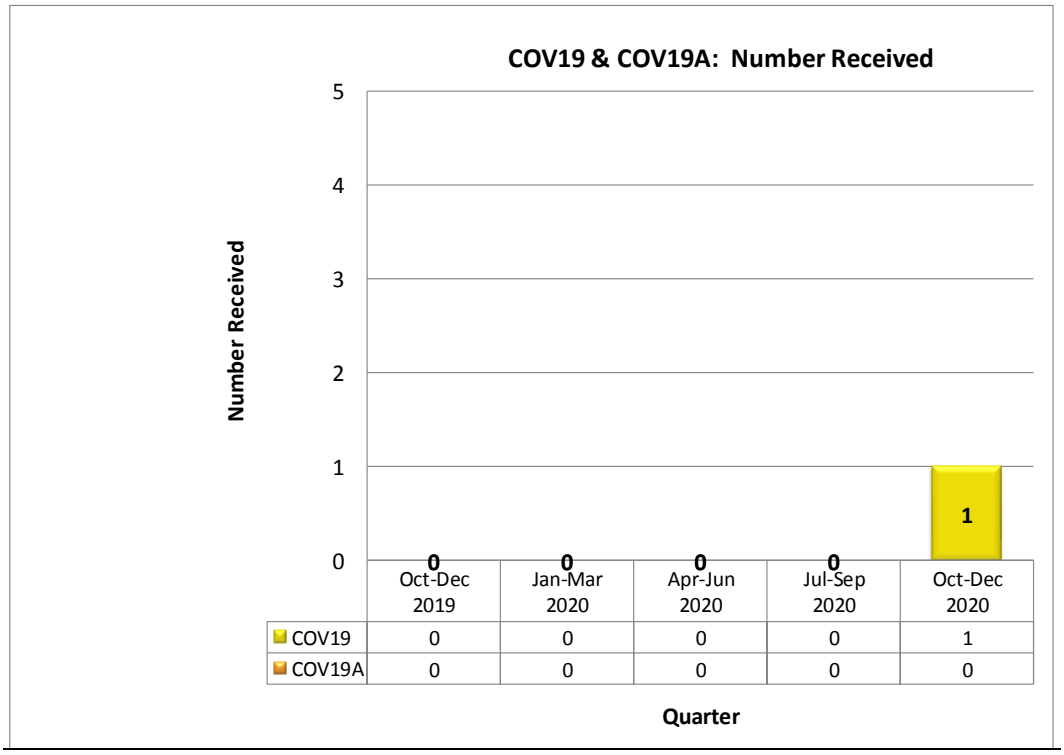
Application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (COV19)

&

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)

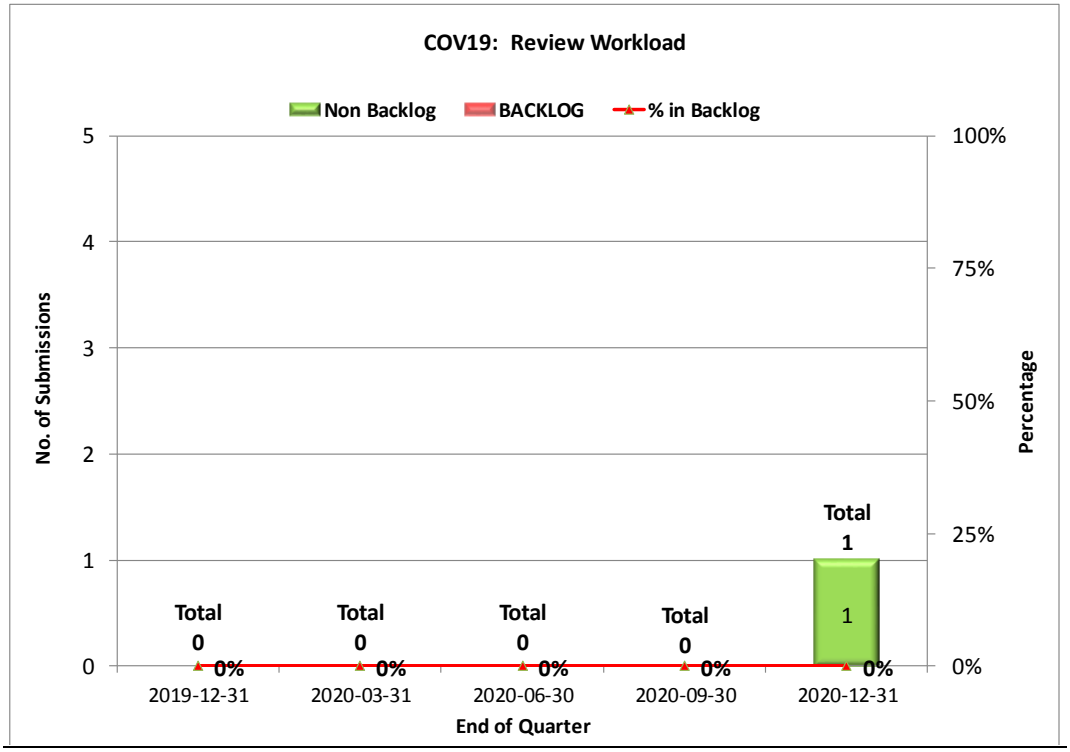
SUBMISSIONS RECEIVED

COV19 & COV19A: Number Received



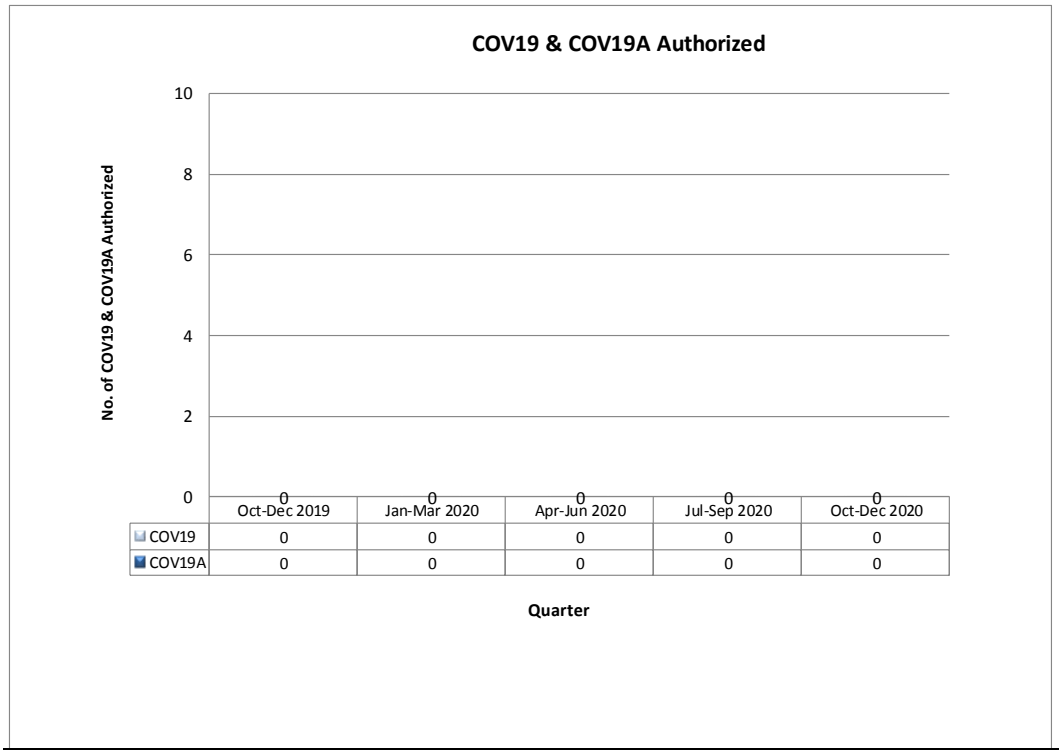
WORKLOAD

COV19: Review Workload



AUTHORIZATIONS

COV19 & COV19A: Number Authorized



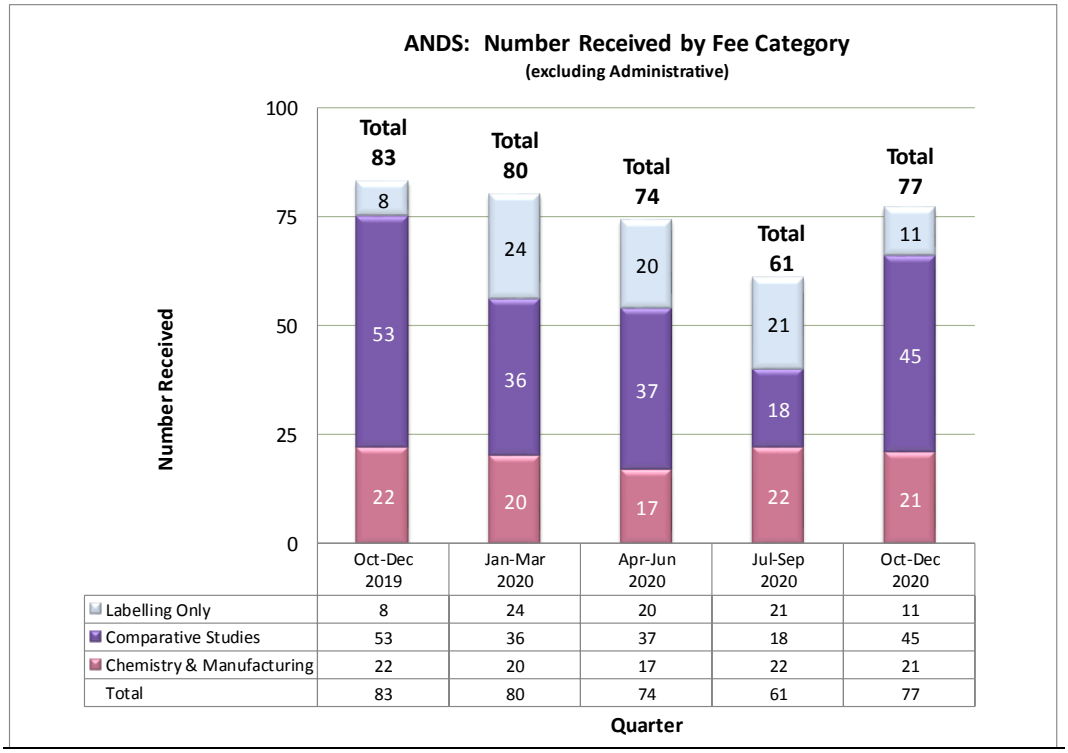
Abbreviated New Drug Submissions (ANDS)

&

Supplement to an Abbreviated New Drug Submissions (SANDS)

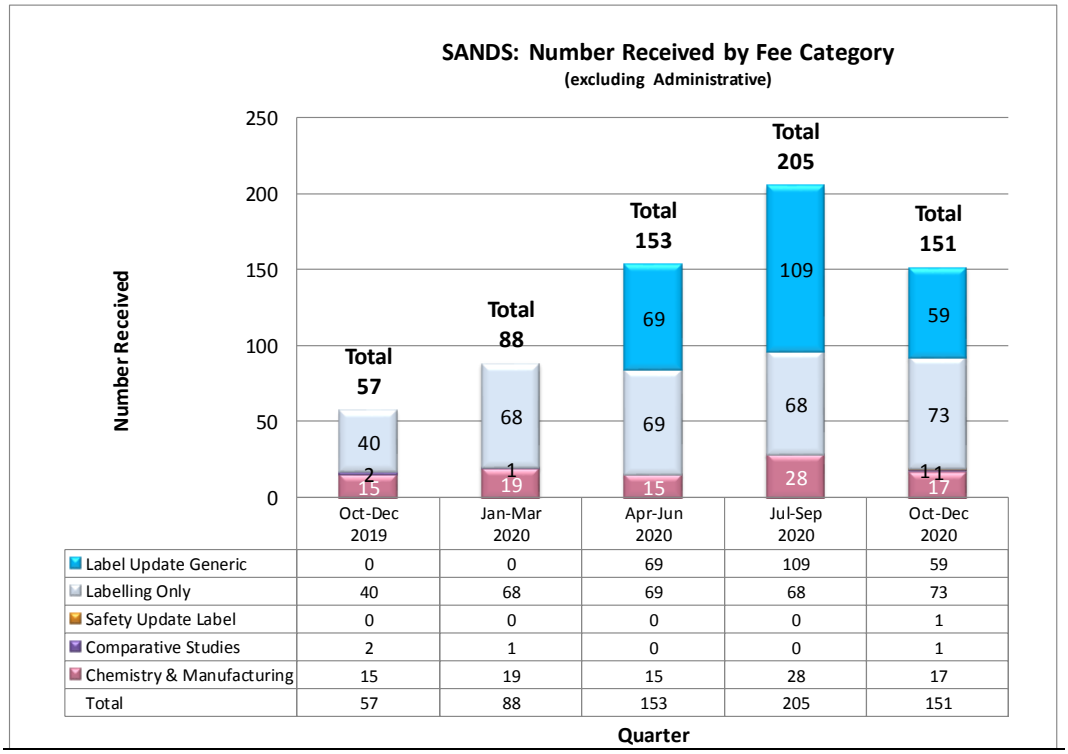
SUBMISSIONS RECEIVED

ANDS: Number Received by Fee Category



	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Labelling Only	8	24	20	21	11
Comparative Studies	53	36	37	18	45
Chemistry & Manufacturing	22	20	17	22	21
Total	83	80	74	61	77

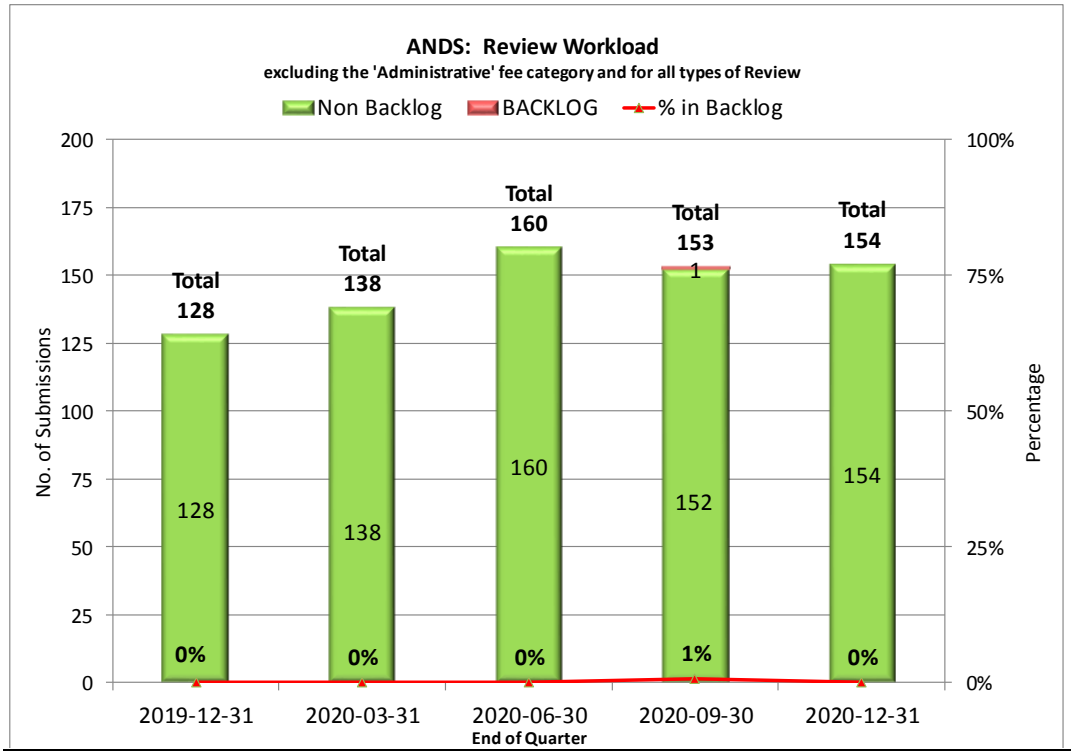
SANDS: Number Received by Fee Category



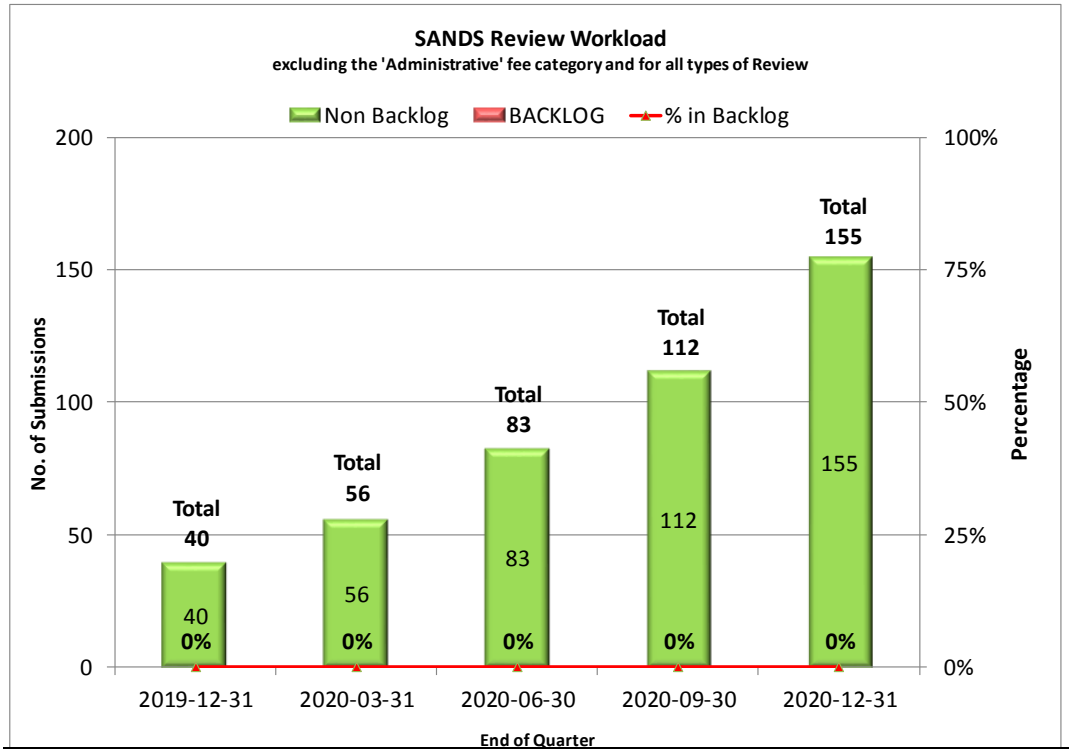
	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Label Update Generic	0	0	69	109	59
Labelling Only	40	68	69	68	73
Safety Update Label	0	0	0	0	1
Comparative Studies	2	1	0	0	1
Chemistry & Manufacturing	15	19	15	28	17
Total	57	88	153	205	151

WORKLOAD

ANDS: Review Workload



SANDS: Review Workload



WORKLOAD

ANDS: Review Workload by Fee Category

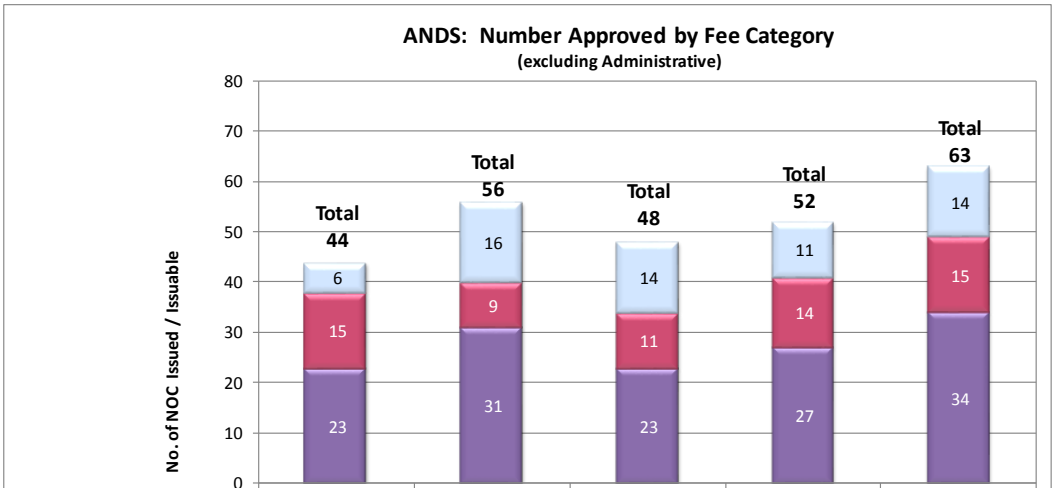
ANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Chemistry & Manufacturing	37	42	47	51	54
Backlog	*0*	*0*	*0*	*1*	*0*
Comparative Studies	87	88	103	84	79
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	4	8	10	18	21
Backlog	*0*	*0*	*0*	*0*	*0*
Total	128	138	160	153	154
Non Backlog	128	138	160	152	154
BACKLOG	0	0	0	1	0
% in Backlog	0%	0%	0%	1%	0%

SANDS: Review Workload by Fee Category

SANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Chemistry & Manufacturing	17	24	28	37	40
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	5	3	1	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	18	29	31	54	85
Backlog	*0*	*0*	*0*	*0*	*0*
Label Update Generic	0	0	23	21	29
Backlog	*0*	*0*	*0*	*0*	*0*
Safety Update Label	0	0	0	0	1
Backlog	*0*	*0*	*0*	*0*	*0*
Total	40	56	83	112	155
Non Backlog	40	56	83	112	155
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

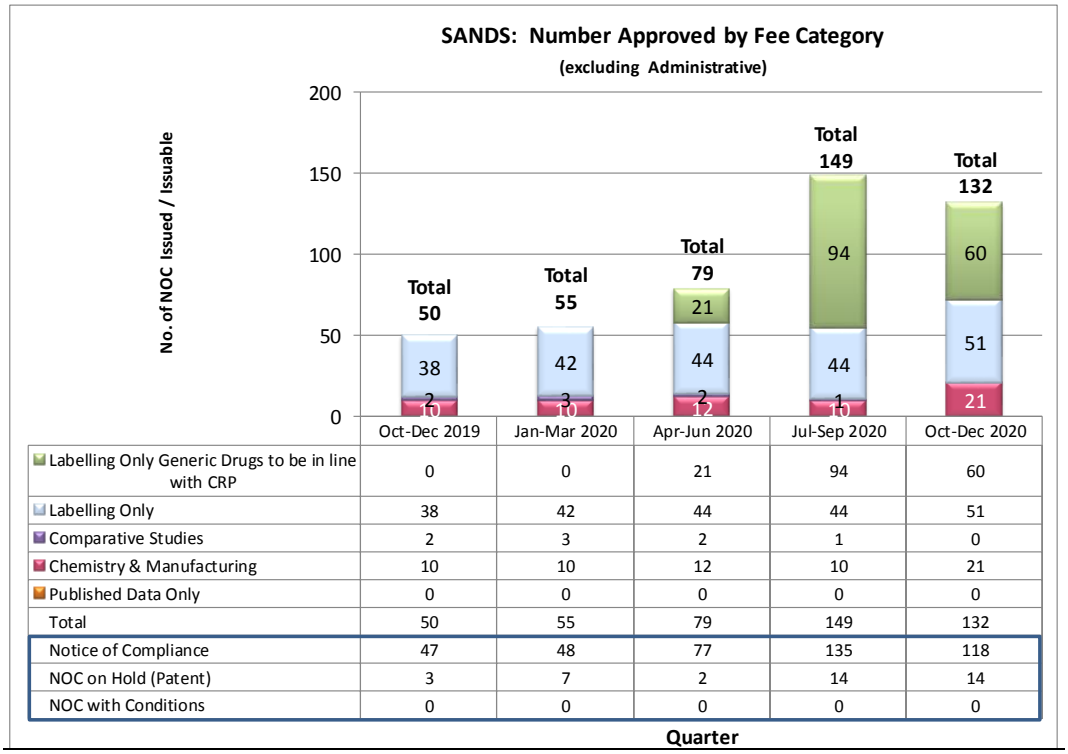
APPROVALS

ANDS: Number Approved by Fee Category and by NOC Type



	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Labelling Only	6	16	14	11	14
Chemistry & Manufacturing	15	9	11	14	15
Comparative Studies	23	31	23	27	34
Total	44	56	48	52	63
Notice of Compliance	28	47	36	34	44
NOC on Hold (Patent)	16	9	12	18	19
NOC with Conditions	0	0	0	0	0

SANDS: Number Approved by Fee Category and by NOC Type



	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Labelling Only Generic Drugs to be in line with CRP	0	0	21	94	60
Labelling Only	38	42	44	44	51
Comparative Studies	2	3	2	1	0
Chemistry & Manufacturing	10	10	12	10	21
Published Data Only	0	0	0	0	0
Total	50	55	79	149	132
Notice of Compliance	47	48	77	135	118
NOC on Hold (Patent)	3	7	2	14	14
NOC with Conditions	0	0	0	0	0

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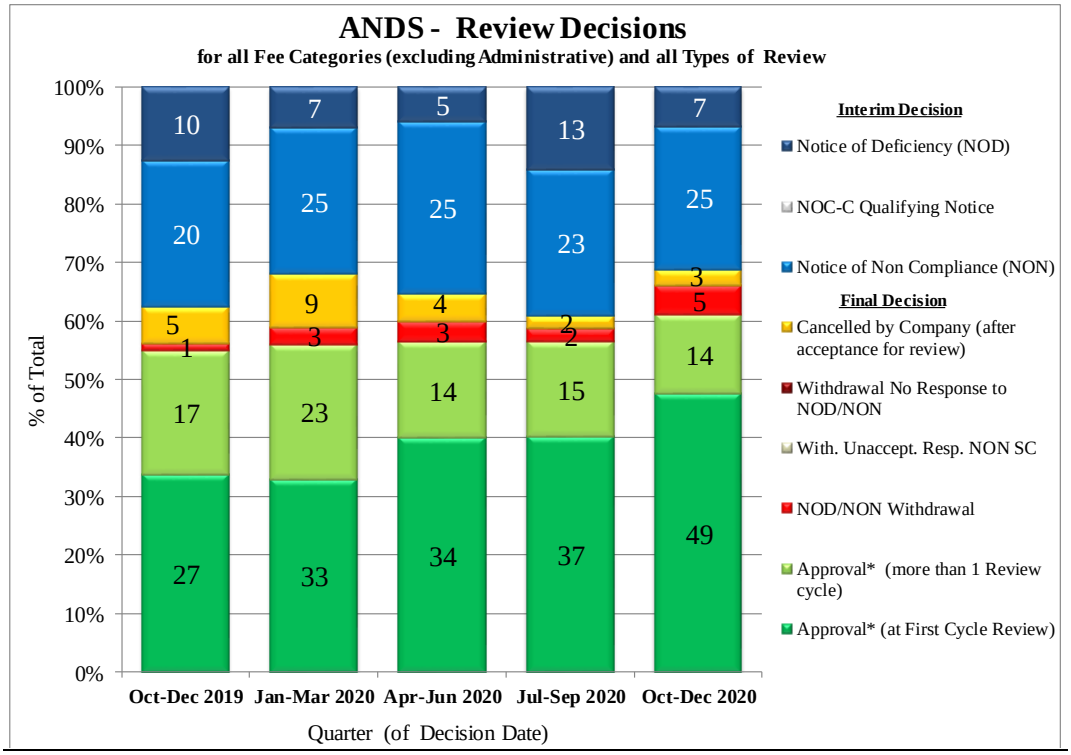
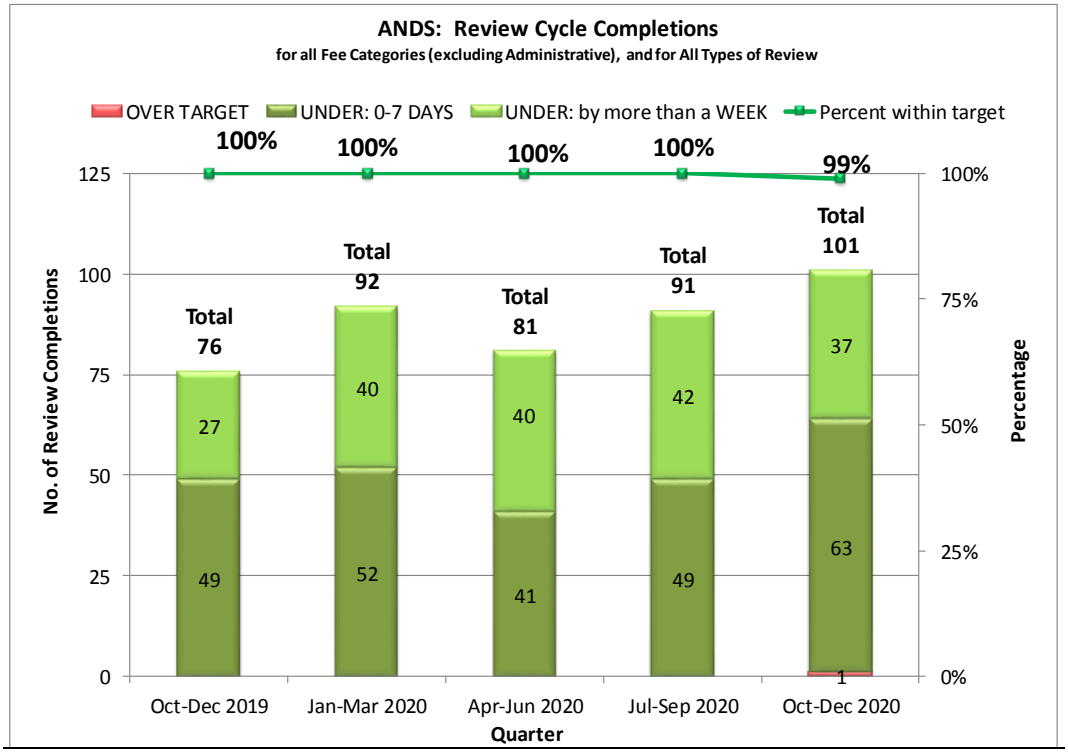
REVIEW PERFORMANCE

ANDS: Review Decisions by Type

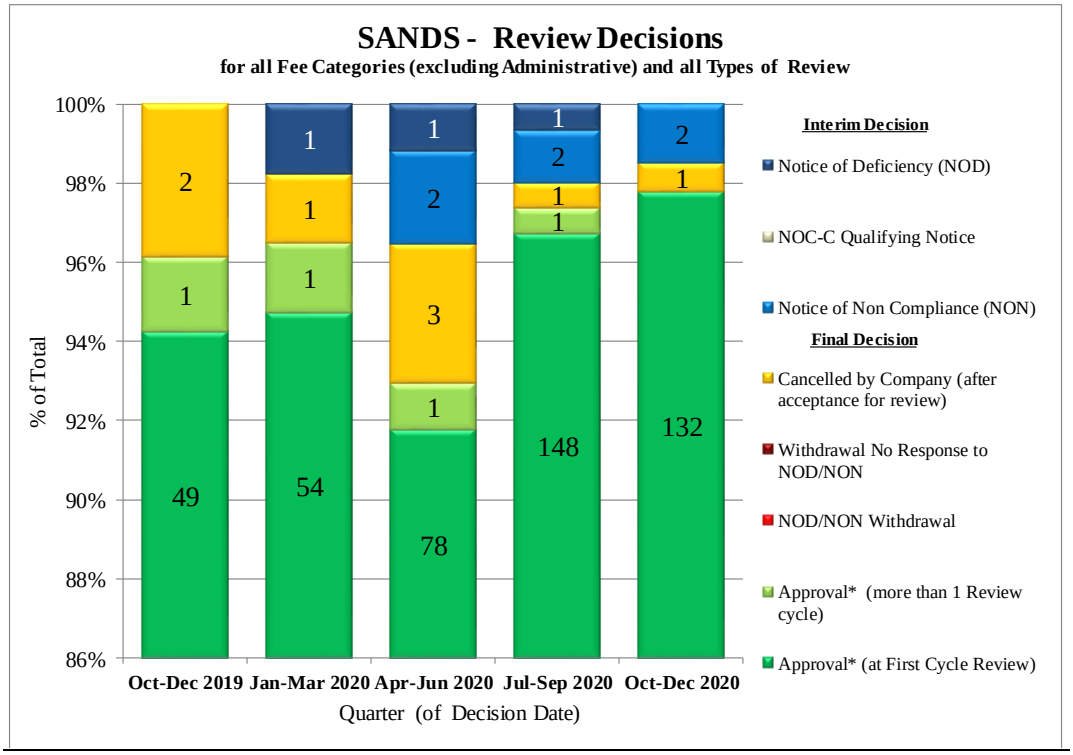


ANDS: Review Cycle Completions

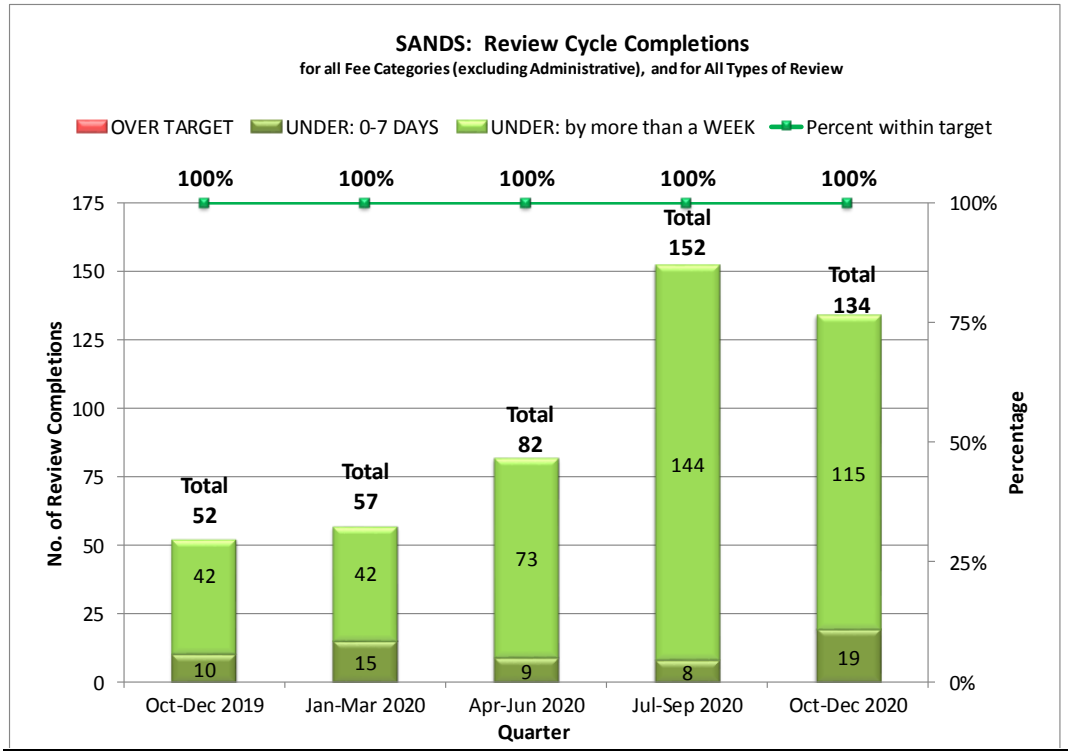


REVIEW PERFORMANCE

SANDS: Review Decisions by Type

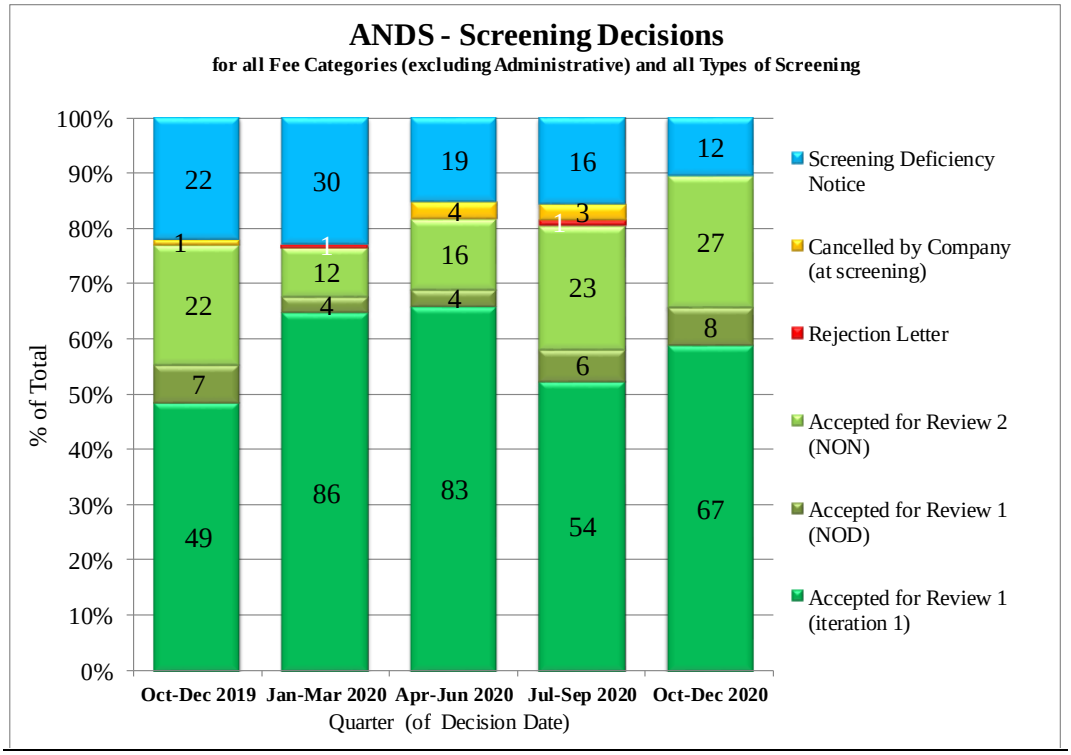


SANDS: Review Cycle Completions

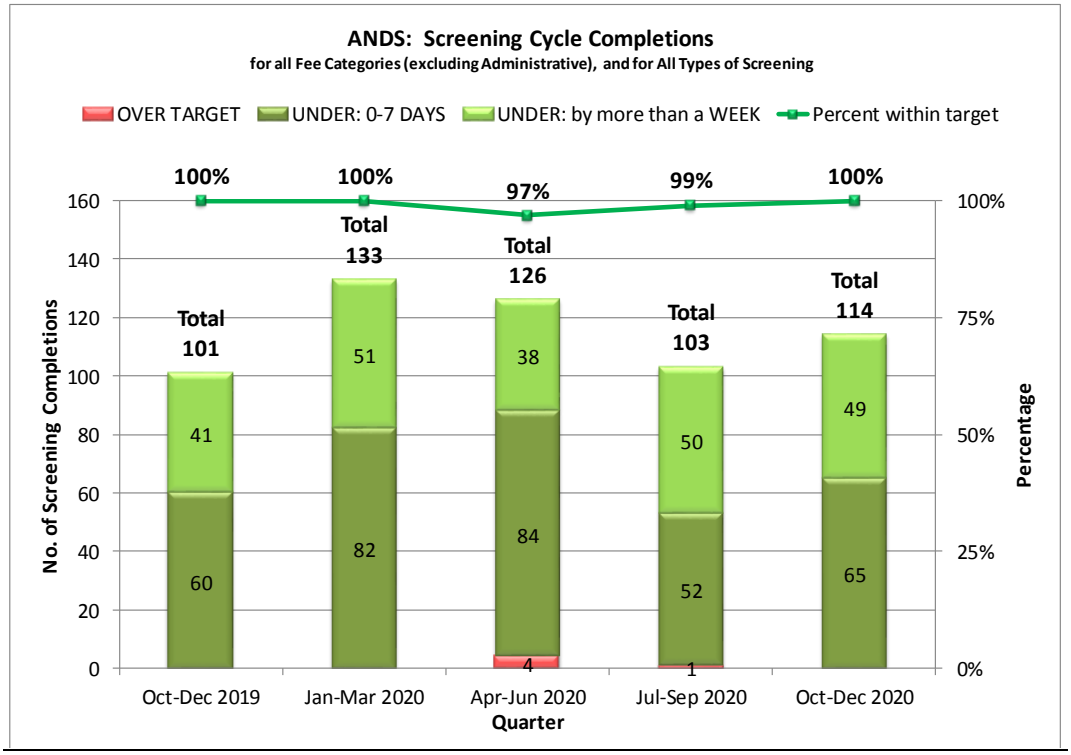


SCREENING PERFORMANCE

ANDS: Screening Decisions by Type

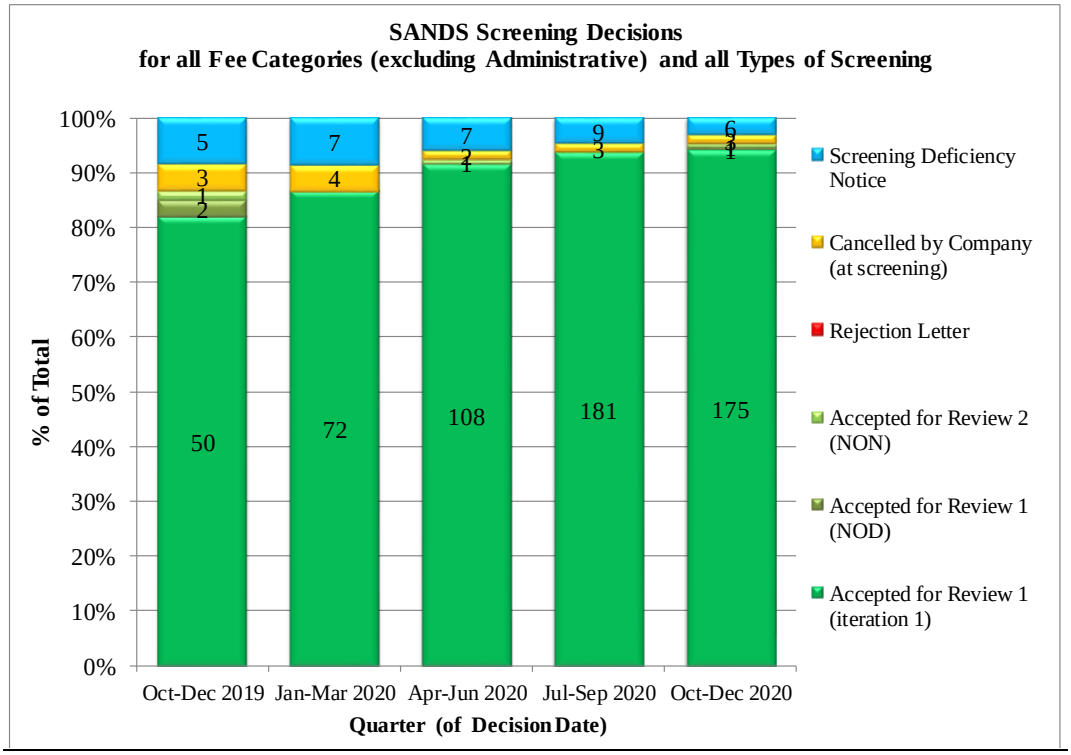


ANDS: Screening Cycle Completions

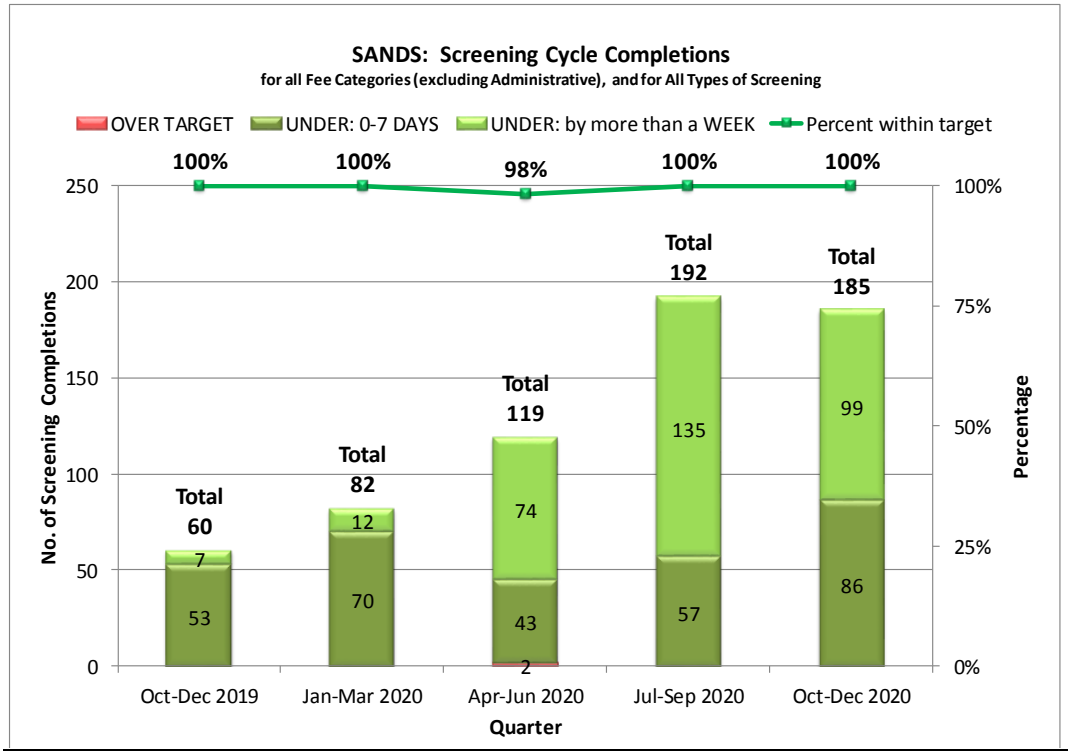


SCREENING PERFORMANCE

SANDS: Screening Decisions by Type

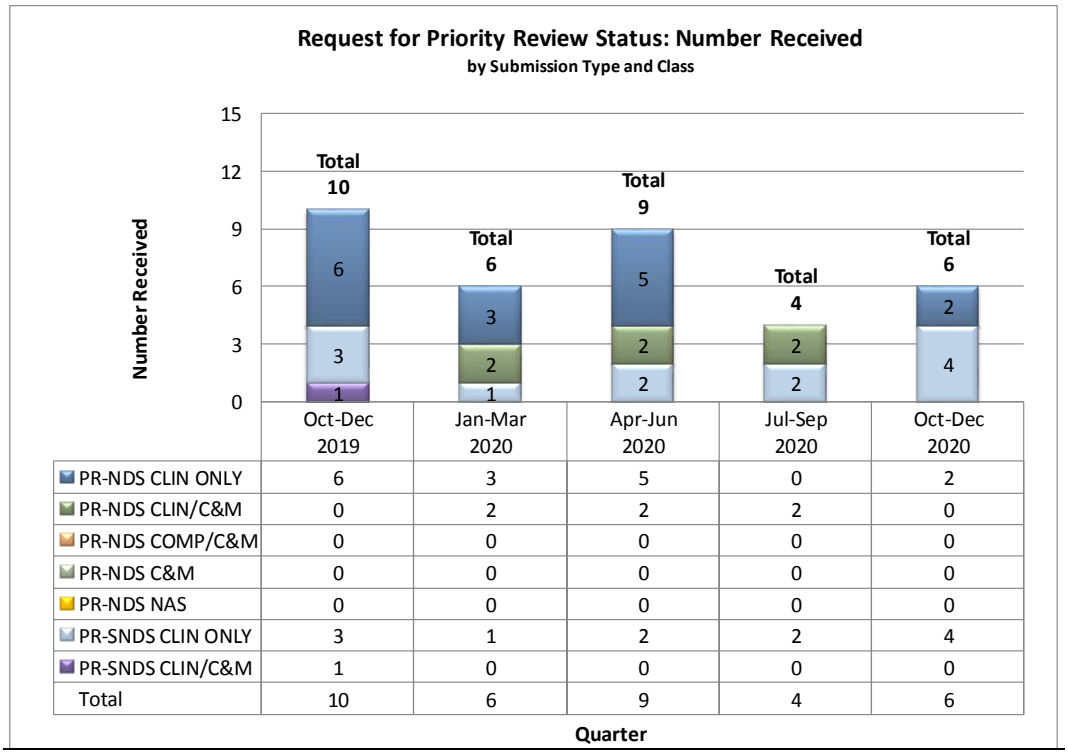


SANDS: Screening Cycle Completions



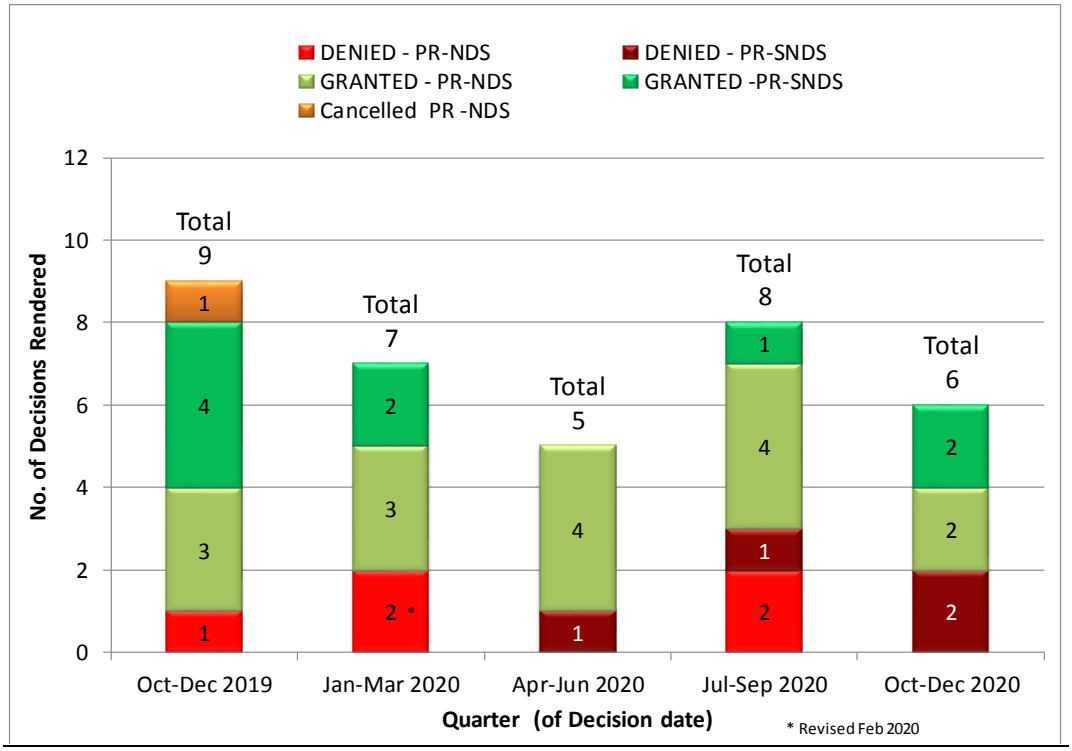
REQUEST FOR PRIORITY REVIEW STATUS (for NDS & SNDS)

Request for Priority Review Status: Number Received

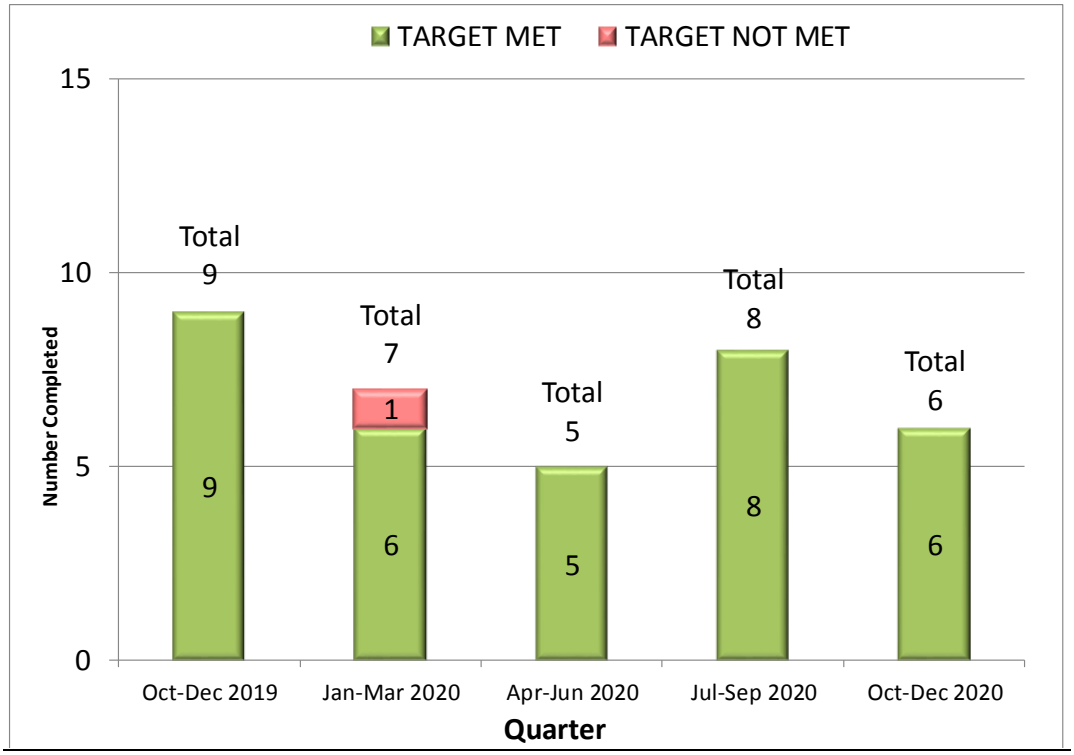


	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
PR-NDS CLIN ONLY	6	3	5	0	2
PR-NDS CLIN/C&M	0	2	2	2	0
PR-NDS COMP/C&M	0	0	0	0	0
PR-NDS C&M	0	0	0	0	0
PR-NDS NAS	0	0	0	0	0
PR-SNDS CLIN ONLY	3	1	2	2	4
PR-SNDS CLIN/C&M	1	0	0	0	0
Total	10	6	9	4	6

Request for Priority Review Status: Decisions Rendered



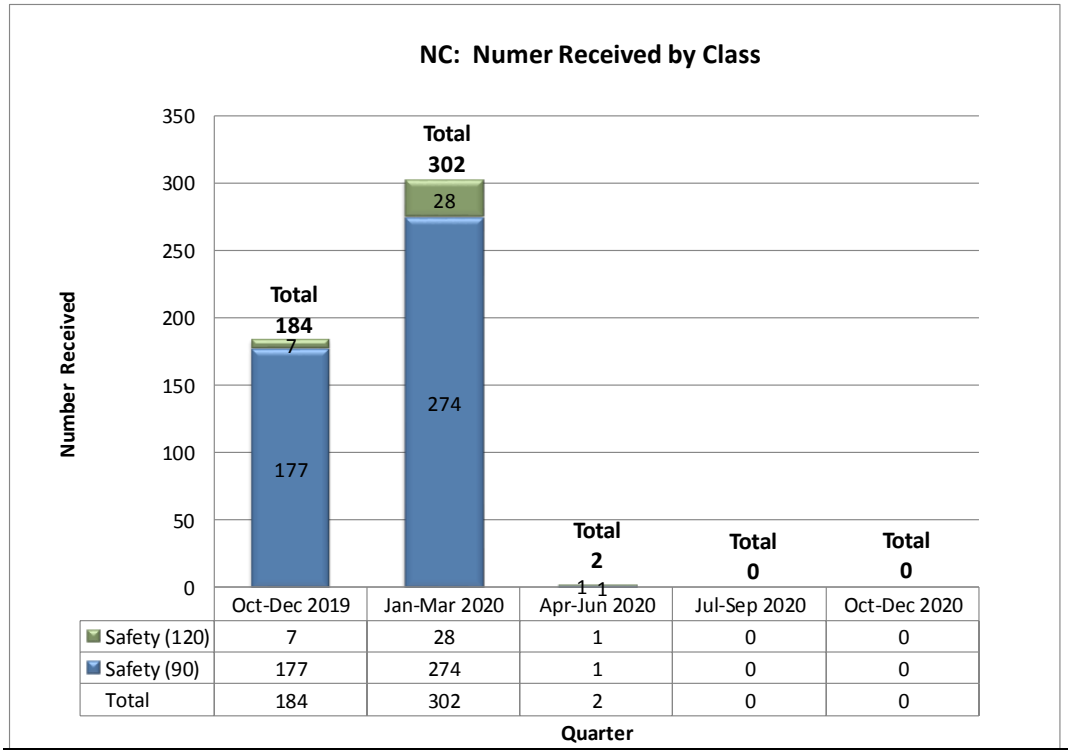
Request for Priority Review Status: Performance



NC: NOTIFIABLE CHANGE

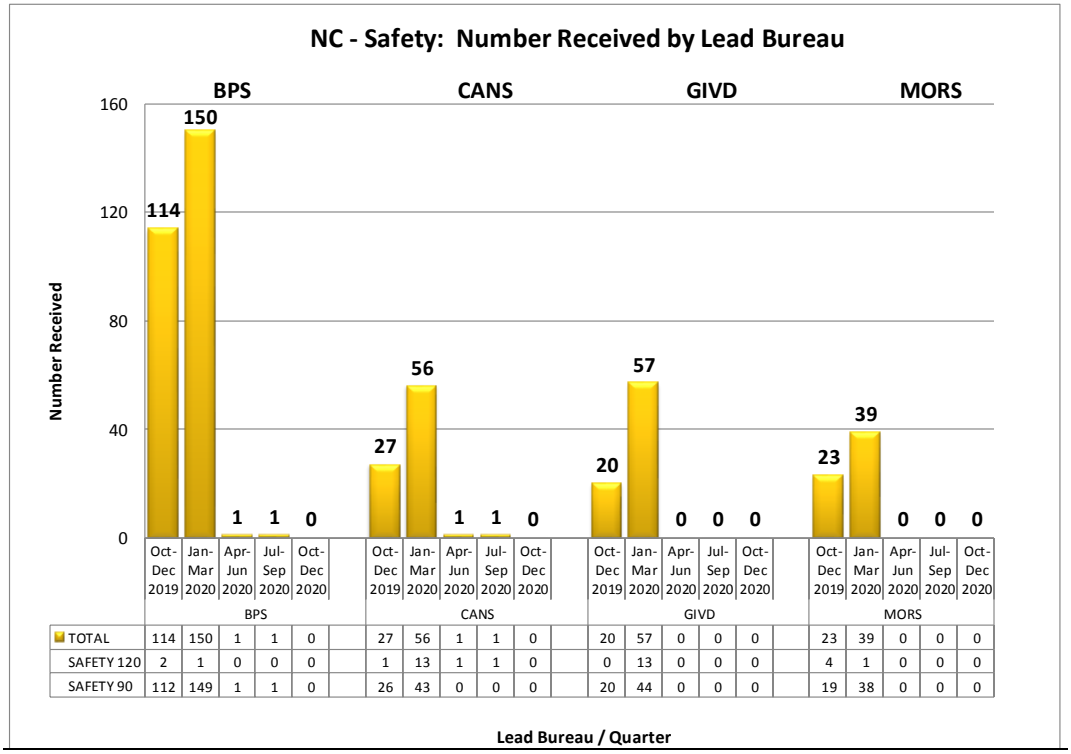
NOTIFIABLE CHANGE
RECEIVED

NC: Number Received by Class



	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Safety (120)	7	28	1	0	0
Safety (90)	177	274	1	0	0
Total	184	302	2	0	0

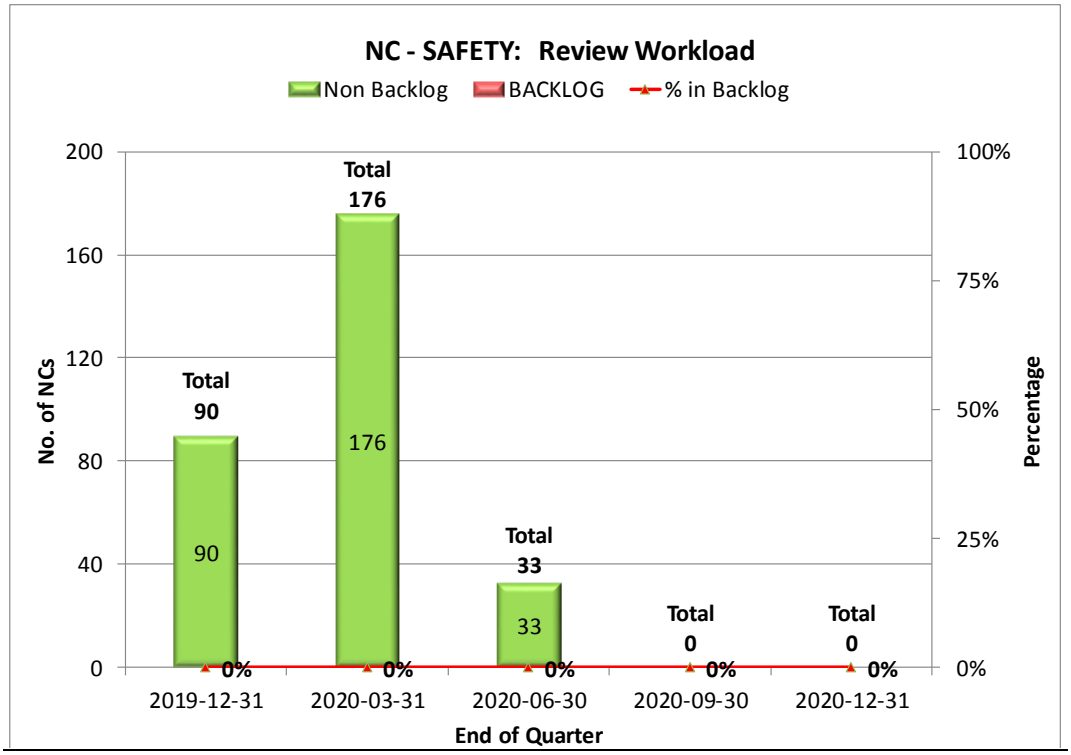
NC-SAFETY: Number Received by Lead Bureau



	BPS					CANS					GIVD					MORS				
	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
TOTAL	114	150	1	1	0	27	56	1	1	0	20	57	0	0	0	23	39	0	0	0
SAFETY 120	2	1	0	0	0	1	13	1	1	0	0	13	0	0	0	4	1	0	0	0
SAFETY 90	112	149	1	1	0	26	43	0	0	0	20	44	0	0	0	19	38	0	0	0

WORKLOAD

NC-SAFETY: Review Workload

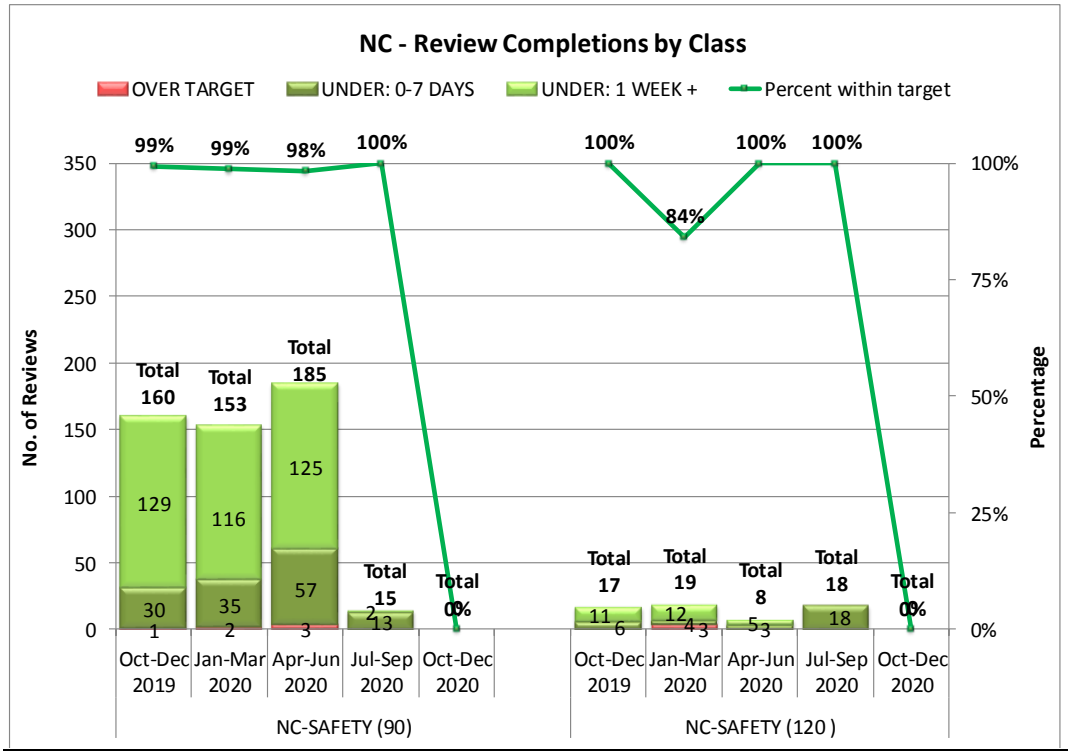


NC-SAFETY: Review Workload by Class

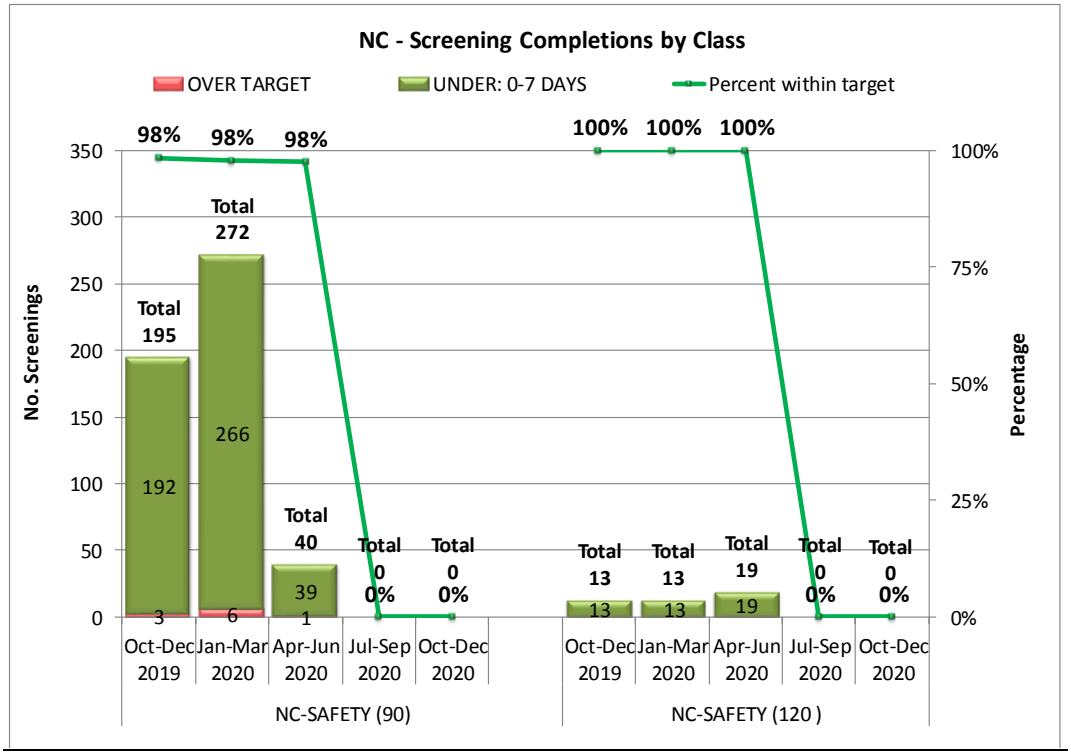
TPD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
Class	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
SAFETY - 90 day	73	166	15	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
SAFETY - 120 day	17	10	18	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	90	176	33	0	0
Non Backlog	90	176	33	0	0
BACKLOG	0	0	0	0	0
% in 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	**Oct-Dec 2019**	**Jan-Mar 2020**	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**
NO OBJECTION LETTER	157	153	181	15	1
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	1	0	0	0	0
SCREENING DEFICIENCY NOTICE	22	22	5	0	0
CANCELLED BY COMPANY	8	6	6	0	0
NC - HOLD (PATENT)	6	5	1	0	0

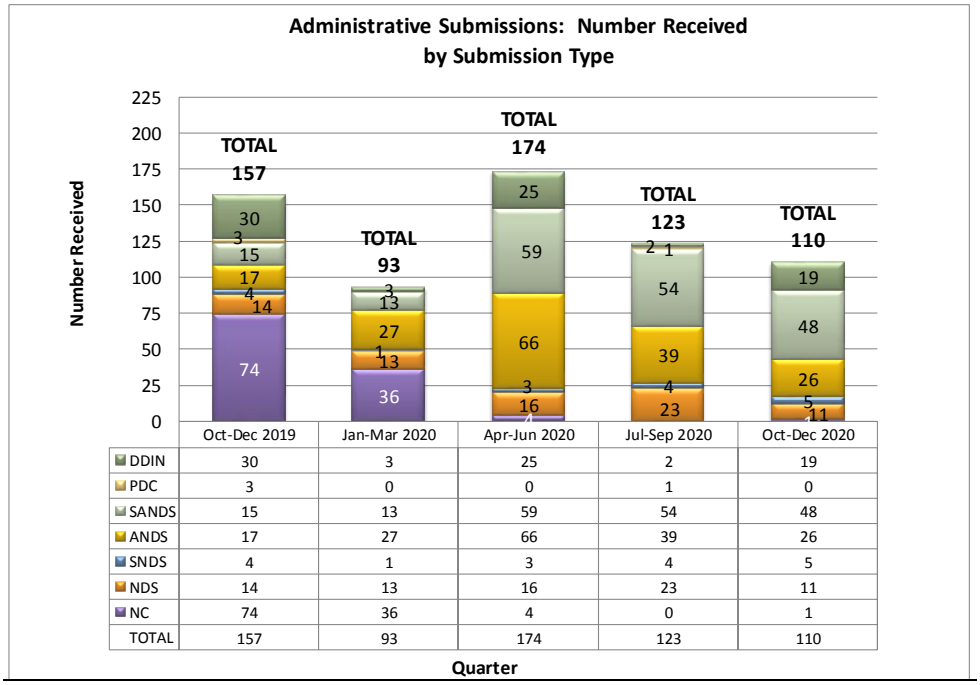
NC - SAFETY (120)					
DOCUMENT TYPE	**Oct-Dec 2019**	**Jan-Mar 2020**	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**
NO OBJECTION LETTER	17	18	8	18	0
NOT SATISFACTORY NOTICE	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	2	1	2	0	0
CANCELLED BY COMPANY	1	5	1	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
NC - HOLD (PATENT)	0	0	0	0	0

ADMINISTRATIVE SUBMISSIONS

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

RECEIVED

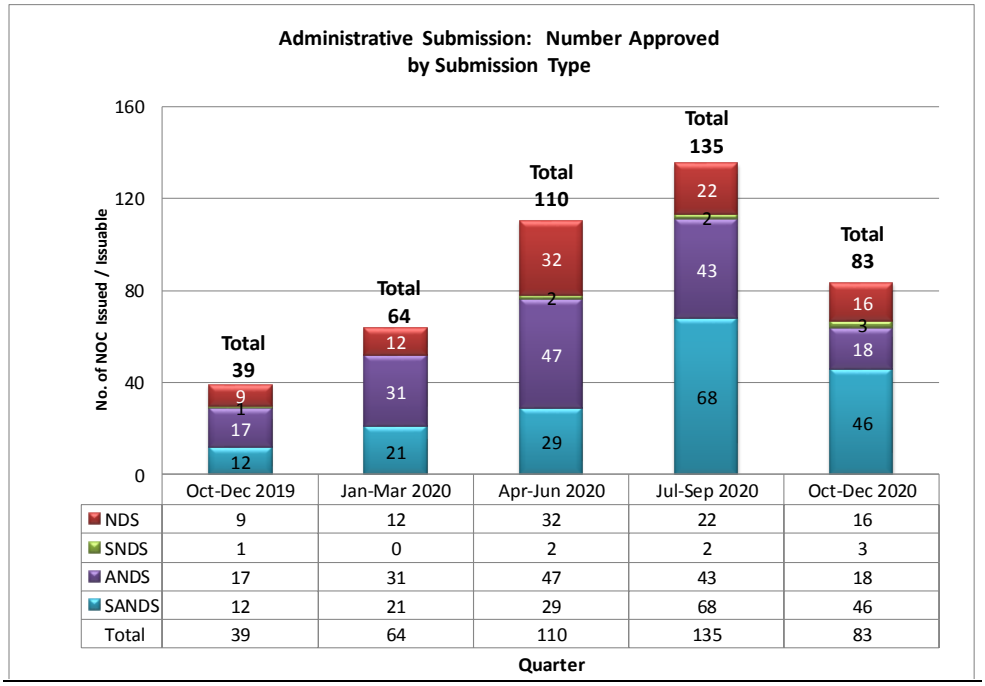
Administrative Submissions: Number Received by Submission Type



	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
DDIN	30	3	25	2	19
PDC	3	0	0	1	0
SANDS	15	13	59	54	48
ANDS	17	27	66	39	26
SNDS	4	1	3	4	5
NDS	14	13	16	23	11
NC	74	36	4	0	1
TOTAL	157	93	174	123	110

APPROVALS

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



	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
NDS	9	12	32	22	16
SNDS	1	0	2	2	3
ANDS	17	31	47	43	18
SANDS	12	21	29	68	46
Total	39	64	110	135	83

[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	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
NOTICE OF COMPLIANCE	9	12	32	22	16
SCREENING DEFICIENCY NOTICE	0	0	0	0	1
CANCELLATION LETTER	3	0	1	0	0
PROCESSING HOLD LETTER	5	8	6	6	2
SNDS	**Oct-Dec 2019**	**Jan-Mar 2020**	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**
NOTICE OF COMPLIANCE	1	0	2	2	3
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLATION LETTER	0	1	0	2	0
PROCESSING HOLD LETTER	0	1	0	2	1
ANDS	**Oct-Dec 2019**	**Jan-Mar 2020**	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**
NOTICE OF COMPLIANCE	17	30	47	42	18
NOC ON IP HOLD	0	1	0	1	0
SCREENING DEFICIENCY NOTICE	0	0	1	2	0
CANCELLATION LETTER	7	4	6	5	2
PROCESSING HOLD LETTER	5	11	13	3	7
SANDS	**Oct-Dec 2019**	**Jan-Mar 2020**	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**
NOTICE OF COMPLIANCE	12	21	29	68	46
NOC ON IP HOLD	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLATION LETTER	2	3	4	2	0
PROCESSING HOLD LETTER	4	2	10	4	5
NC	**Oct-Dec 2019**	**Jan-Mar 2020**	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**
NO OBJECTION LETTER	26	49	1	1	0
NC - HOLD (PATENT)	0	0	0	0	0
CANCELLATION LETTER	7	12	4	0	0
PROCESSING HOLD LETTER	1	1	0	0	2
SCREENING DEFICIENCY NOTICE	0	0	0	0	1
DINA	**Oct-Dec 2019**	**Jan-Mar 2020**	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**
NOTIFICATION FORM / DIN ISSUED	4	1	12	12	15
NO OBJECTION LETTER	1	0	1	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLATION LETTER	0	0	8	2	1
PROCESSING HOLD LETTER	0	1	4	0	0
PDC	**Oct-Dec 2019**	**Jan-Mar 2020**	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**
NO OBJECTION LETTER	0	0	0	0	0
CANCELLATION LETTER	0	0	0	1	0
PROCESSING HOLD LETTER	0	0	0	0	0

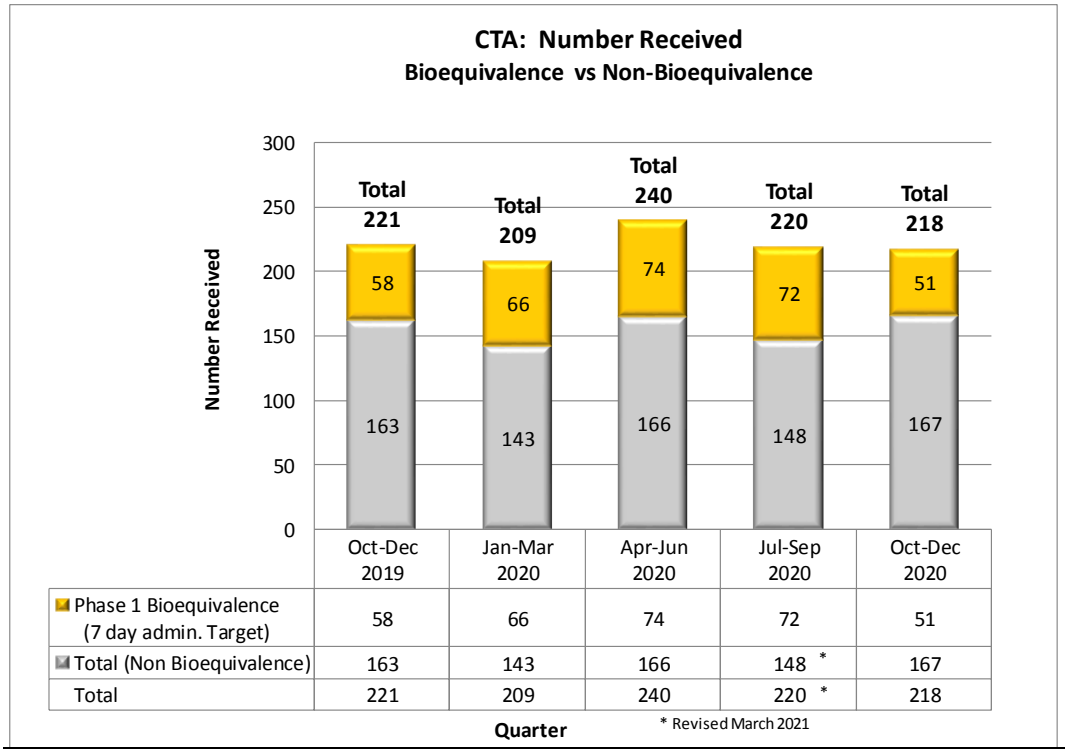
[10] The screening functions for Administrative submissions and the review functions for Labelling Only submissions with an Administrative component were moved from the Office of Submissions and Intellectual Property (OSIP) to the labelling area of the Bureau of Gastroenterology, Infection and Viral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

Clinical Trial Applications and Amendments

(CTA & CTA-A)

CTA: CLINICAL TRIAL APPLICATIONS

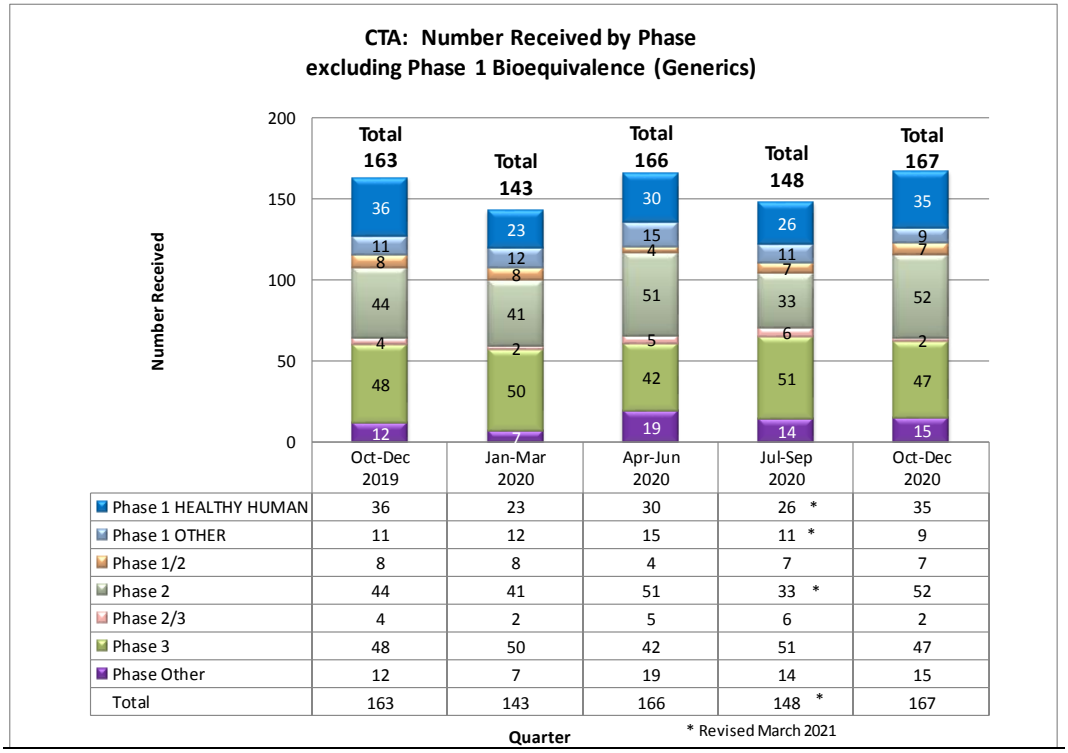
CTA: Number Received



	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Phase 1 Bioequivalence (7 day admin. Target)	58	66	74	72	51
Total (Non Bioequivalence)	163	143	166	148 *	167
Total	221	209	240	220 *	218

* Revised March 2021

CTA: Number Received by Phase



	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Phase 1 HEALTHY HUMAN	36	23	30	26 *	35
Phase 1 OTHER	11	12	15	11 *	9
Phase 1/2	8	8	4	7	7
Phase 2	44	41	51	33 *	52
Phase 2/3	4	2	5	6	2
Phase 3	48	50	42	51	47
Phase Other	12	7	19	14	15
Total	163	143	166	148 *	167

* Revised March 2021

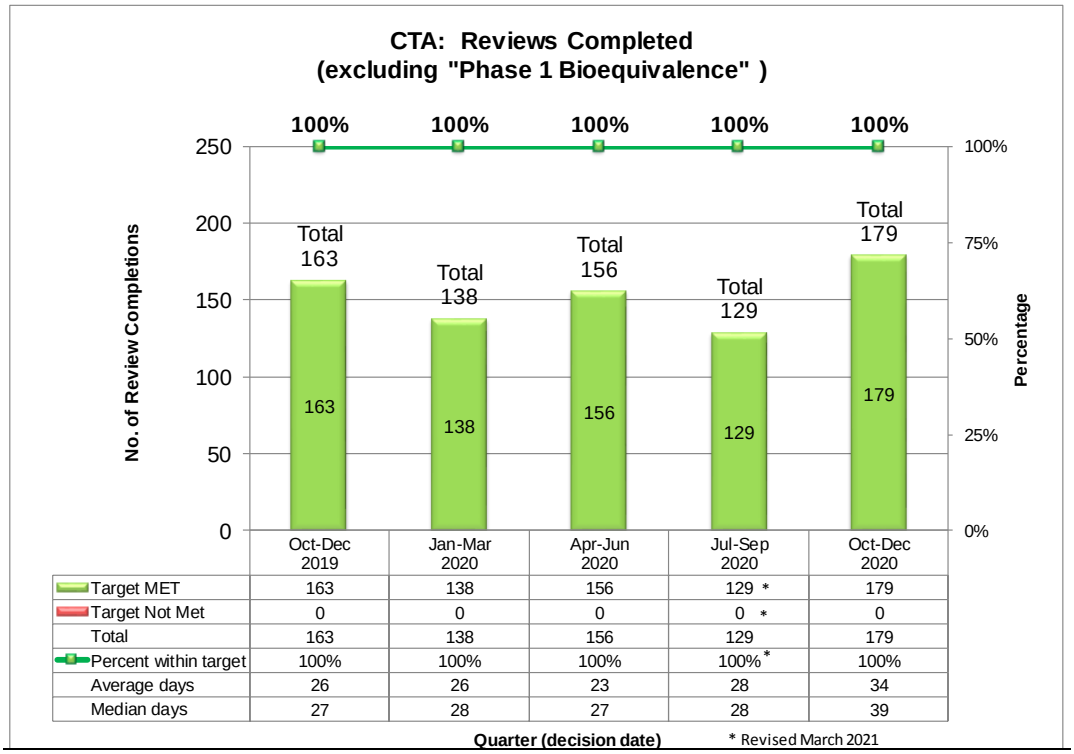
DECISION DOCUMENTS

CTA: Number of Decisions by Type

CTA					
DOCUMENT TYPE	**Oct-Dec 2019**	**Jan-Mar 2020**	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**
NO OBJECTION LETTER	203	186	215	186	217
CANCELLED BY COMPANY DURING REVIEW	19	17	17	8	12
CANCELLED BY COMPANY AT PROCESSING	2	9	5	4	1
NOTICE OF AUTHORIZATION	0	0	1	1	7

PERFORMANCE

CTA: Reviews Completed (excluding Phase 1 Bioequivalence)

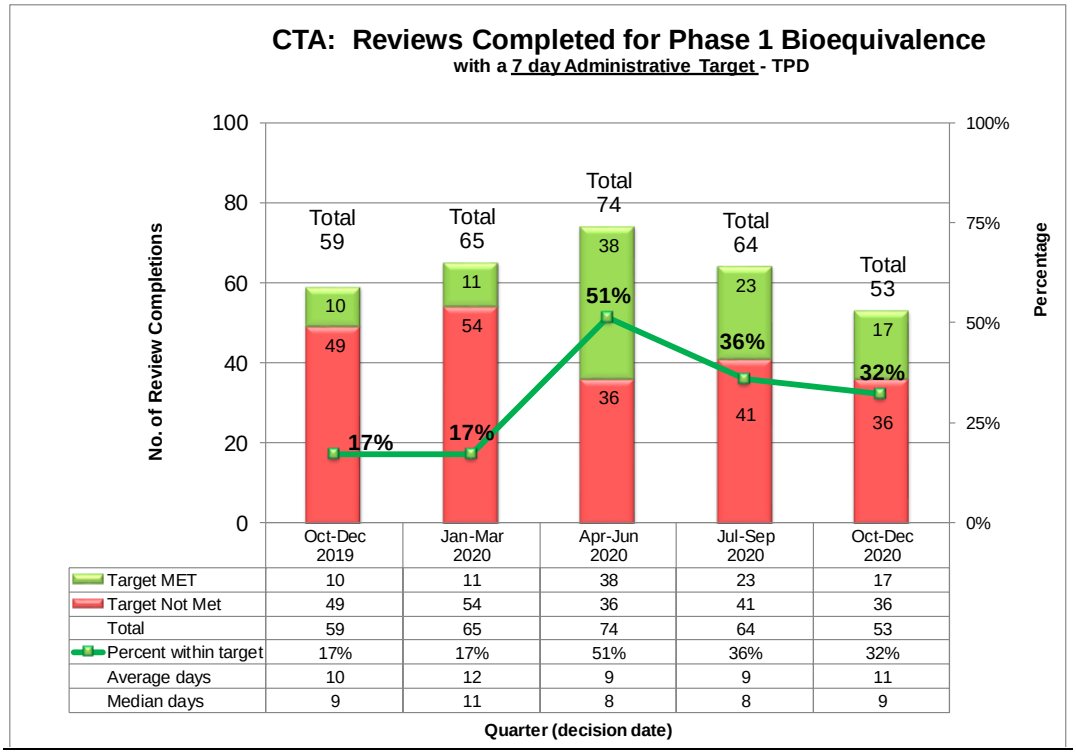


	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Target MET	163	138	156	129 *	179
Target Not Met	0	0	0	0 *	0
Total	163	138	156	129	179
Percent within target	100%	100%	100%	100% *	100%
Average days	26	26	23	28	34
Median days	27	28	27	28	39

Quarter (decision date)

* Revised March 2021

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

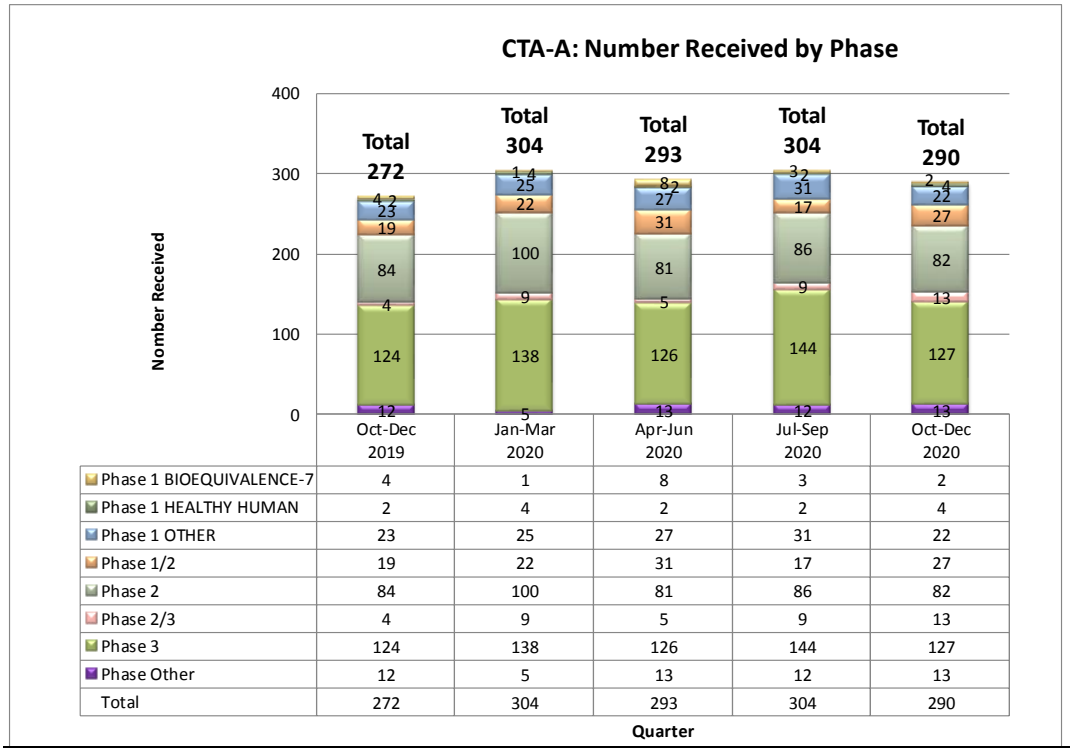


	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Target MET	10	11	38	23	17
Target Not Met	49	54	36	41	36
Total	59	65	74	64	53
Percent within target	17%	17%	51%	36%	32%
Average days	10	12	9	9	11
Median days	9	11	8	8	9

Quarter (decision date)

CTA-A: CLINICAL TRIAL APPLICATION-AMENDMENTS

CTA-A: Number Received by Phase



	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Phase 1 BIOEQUIVALENCE-7	4	1	8	3	2
Phase 1 HEALTHY HUMAN	2	4	2	2	4
Phase 1 OTHER	23	25	27	31	22
Phase 1/2	19	22	31	17	27
Phase 2	84	100	81	86	82
Phase 2/3	4	9	5	9	13
Phase 3	124	138	126	144	127
Phase Other	12	5	13	12	13
Total	272	304	293	304	290

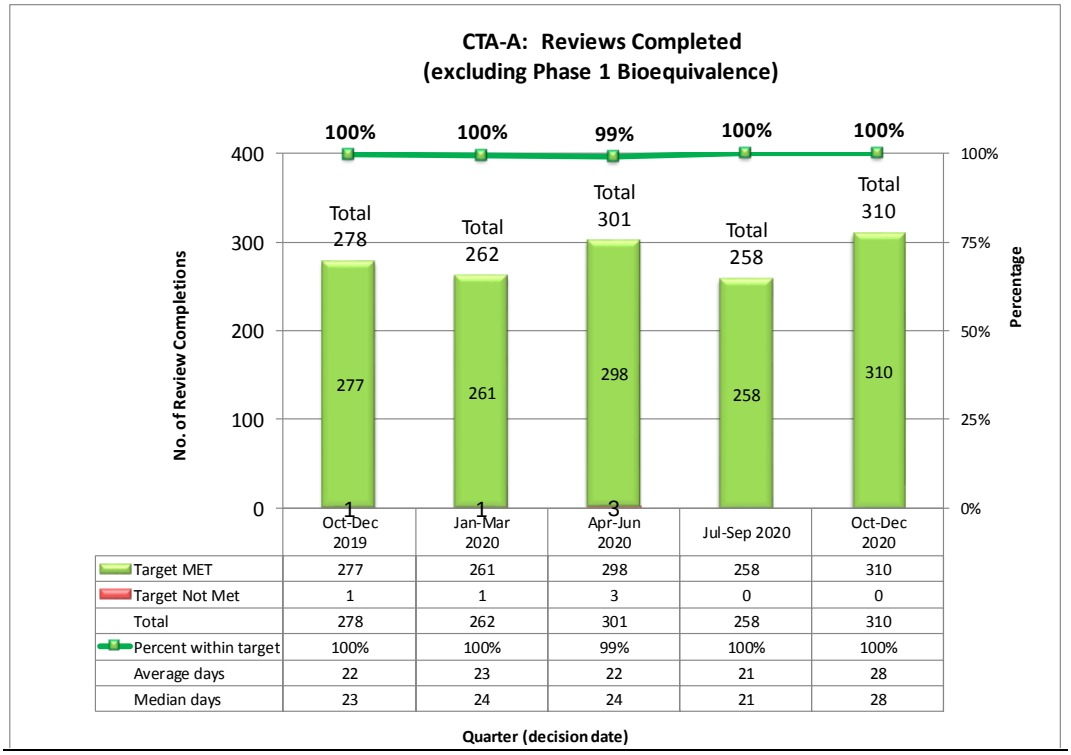
DECISIONS

CTA-A: Number of Decisions by Type

CTA-A (excluding administrative)					
DOCUMENT TYPE	**Oct-Dec 2019**	**Jan-Mar 2020**	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**
NO OBJECTION LETTER	276	252	307	259	302
CANCELLED BY COMPANY DURING REVIEW	5	12	5	2	5
CANCELLED BY COMPANY AT PROCESSING	7	15	7	14	8
NOT SATISFACTORY NOTICE	0	1	0	0	0
NOTICE OF AUTHORIZATION	0	0	0	0	1

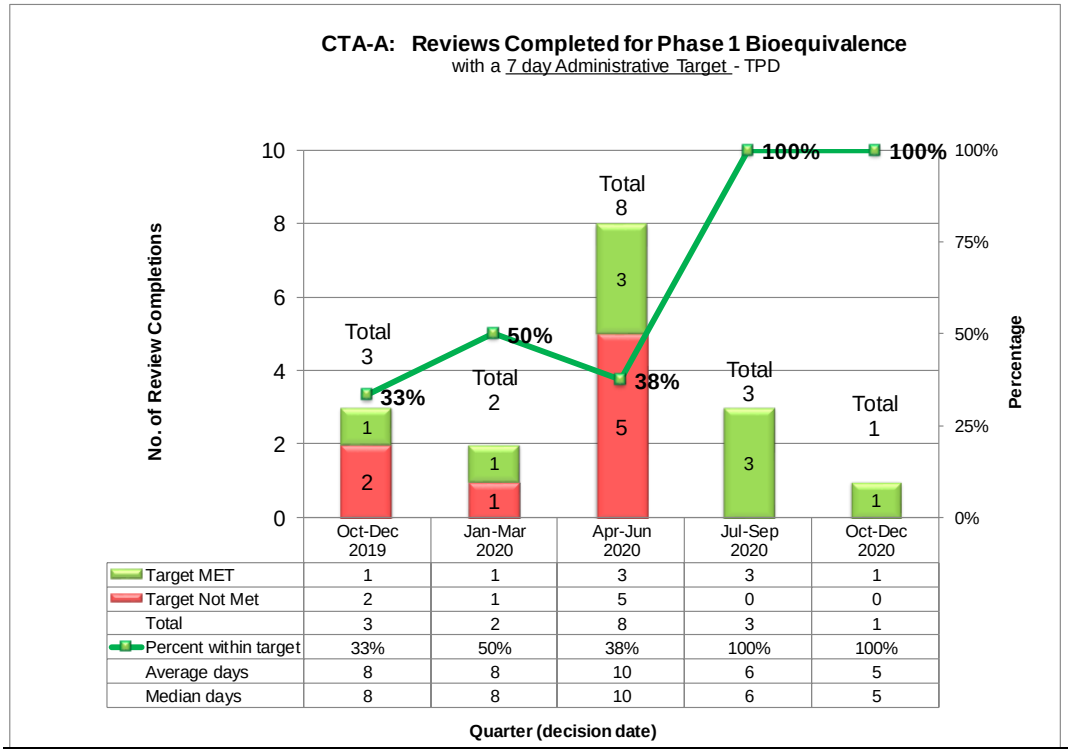
PERFORMANCE

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



	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Target MET	277	261	298	258	310
Target Not Met	1	1	3	0	0
Total	278	262	301	258	310
Percent within target	100%	100%	99%	100%	100%
Average days	22	23	22	21	28
Median days	23	24	24	21	28

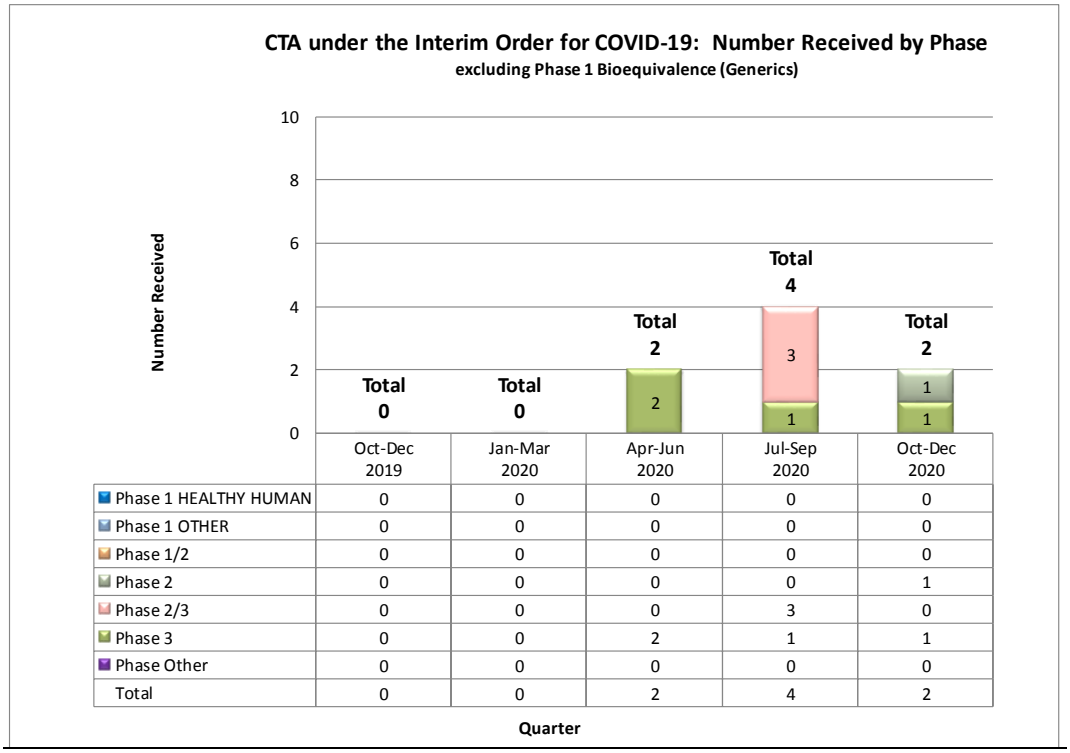
CTA-A: Reviews Completed for Phases with a 7 Day Administrative Target



	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Target MET	1	1	3	3	1
Target Not Met	2	1	5	0	0
Total	3	2	8	3	1
Percent within target	33%	50%	38%	100%	100%
Average days	8	8	10	6	5
Median days	8	8	10	6	5

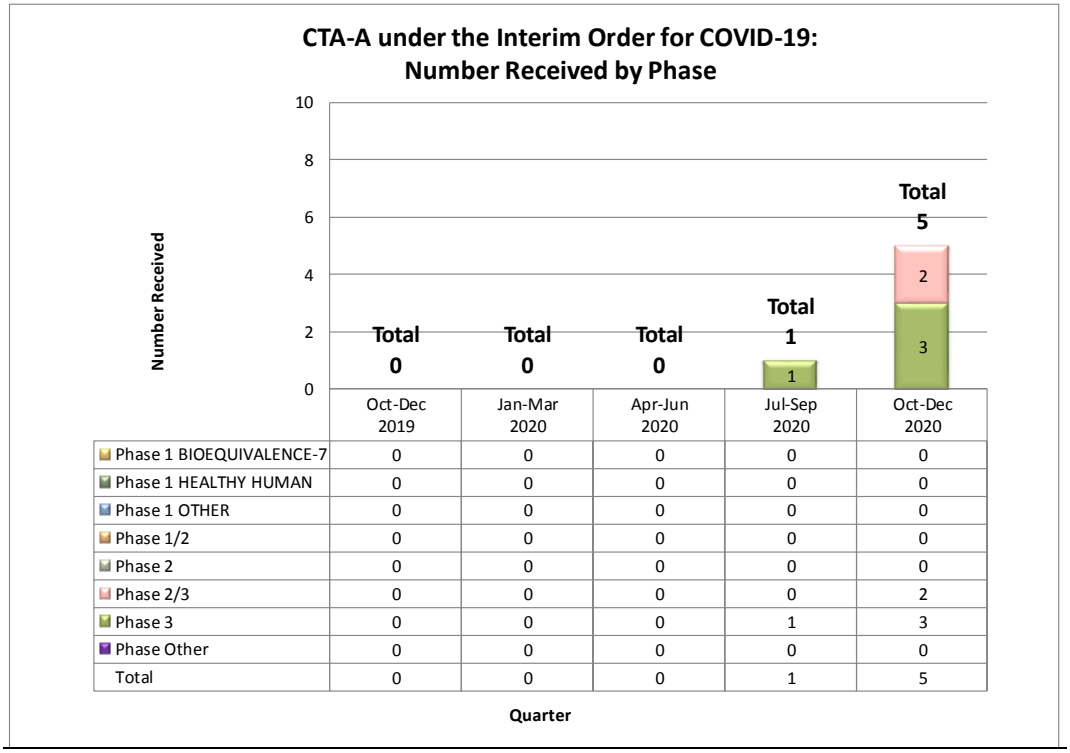
CTA & CTA-A RECEIVED UNDER THE INTERIM ORDER COVID 19

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



	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Phase 1 HEALTHY HUMAN	0	0	0	0	0
Phase 1 OTHER	0	0	0	0	0
Phase 1/2	0	0	0	0	0
Phase 2	0	0	0	0	1
Phase 2/3	0	0	0	3	0
Phase 3	0	0	2	1	1
Phase Other	0	0	0	0	0
Total	0	0	2	4	2

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



	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Phase 1 BIOEQUIVALENCE-7	0	0	0	0	0
Phase 1 HEALTHY HUMAN	0	0	0	0	0
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	0	0	0	2
Phase 3	0	0	0	1	3
Phase Other	0	0	0	0	0
Total	0	0	0	1	5

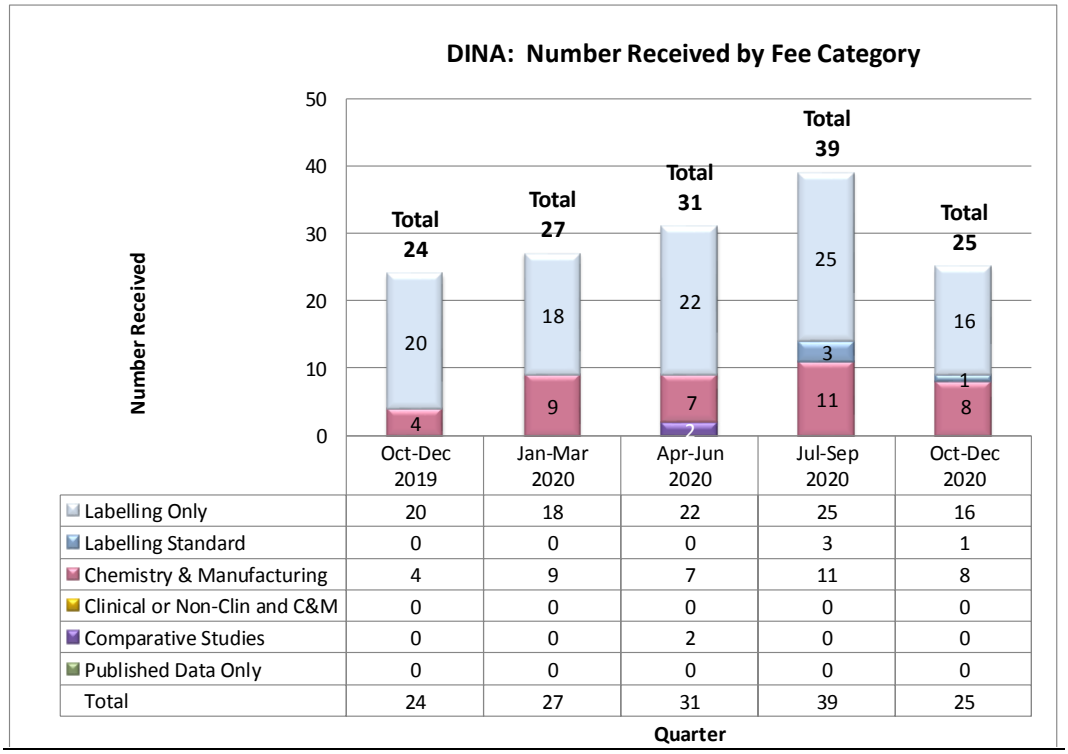
These figures are a subset of the total CTA and CTA-A received.

DINA

Application for a Drug Identification Number

DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER [11]

DINA: Number Received by Fee Category

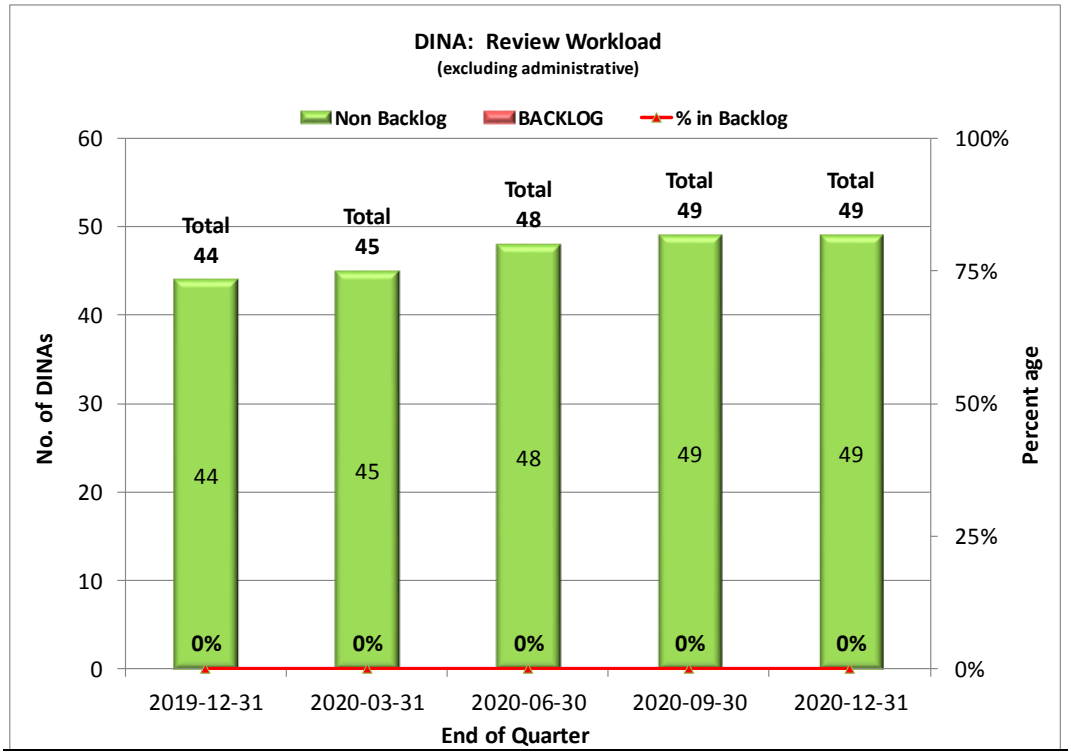


	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
Labelling Only	20	18	22	25	16
Labelling Standard	0	0	0	3	1
Chemistry & Manufacturing	4	9	7	11	8
Clinical or Non-Clin and C&M	0	0	0	0	0
Comparative Studies	0	0	2	0	0
Published Data Only	0	0	0	0	0
Total	24	27	31	39	25

[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

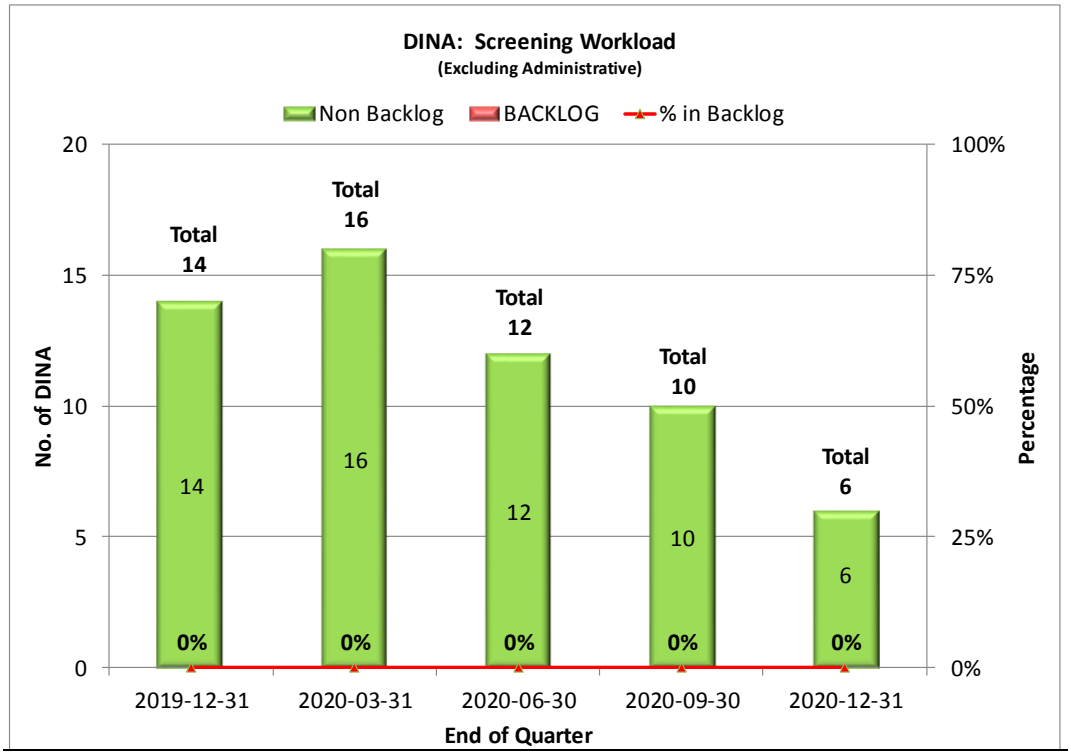


DINA: Review Workload by Fee Category

DINA: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	**2019-12-31**	**2020-03-31**	**2020-06-30**	**2020-09-30**	**2020-12-31**
Labelling Only	**24**	**29**	**35**	**36**	**29**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**19**	**15**	**12**	**11**	**18**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**1**	**1**	**0**	**0**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**0**	**0**	**1**	**2**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**44**	**45**	**48**	**49**	**49**
Non Backlog	**44**	**45**	**48**	**49**	**49**
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	**2019-12-31**	**2020-03-31**	**2020-06-30**	**2020-09-30**	**2020-12-31**
Labelling Only	**11**	**10**	**8**	**2**	**3**
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Standard	**0**	**0**	**0**	**2**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**3**	**6**	**3**	**6**	**3**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**0**	**0**	**1**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**14**	**16**	**12**	**10**	**6**
Non Backlog	**14**	**16**	**12**	**10**	**6**
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	**Oct-Dec 2019**	**Jan-Mar 2020**	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**
NOTIFICATION FORM/DIN ISSUED	1	0	4	5	2
NO OBJECTION LETTER	19	12	13	22	19
CANCELLED BY COMPANY	1	0	2	3	0
NEW DRUG LETTER SCREEN	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	1	0	0
NOTICE OF NON-COMPLIANCE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	1	1	2	0	0

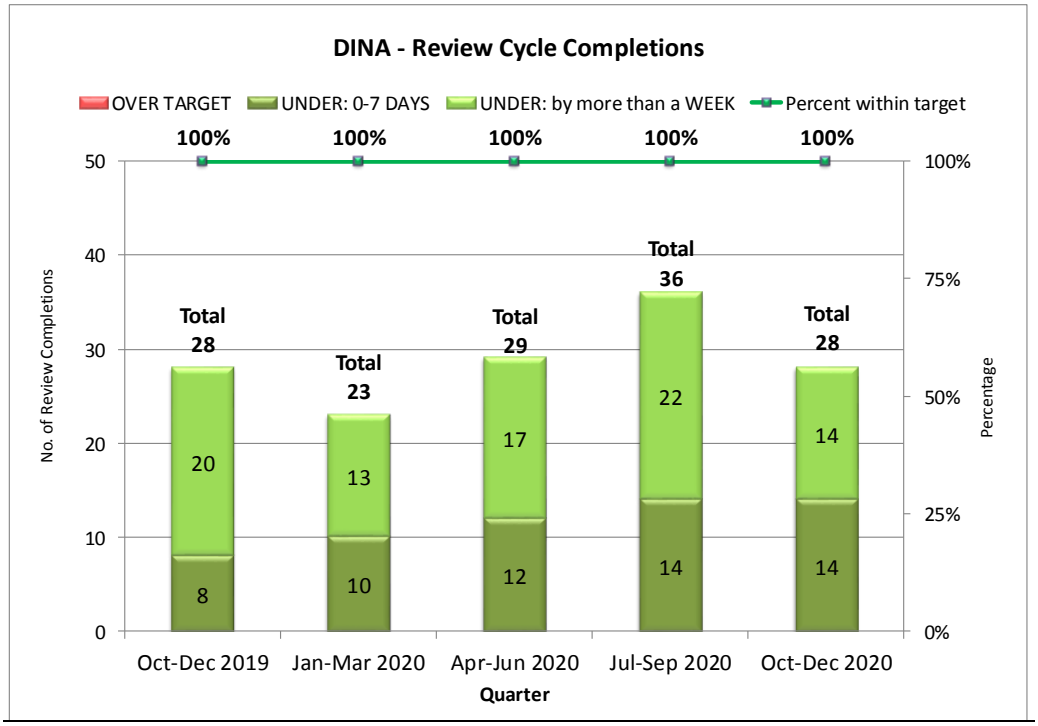
DINA - CHEMISTRY AND MANUFACTURING					
DOCUMENT TYPE	**Oct-Dec 2019**	**Jan-Mar 2020**	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**
NOTIFICATION FORM/DIN ISSUED	2	7	6	4	0
NO OBJECTION LETTER	3	4	3	5	4
NOD WITHDRAWAL LETTER	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	2	0	0	0	2
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	0	2	5	5	7
CANCELLED BY COMPANY	0	0	0	1	0

DINA - COMPARATIVE STUDIES					
DOCUMENT TYPE	**Oct-Dec 2019**	**Jan-Mar 2020**	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	1
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

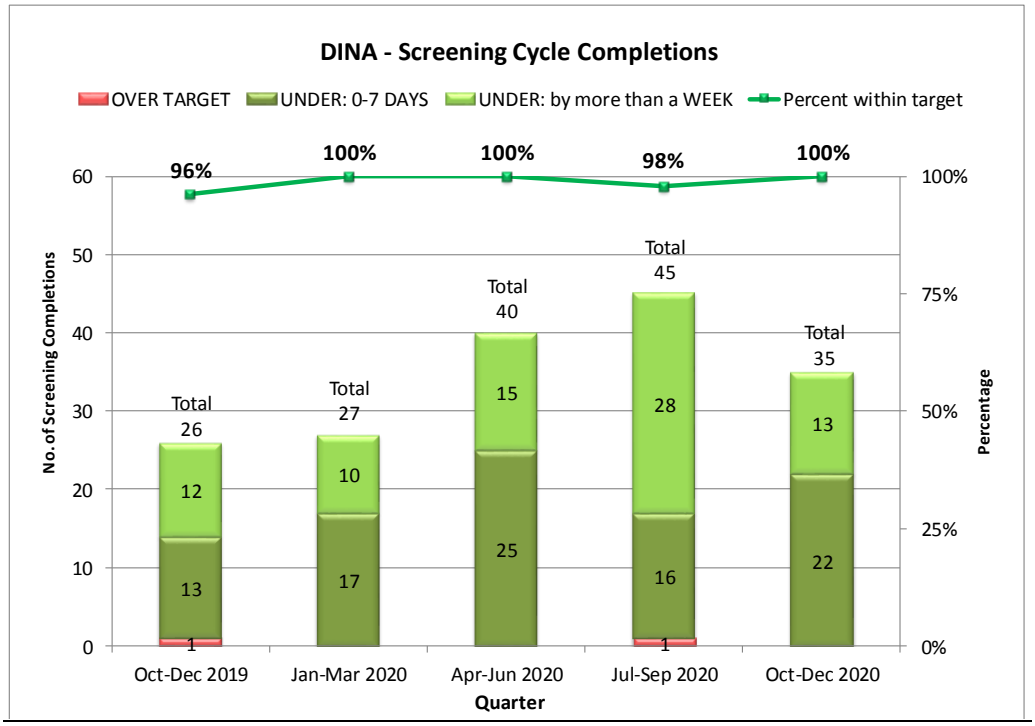
DINA - CLINICAL OR NON CLINICAL DATA AND C&M					
DOCUMENT TYPE	**Oct-Dec 2019**	**Jan-Mar 2020**	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**
CANCELLED BY COMPANY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	0	0	1	0	0
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0

PERFORMANCE

DINA: Review Cycle Completions

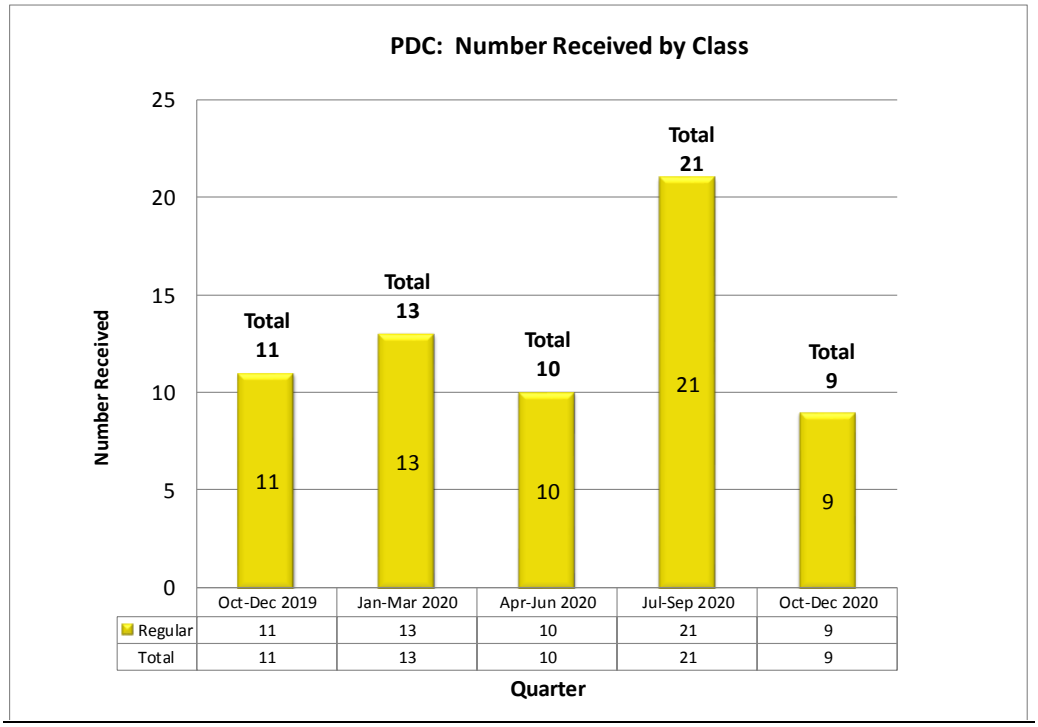


DINA: Screening Cycle Completions



PDC: POST-AUTHORIZATION DIVISION 1 CHANGE

PDC: Number Received

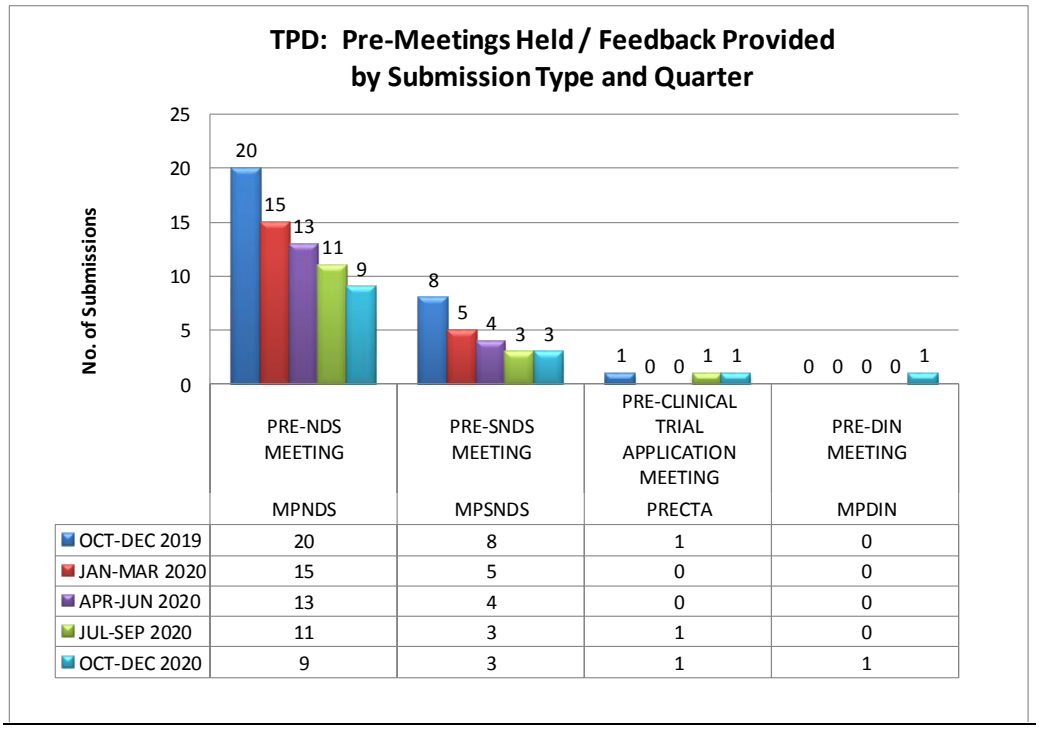


PDC: Number of Decisions by Type

PDC					
DOCUMENT TYPE	**Oct-Dec 2019**	**Jan-Mar 2020**	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**
REGULAR					
CANCELLED BY COMPANY	7	1	2	8	3
NO OBJECTION LETTER	0	11	9	7	11
NOT SATISFACTORY NOTICE	0	0	1	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)
OCT-DEC 2019	20	8	1	0
JAN-MAR 2020	15	5	0	0
APR-JUN 2020	13	4	0	0
JUL-SEP 2020	11	3	1	0
OCT-DEC 2020	9	3	1	1

[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.