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**Biologics and Genetic Therapies  
Directorate  
Drug Submission Performance  
Quarterly Report  
  
April - June  
2012**



Canada 

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# OVERVIEW

The Biologics and Genetic Therapies Directorate (BGTD) Quarterly Drug Submission Performance Report reflects biologic and radiopharmaceutical drug submission review activity over five consecutive quarters: from April - June 2011 to April - June 2012. Statistics are provided by Submission Type and show the number received, the number in workload, the number of decisions and the number of approvals.

## What's New

- The new Cost Recovery Fee Categories<sup>1</sup> introduced on April 1<sup>st</sup> 2011 have been incorporated into the reports.
- Performance continues to be measured against performance standards for Submission Type/Submission Class/ Status combinations as set out in Appendix 3 of the [Guidance for Industry: Management of Drug Submissions](#)<sup>2</sup>.
- 'Labelling Only' are now reported along with the other Fee Categories. The Fee Category "Administrative Submission" is reported in a separate section of the report.
- Final results from confirmatory trials submitted in the form of an SNDS-C<sup>3</sup> are now included in the SNDS Received, Workload and Performance figures. SNDS-C are not included in the SNDS Approval figures.
- 'Requests for Reconsideration of Final Decision' figures will continue to be reported on an annual basis but have been removed from the quarterly reports.

## General Information

There are several steps involved in the drug submission review<sup>4</sup> and approval process:

- administrative processing,
- regulatory and scientific screening and
- in-depth scientific review.

When deficiencies or non-compliance issues are found, a company may submit responses before a final decision can be reached and thus multiple review cycles may be required. A submission's approval time can vary depending on the number and type of review cycles needed.

**Submissions Received** are counts of submissions received during the year using the filing date (CR date) which is the date the submission is considered administratively complete by Health Canada.

<sup>1</sup> For further clarification refer to the Fees in Respect of Human Drugs and Medical Devices at <http://www.hc-sc.gc.ca/dhp-mps/finance/fees-frais/index-eng.php>

<sup>2</sup> This is not to be confused with the 'UF Review 1(iteration 1)' performance standards that will be employed to measure performance to meet the *User Fees Act* reporting Requirements in the 'Health Canada Departmental Performance Report (DPR)

<sup>3</sup> For further Clarification refer to the [Guidance Document: Notice of Compliance with Conditions \(NOC/c\)](#). [http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/compli-conform/noccg\\_accd-eng.php#a3.3](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/compli-conform/noccg_accd-eng.php#a3.3)

<sup>4</sup> For further clarification refer to the [Guidance for Industry: Management of Drug Submissions](#).

**Workload** is the number of submissions “under active review” on a given day. **“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** 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 Patent regulations or due to de-scheduling (from prescription to Over the Counter).

A **review cycle completion**<sup>5</sup> is counted upon the conclusion of an in-depth scientific review that then results in a decision of approval or non-approval. The time taken is compared to a set [performance standard](#)<sup>2</sup> which is based on the type of submission, class and cycle (status). For example, in the case of a Priority NDS, the performance standard is 180 days for Review1 and 90 days for Review2. Health Canada has set a goal of 90% of review cycle completions to be rendered within performance standards.

**"First Cycle Review" Approvals** are those submissions approved without having to go through several review cycles to resolve submission deficiencies or non-compliance issues, and exclude “refiled”<sup>6</sup> submissions.

Any questions or comments on this report should be forwarded to:  
Office of Submissions and Intellectual Property (OSIP) (formerly SIPD)  
Finance Building (#2), A.L. # 0201A1  
101 Tunney’s Pasture Driveway, Tunney’s Pasture  
Ottawa, Ontario, K1A 1B9  
Tel: (613) 957-3123 Fax: (613) 941-0825  
Email: [SIPDMAIL@hc-sc.gc.ca](mailto:SIPDMAIL@hc-sc.gc.ca)

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<sup>5</sup> 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.

<sup>6</sup> For further clarification refer to the [Guidance for Industry: Management of Drug Submissions](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/mgmt-gest/mands_gespd-eng.php#a5.7) [http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/mgmt-gest/mands\\_gespd-eng.php#a5.7](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/mgmt-gest/mands_gespd-eng.php#a5.7)

# ACRONYMS

## Submission Types

CTA	- Clinical Trial Application
CTA-A	- Clinical Trial Application-Amendment
DINB	- Application for a Drug Identification Number - Biological Product
MP-NDS	Pre- New Drug Submission Meeting
MP-SNDS	Pre- Supplemental New Drug Submission Meeting
NDS	- New Drug Submission
NC	- Notifiable Change (Level II) – New Drug
PDC	- Post Din Changes
PRNDS	- Request for Priority Review Status: New Drug Submission
PRSNDS	- Request for Priority Review Status: Supplemental New Drug Submission
SNDS	- Supplemental New Drug Submission
SNDS-C	- Supplemental New Drug Submission – CONFIRMATORY
YPBR	- Yearly Biologic Product Report

## Documents

NOC	- Notice of Compliance
NOC-c	- Notice of Compliance with Conditions
Issuable NOC (Patent)	- NOC on Hold due to Patent Regulations
Issuable NOC (Rx to OTC)	- NOC on Hold due to De-Scheduling
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	Fee Category Description
<b>New Active Substance (NAS)*</b> <i>This new NAS definition came into effect on April 1 2011</i>	Submissions in support of a drug, excluding a disinfectant, that contains a medicinal ingredient not previously approved in a drug for sale in Canada, and that is not a variation of a previously approved ingredient such as a salt, ester, enantiomer, solvate or polymorph.
<b>Clinical or non-clinical data and chemistry and manufacturing data</b>	Submissions based on clinical or non-clinical data and chemistry and manufacturing data for a drug that does not include a new active substance.
<b>Clinical or non-clinical data only</b>	Submissions based only on clinical or non-clinical data for a drug that does not include a new active substance.
<b>Comparative studies</b>	Submissions based on comparative studies (e.g. clinical or non-clinical data, bioavailability, pharmacokinetic and pharmacodynamic data) with or without chemistry and manufacturing data for a drug that does not include a new active substance.
<b>Chemistry and manufacturing data only</b>	Submissions based only on chemistry and manufacturing data for a drug that does not include a new active substance.
<b>Published data only</b>	Submissions based only on published clinical or non-clinical data for a drug that does not include a new active substance.
<b>Switch from prescription to nonprescription status</b>	Submissions based only on data that support the modification or removal of a medicinal ingredient listed in Schedule F to the <i>Food and Drug Regulations</i> (i.e. identical claim for existing drug).
<b>Labelling only</b>	Submissions of labelling material (i.e. does not include supporting clinical or non-clinical data or chemistry and manufacturing data).
<b>Administrative submission</b>	Submissions in support of a manufacturer or product name change.
<b>Disinfectants</b>	Submissions and applications that include data in support of a disinfectant.
<b>Drug Identification Number application - labelling standards</b>	Applications attesting to 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.

For further information refer to the Guidance Document - Fees for the Review of Drug Submissions and Applications [http://www.hc-sc.gc.ca/dhp-mps/prodpharma/fees-frais/fee\\_frais\\_guide-eng.php#app1](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/fees-frais/fee_frais_guide-eng.php#app1)

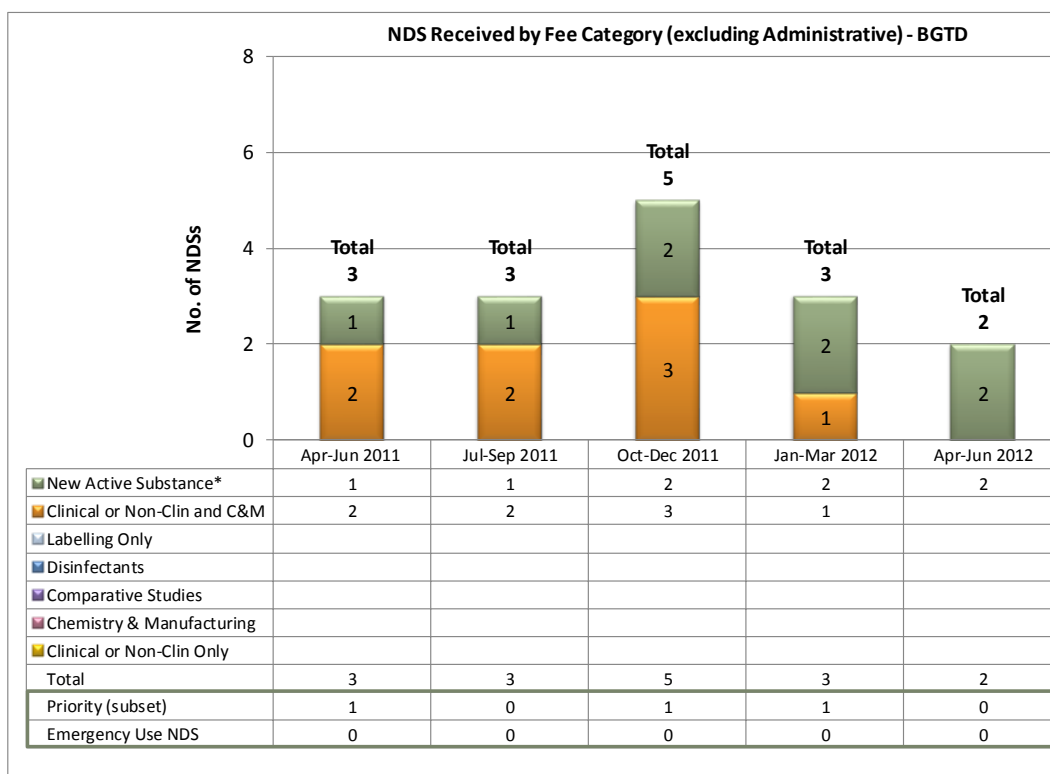
**New Drug Submissions  
(NDS)**

**&**

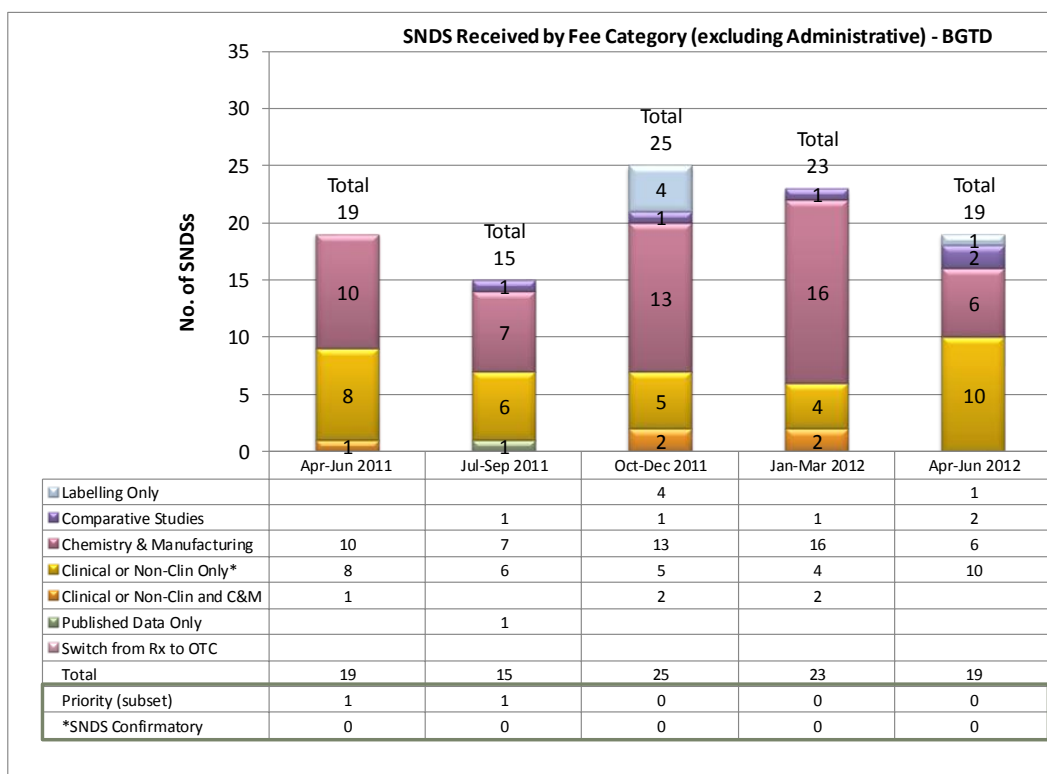
**Supplemental New Drug Submissions  
(SNDS)**

## SUBMISSIONS RECEIVED

### New Drug Submissions (NDS) Received by Fee Category

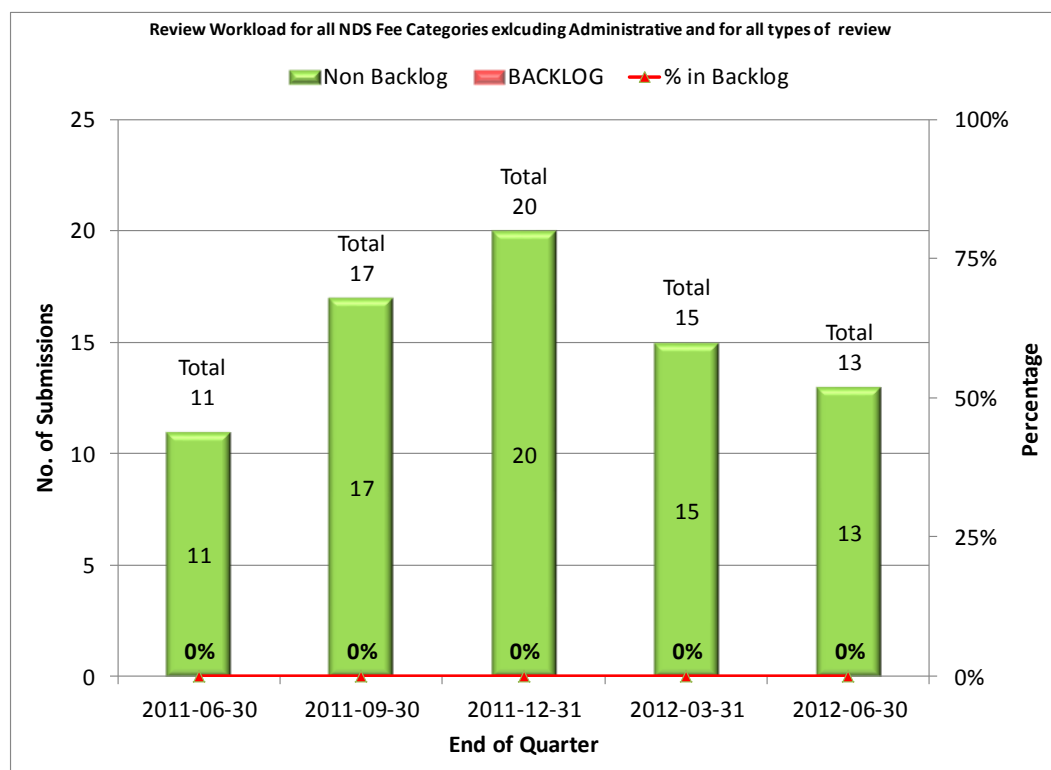


### Supplemental New Drug Submissions (SNDS) Received by Fee Category

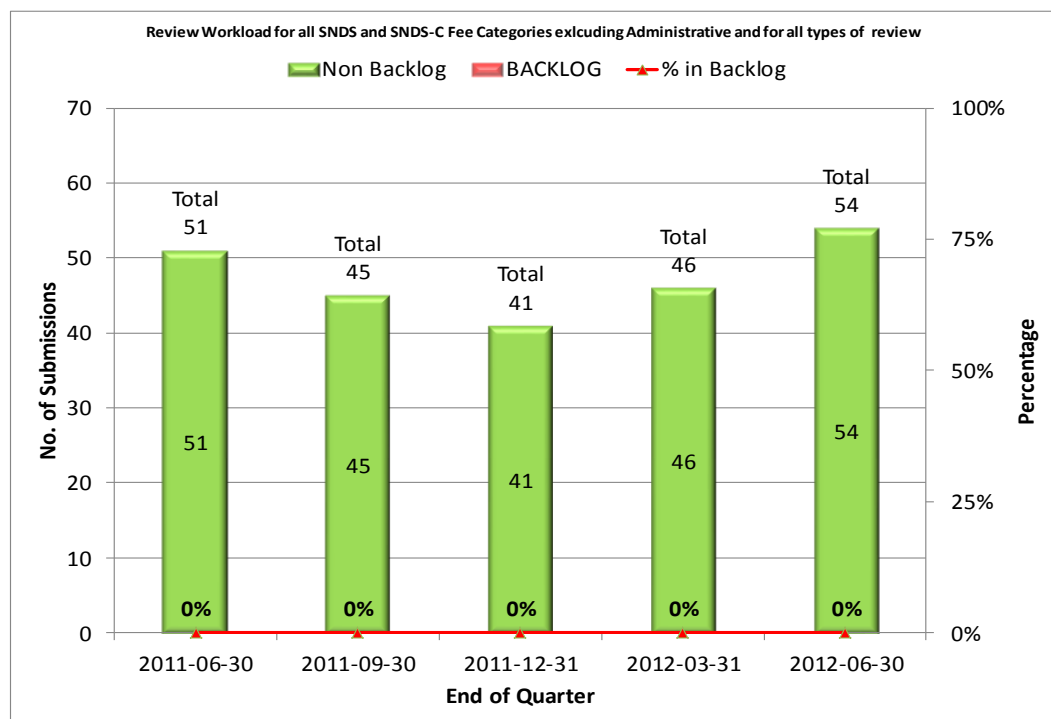


## WORKLOAD

### New Drug Submission (NDS) Review Workload / Backlog



### Supplemental New Drug Submission (SNDS) Review Workload / Backlog



## WORKLOAD

### New Drug Submission (NDS) Review Workload by Fee Category

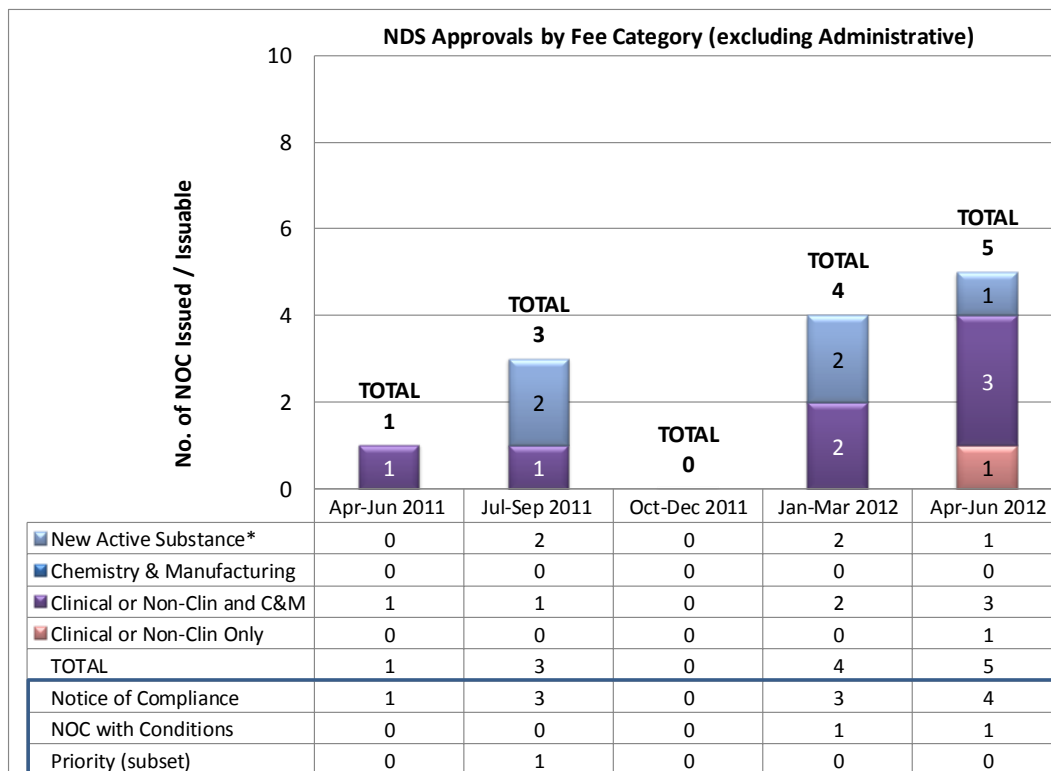
BGTD NDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2011-06-30	2011-09-30	2011-12-31	2012-03-31	2012-06-30
<b>Clinical or Non-Clin Only</b>	1	1	1	1	0
<i>Backlog</i>	0	0	0	0	0
<b>Clinical or Non-Clin and C&amp;M</b>	5	11	12	9	6
<i>Backlog</i>	0	0	0	0	0
<b>New Active Substance</b>	5	5	7	5	7
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>11</b>	<b>17</b>	<b>20</b>	<b>15</b>	<b>13</b>
<b>Non Backlog</b>	<b>11</b>	<b>17</b>	<b>20</b>	<b>15</b>	<b>13</b>
<b>Backlog</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>
<b>Priority (subset)</b>	1	1	1	1	2
Non Backlog	1	1	1	1	2
Backlog	0	0	0	0	0

### Supplemental New Drug Submission (SNDS) Review Workload by Fee Category

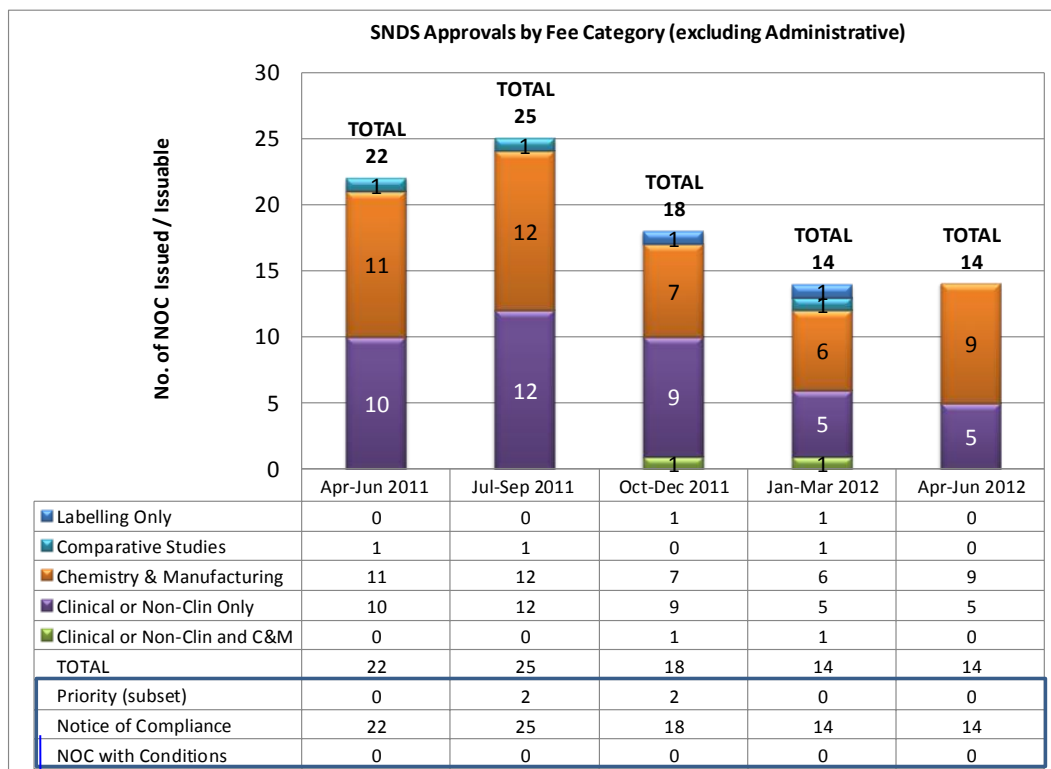
BGTD SNDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2011-06-30	2011-09-30	2011-12-31	2012-03-31	2012-06-30
<b>Comparative Studies</b>	1	1	1	1	4
<i>Backlog</i>	0	0	0	0	0
<b>Chemistry &amp; Manufacturing</b>	19	13	16	24	26
<i>Backlog</i>	0	0	0	0	0
<b>Clinical or Non-Clin Only</b>	28	26	20	18	17
<i>Backlog</i>	0	0	0	0	0
<b>Clinical or Non-Clin and C&amp;M</b>	3	4	2	3	6
<i>Backlog</i>	0	0	0	0	0
<b>Published Data</b>	0	1	1	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Labelling Only</b>	0	0	1	0	1
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>51</b>	<b>45</b>	<b>41</b>	<b>46</b>	<b>54</b>
<b>Non Backlog</b>	<b>51</b>	<b>45</b>	<b>41</b>	<b>46</b>	<b>54</b>
<b>Backlog</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>
<b>Priority (subset)</b>	0	3	2	0	0
Non Backlog	0	3	2	0	0
Backlog	0	0	0	0	0

## APPROVALS

### New Drug Submission (NDS) Approvals by Fee Category and by NOC Type



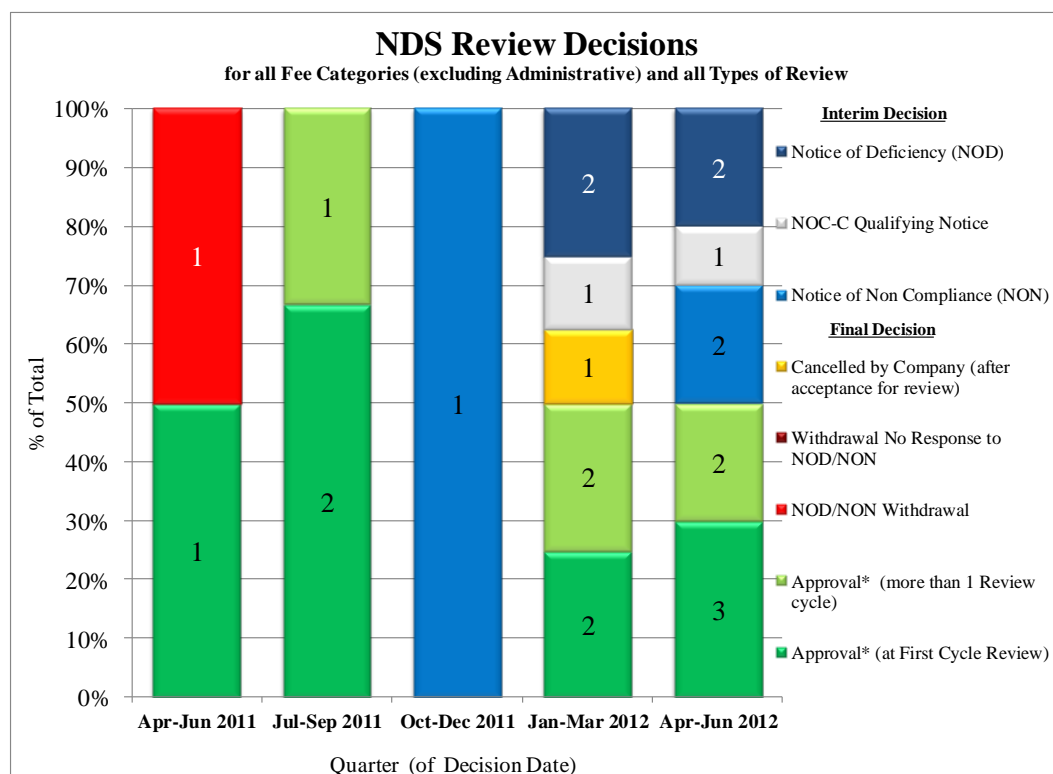
### Supplemental New Drug Submission (SNDS) Approvals by Fee Category and by NOC Type



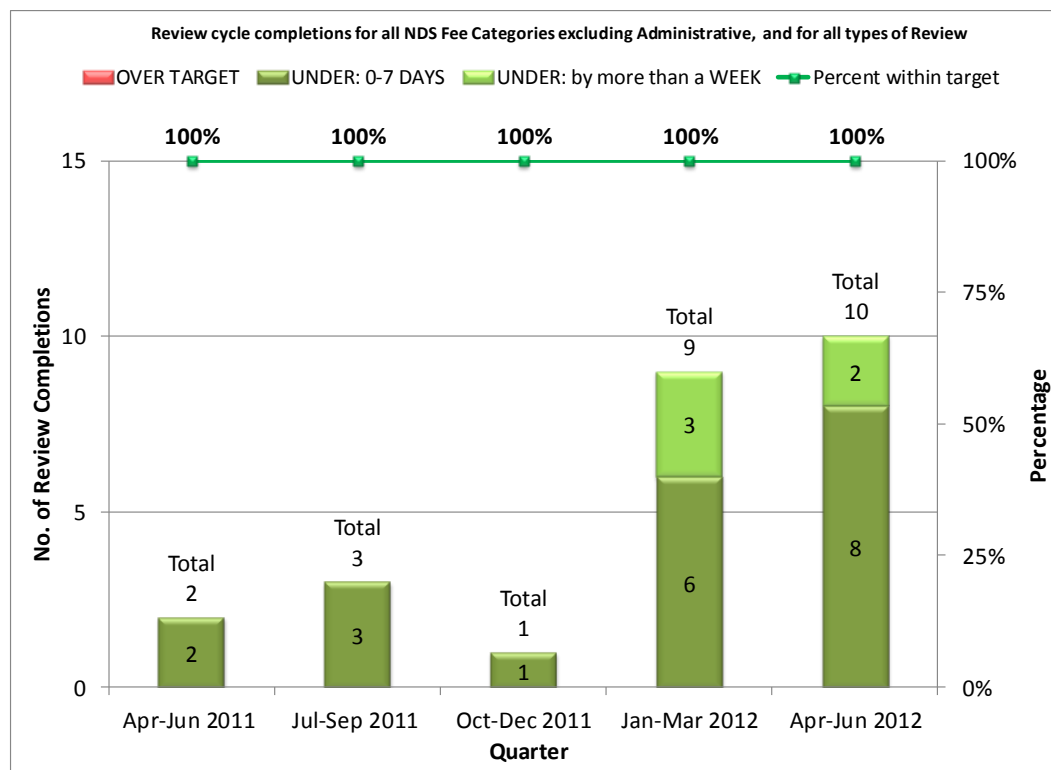
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## REVIEW CYCLE DECISIONS

### New Drug Submission (NDS) Review Decisions



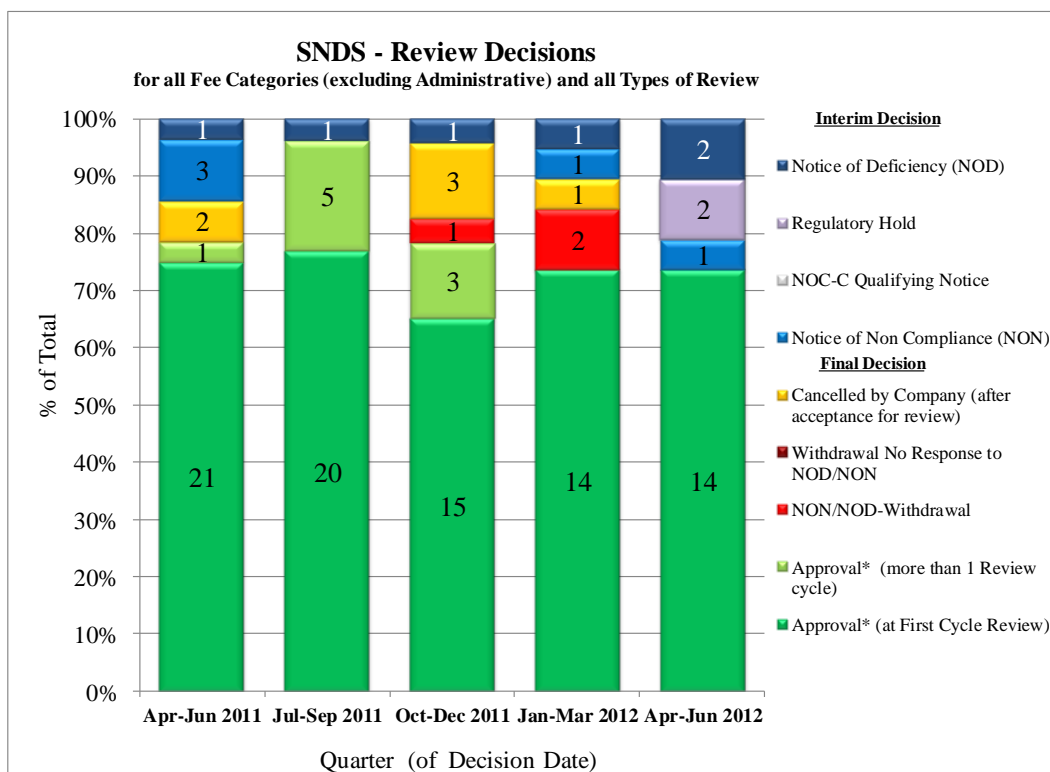
### NDS - Review Cycle Completions Showing Percentage Within Target



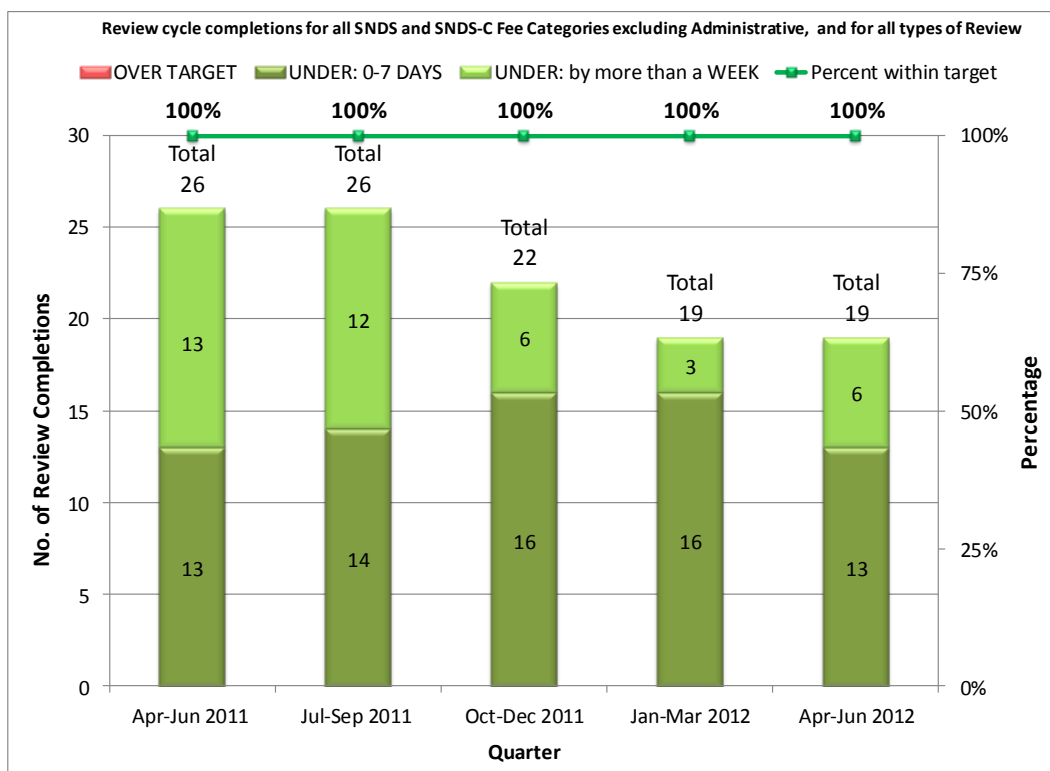


## REVIEW CYCLE DECISIONS

### Supplemental New Drug Submission (SNDS) Review Decisions

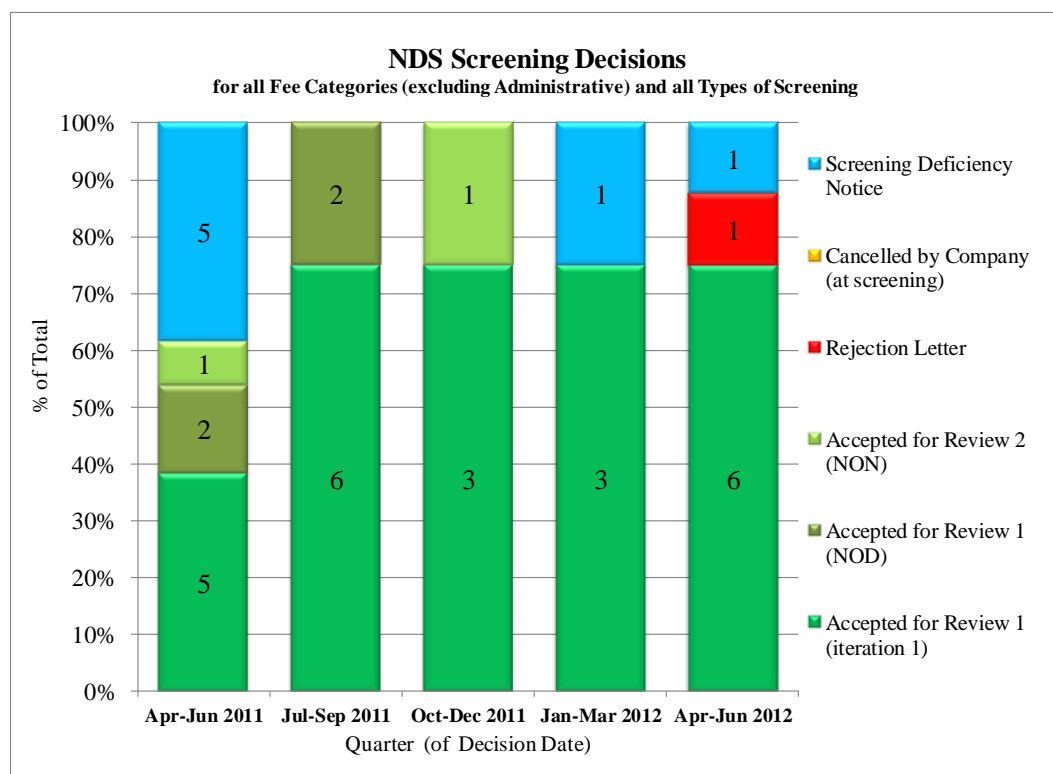


### SNDS - Review Cycle Completions Showing Percentage Within Target

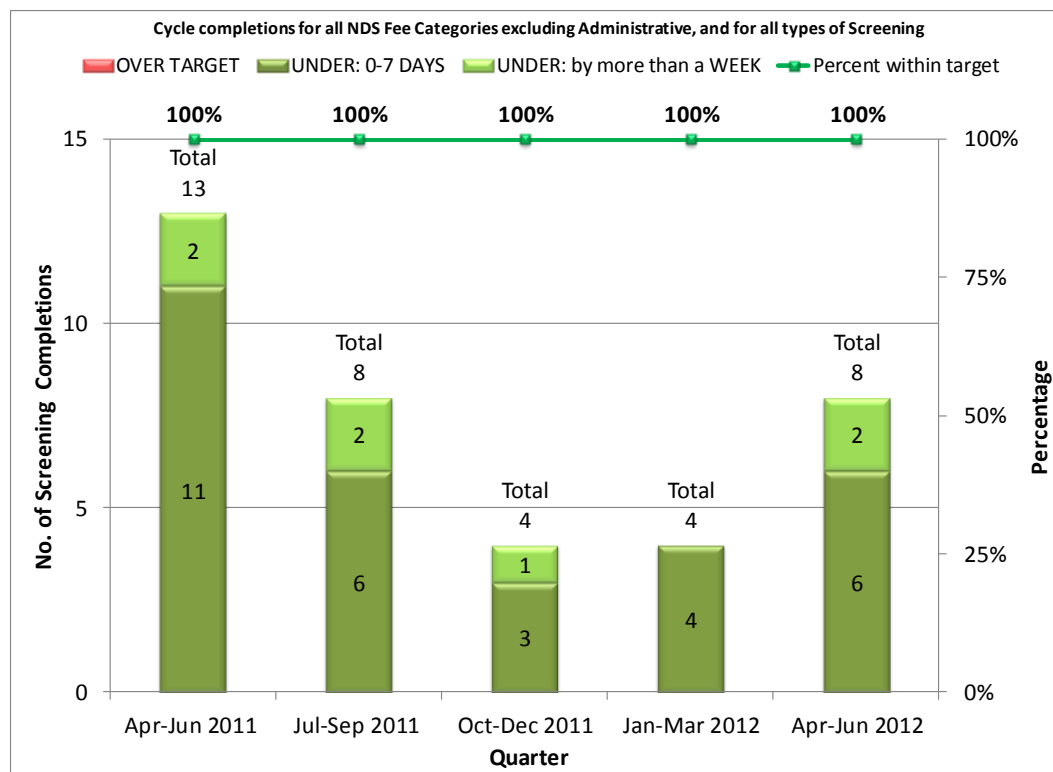


## SCREENING CYCLE DECISIONS

### New Drug Submission (NDS) Screening Decisions

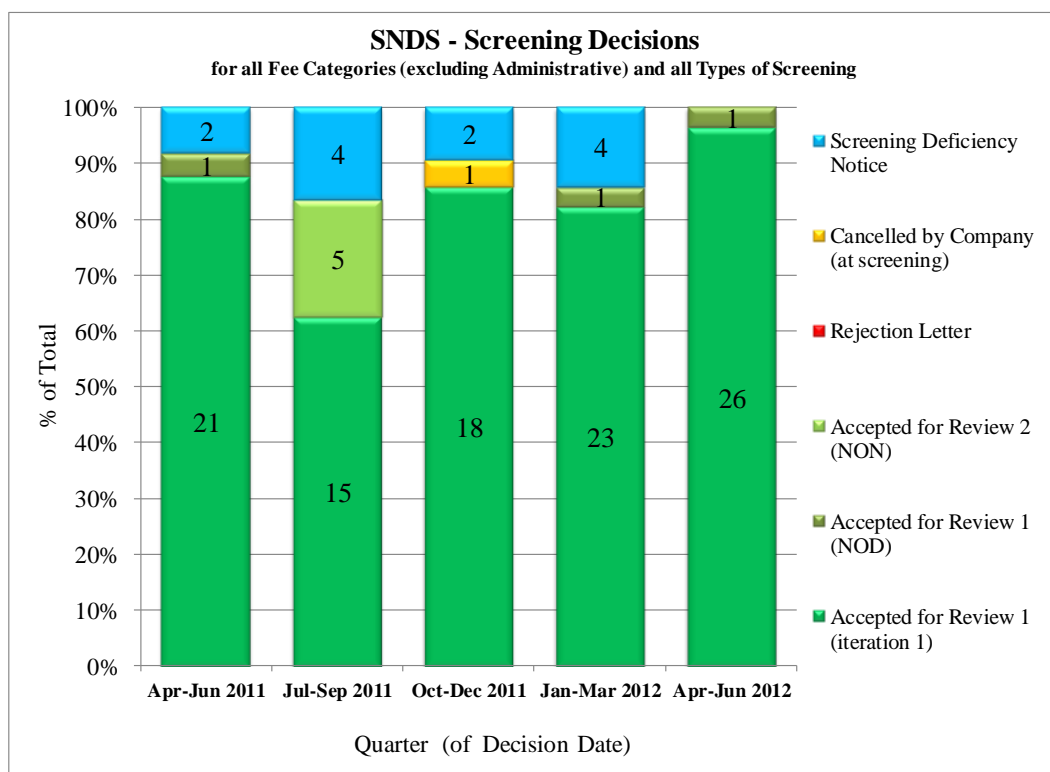


### NDS - Screening Cycle Completions Showing Percentage Within Target

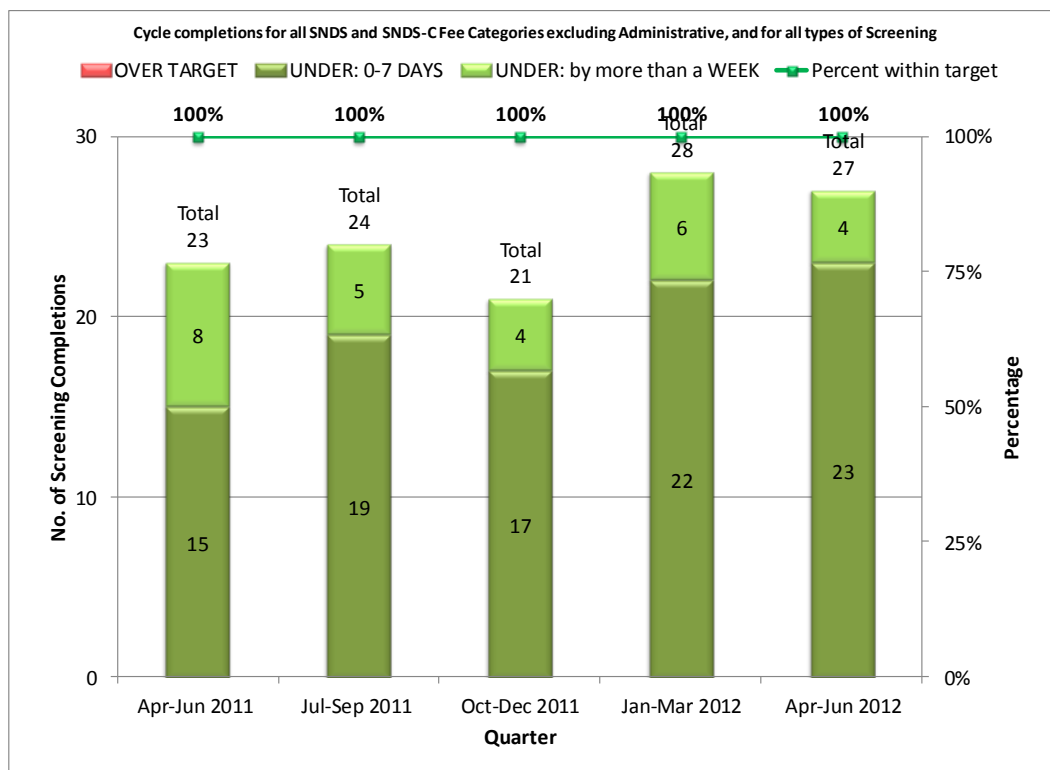


## SCREENING CYCLE DECISIONS

### Supplemental New Drug Submission (SNDS) Screening Decisions

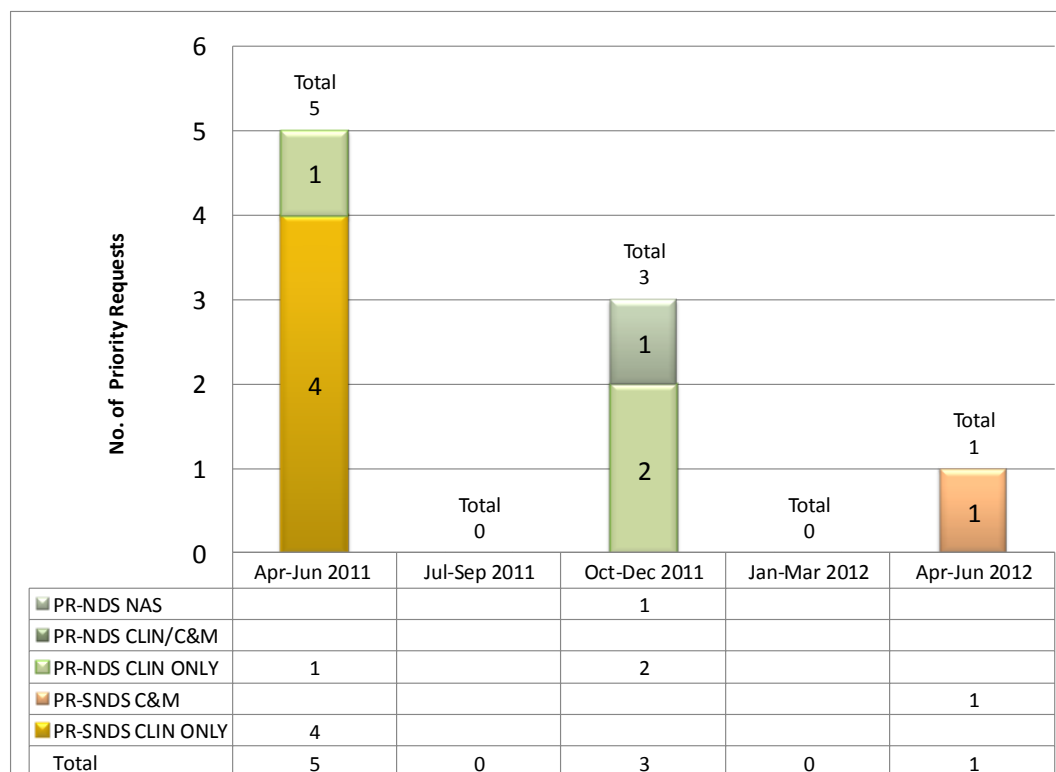


### SNDS - Screening Cycle Completions Showing Percentage Within Target

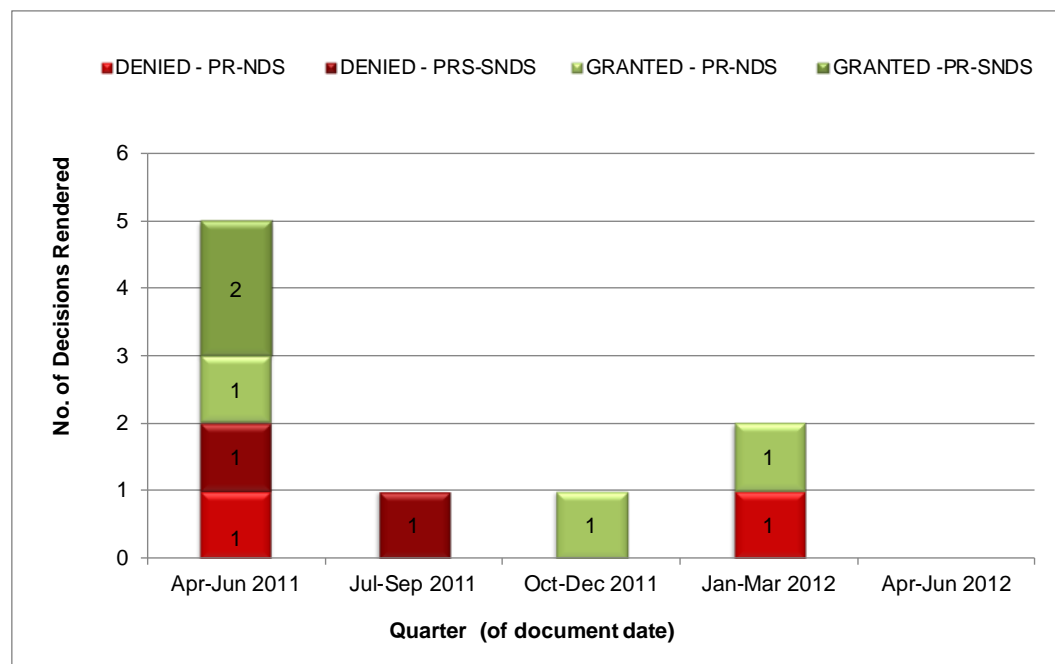


## PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

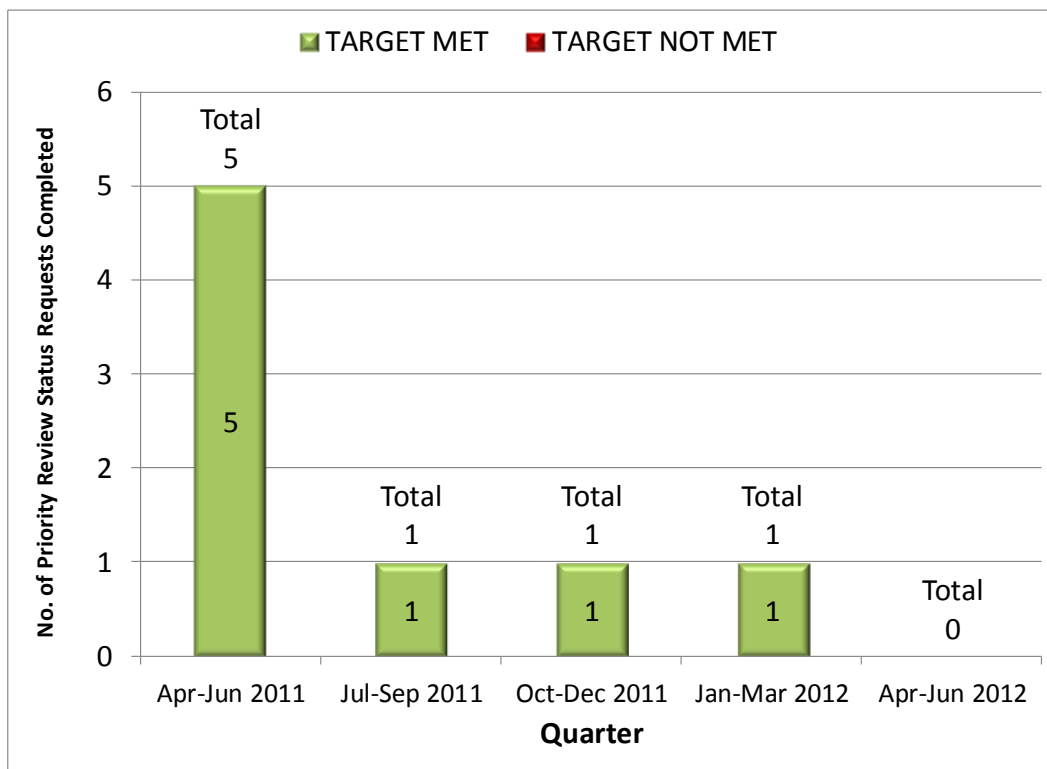
### Priority Review Status Requests Received



### Priority Review Status Requests: Decisions Rendered



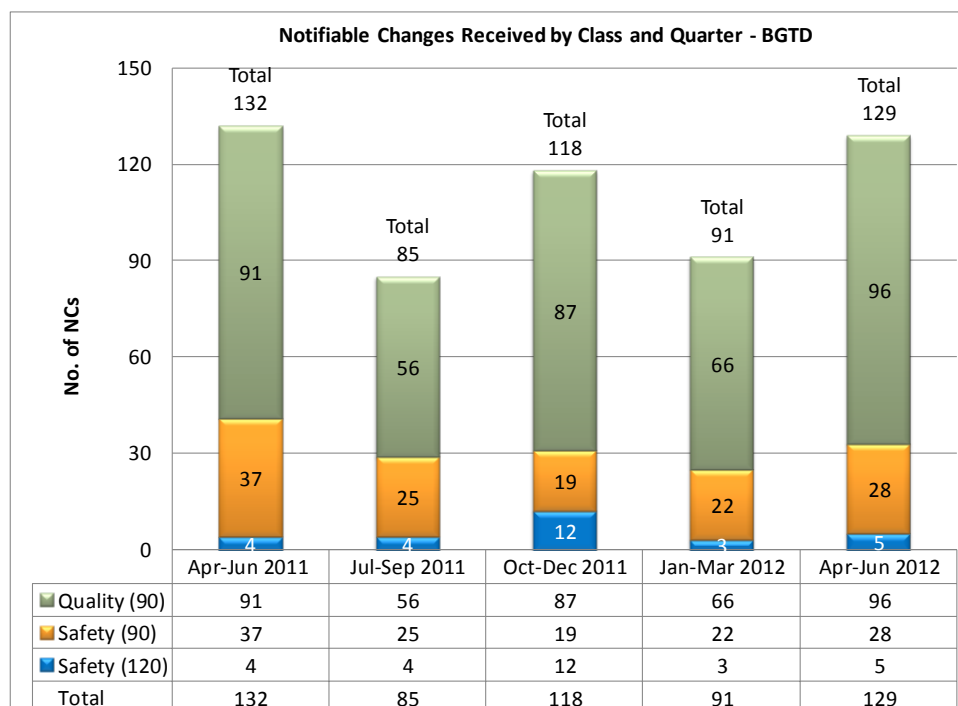
## Priority Review Status Request: Performance



## **NOTIFIABLE CHANGES (NC)**

## NOTIFIABLE CHANGE<sup>7, 8</sup>

### Submissions Received - Notifiable Change (NC)



### Decision Documents by Class - Notifiable Change (NC)

NC - SAFETY (90)					
DOCUMENT TYPE	Apr-Jun 2011	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012
NO OBJECTION LETTER	20	42	18	15	28
REJECTION LETTER (SCREENING)		2	3		3
CANCELLED BY COMPANY	1		3		1
SCREENING DEFICIENCY NOTICE					

NC - QUALITY (90)					
DOCUMENT TYPE	Apr-Jun 2011	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012
NO OBJECTION LETTER	72	72	54	85	35
NOT SATISFACTORY NOTICE		1	4		
REJECTION LETTER (SCREENING)	3	2	5	17	9
SCREENING DEFICIENCY NOTICE	1	2	2	2	
CANCELLED BY COMPANY	3	3			5

NC - SAFETY (120)					
DOCUMENT TYPE	Apr-Jun 2011	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012
NO OBJECTION LETTER	9	4	2	10	4
NOT SATISFACTORY NOTICE					
REJECTION LETTER (SCREENING)	1		2		
SCREENING DEFICIENCY NOTICE			1		

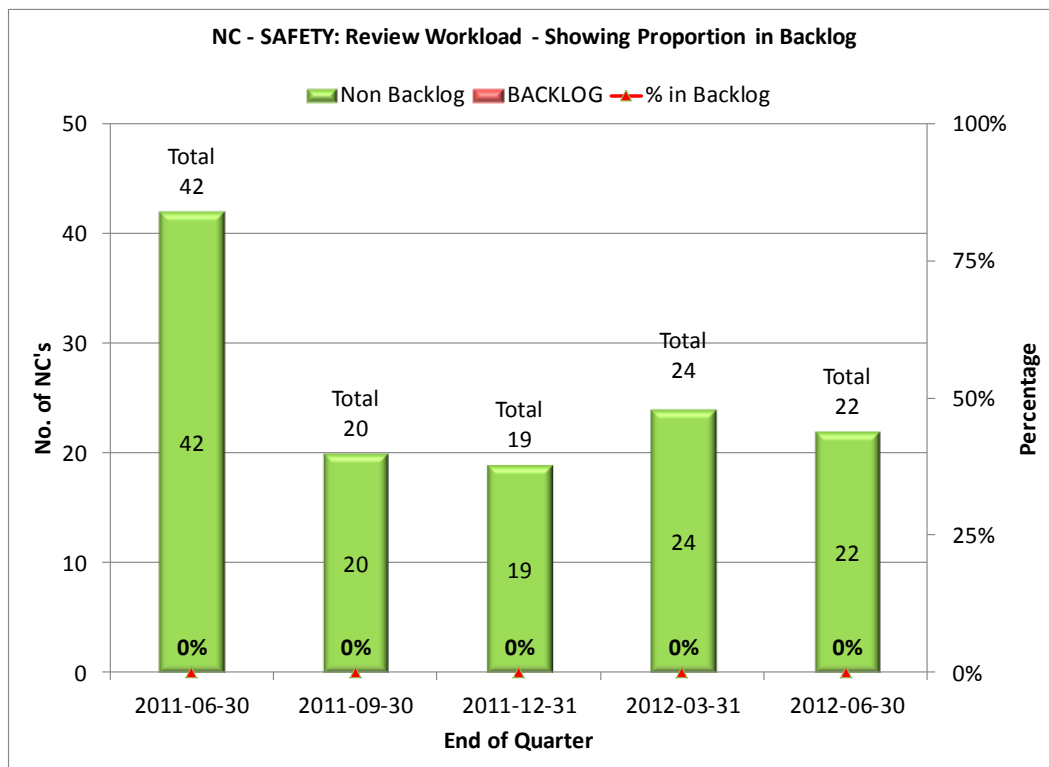
NC - ADMINISTRATIVE (QUALITY)					
DOCUMENT TYPE	Apr-Jun 2011	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012
NO OBJECTION LETTER	21	9	3	5	7
CANCELLED BY COMPANY				1	

<sup>7</sup> [Post-Notice of Compliance \(NOC\) Changes Guidance Documents](http://www.hc-sc.gc.ca/dhp-mpps/prodpharma/applic-demanded/guide-ld-postnoc_change_apresac/noc_postnotice_ac_apresavis_change-eng.php), were effective as of September 30, 2009

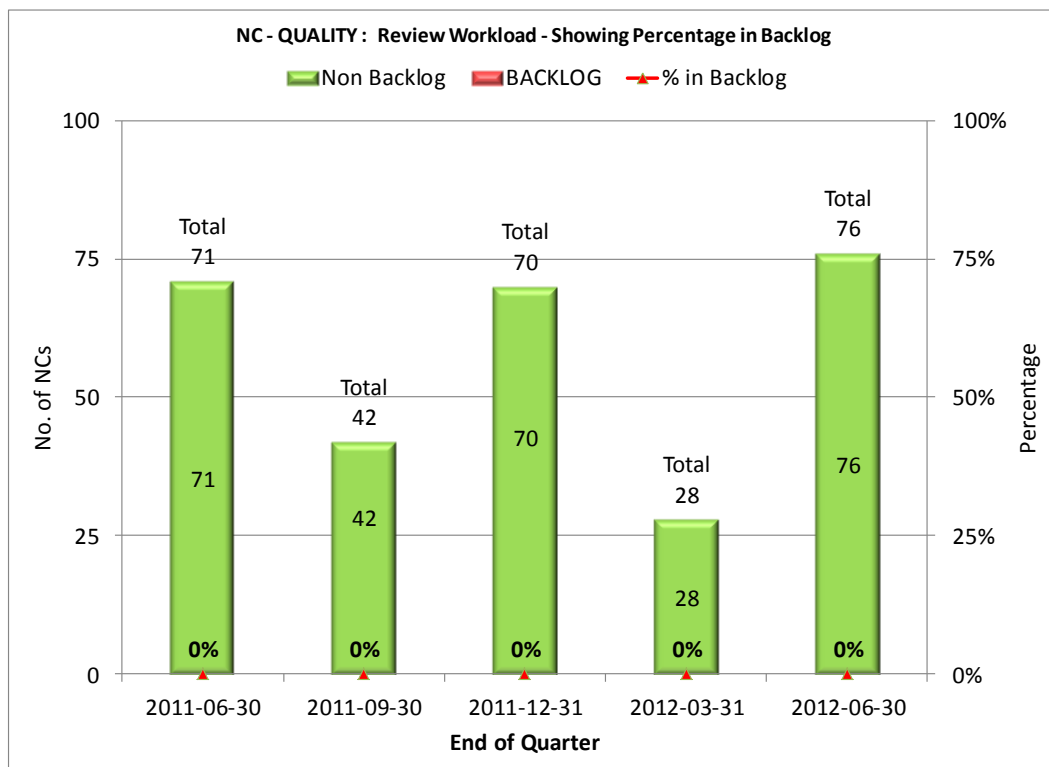
<sup>8</sup> Post-Notice of Compliance (NOC) Changes - Quality Guidance Appendix 1 for Human Pharmaceuticals became effective October 17, 2011.

## WORKLOAD

### Notifiable Change (NC) SAFETY - Review Workload / Backlog



### Notifiable Change (NC) QUALITY - Review Workload / Backlog





## WORKLOAD

### Notifiable Change (NC) SAFETY - Review Workload by Class

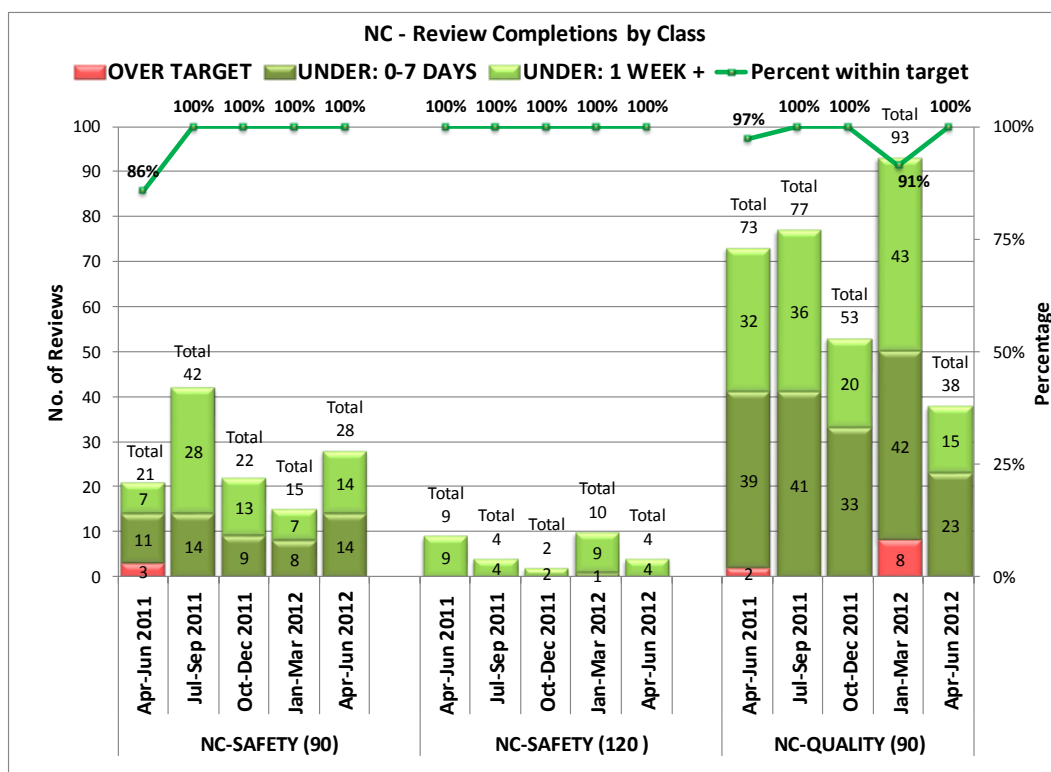
BGTD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
CLASS	2011-06-30	2011-09-30	2011-12-31	2012-03-31	2012-06-30
SAFETY - 90 day	36	19	10	22	20
Backlog	0	0	0	0	0
SAFETY - 120 day	6	1	9	2	2
	0	0	0	0	0
Total	42	20	19	24	22
Non Backlog	42	20	19	24	22
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

### Notifiable Change (NC) QUALITY - Review Workload by Class

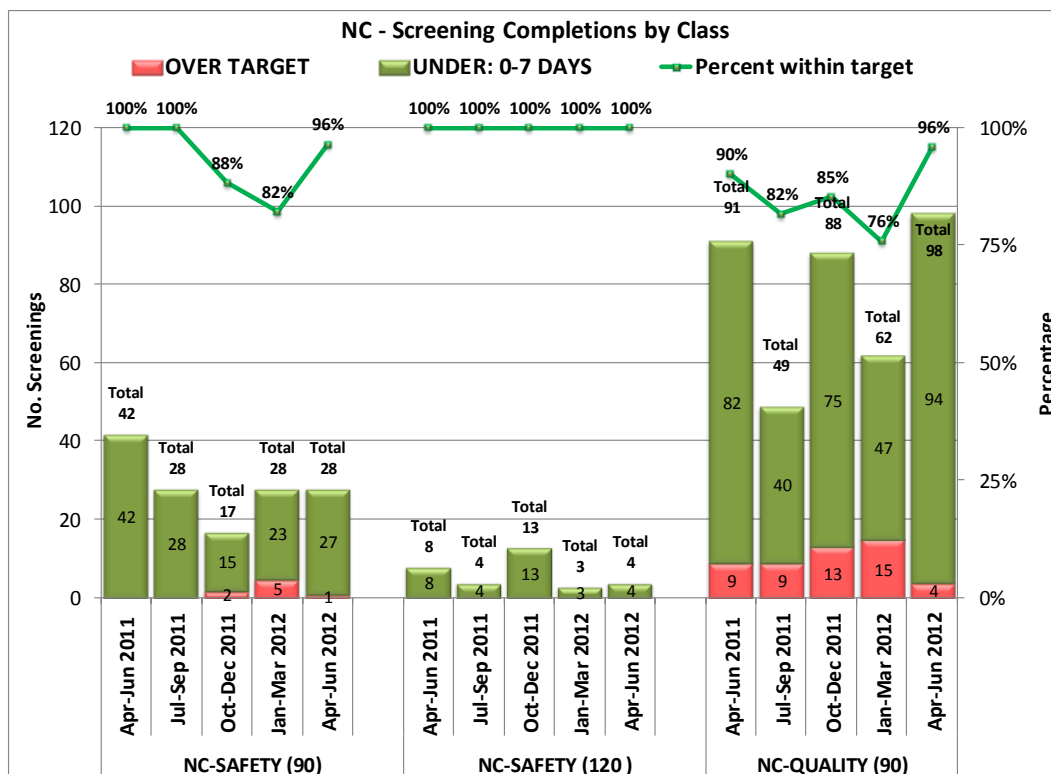
BGTD NC - QUALITY: REVIEW WORKLOAD AT END OF QUARTER					
CLASS	2011-06-30	2011-09-30	2011-12-31	2012-03-31	2012-06-30
QUALITY - 90 day	71	42	70	28	76
Backlog	0	0	0	0	0
Total	71	42	70	28	76
Non Backlog	71	42	70	28	76
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

## PERFORMANCE

### REVIEW Completions by Class - Notifiable Change (NC)



### SCREENING Completions by Class - Notifiable Changes (NC)



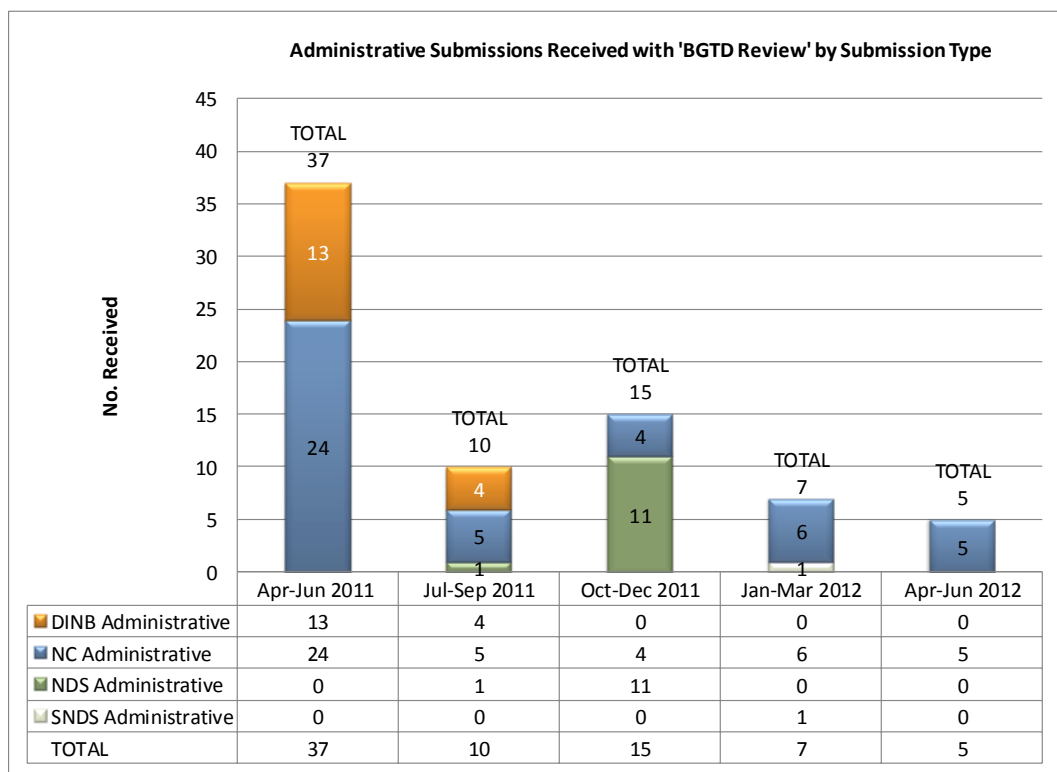
# **Administrative Submissions**

Submissions in support of a manufacturer or product name change.

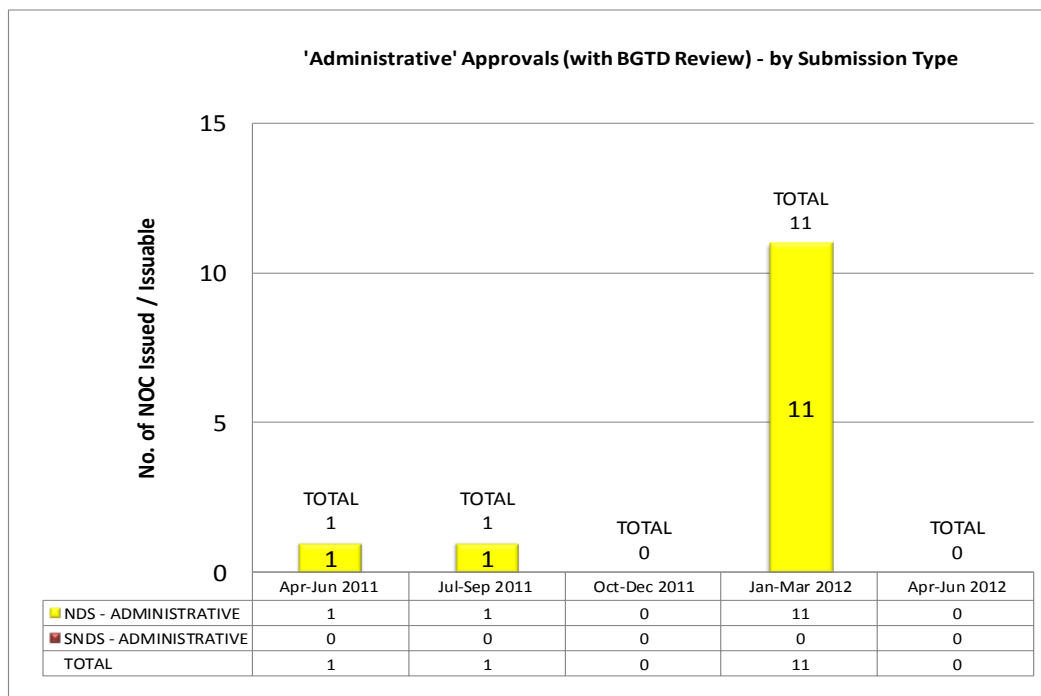
## ADMINISTRATIVE SUBMISSIONS (with BGTD Review)

(such as product name change that requires a drug name review)

### Administrative Submissions Received (with BGTD Review)



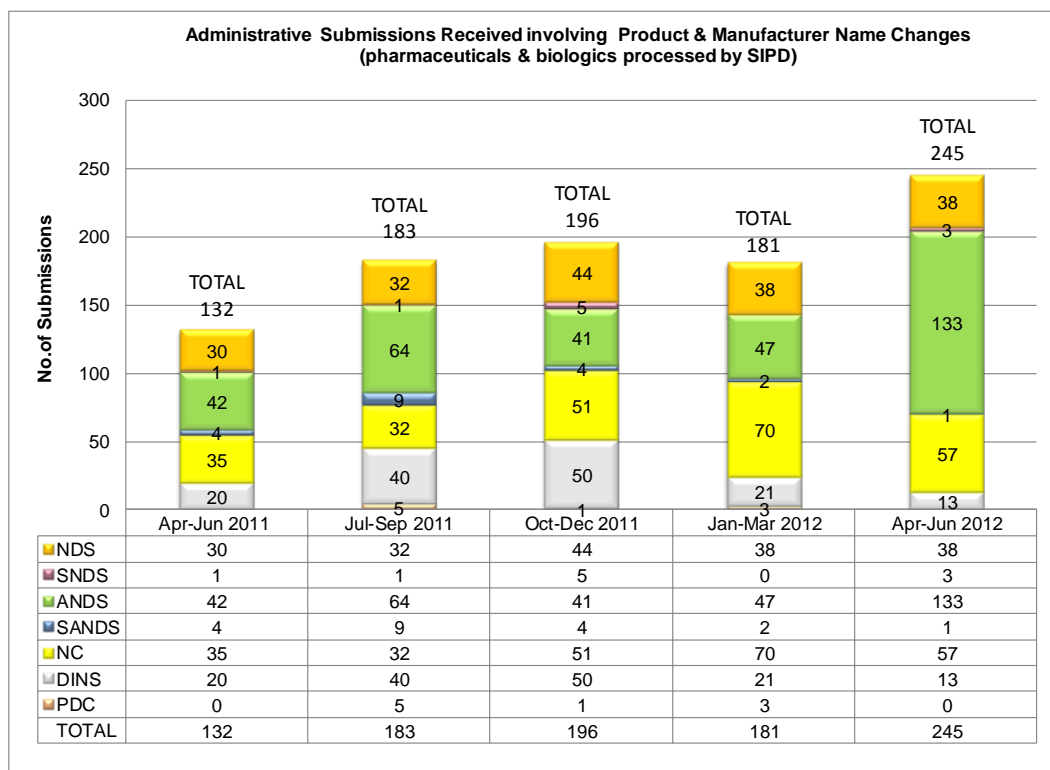
### Administrative Submission Approvals (with BGTD Review)



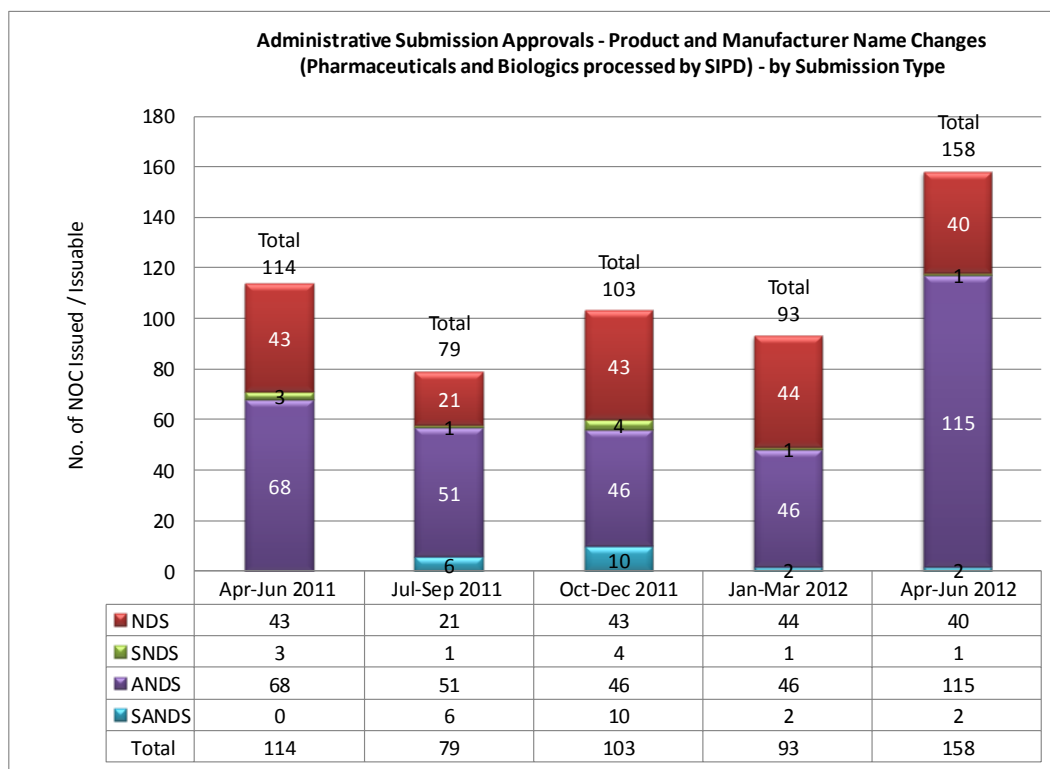
## ADMINISTRATIVE SUBMISSIONS (Processed by SIPD)

(Product & Manufacturer Name Changes)

### Administrative Submissions Received by Submission Type (SIPD)



### Administrative Submission Approvals (SIPD) - for NDS, SNDS, ANDS and SANDS

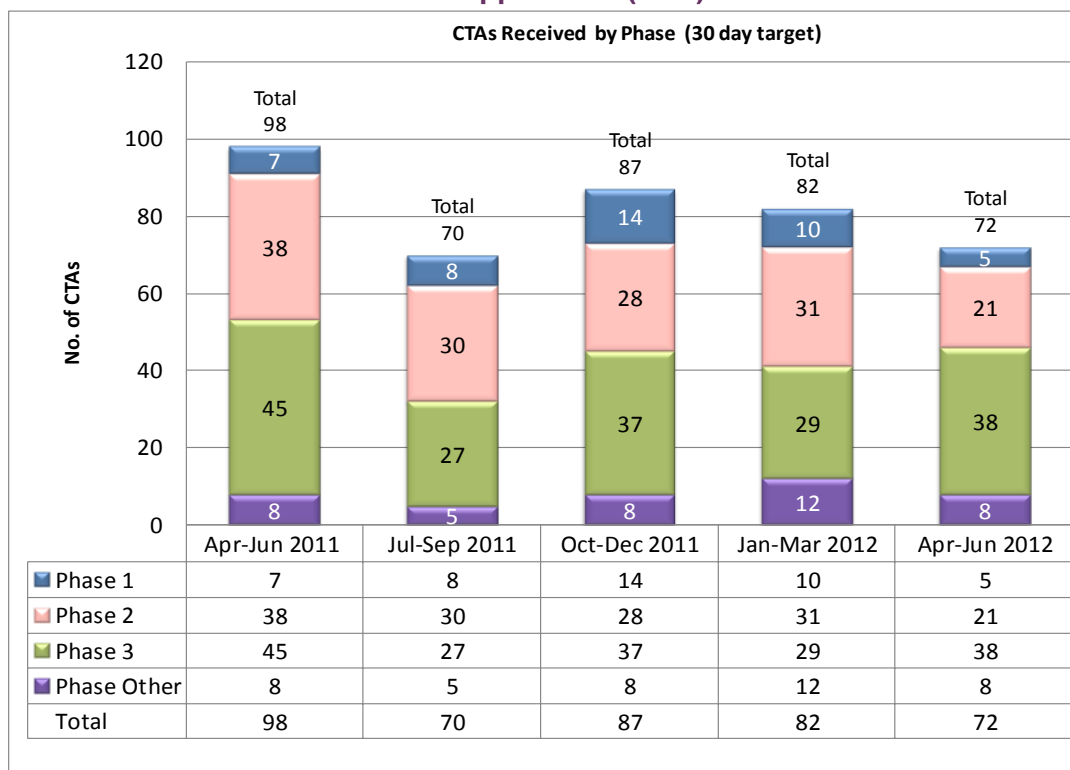


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# **Clinical Trial Applications and Amendments (CTA & CTA-A)**

## CLINICAL TRIAL APPLICATIONS

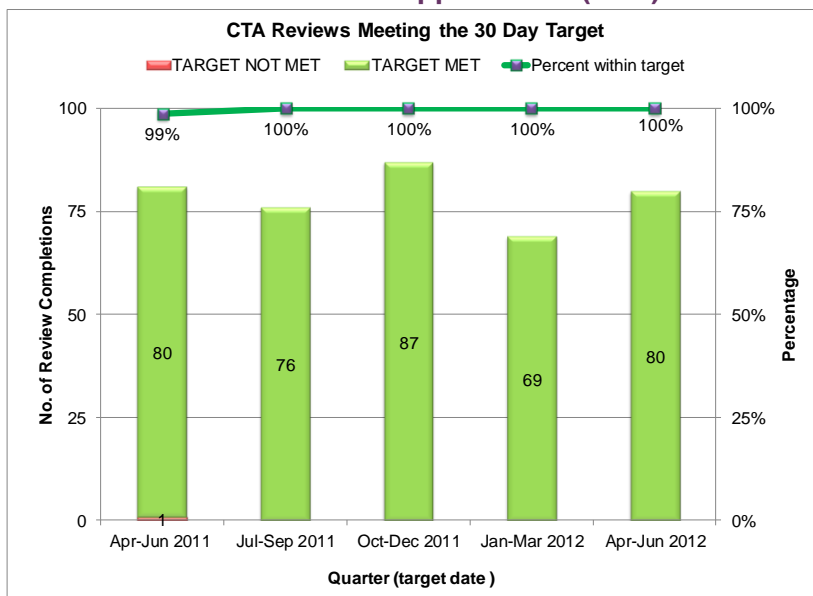
### Number Received - Clinical Trial Application (CTA)



### Decision Documents - Clinical Trial Application (CTA)

CTA					
DOCUMENT TYPE	Apr-Jun 2011	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012
NO OBJECTION LETTER	78	75	80	66	79
CANCELLED BY COMPANY	6	4	6	6	1
NOT SATISFACTORY NOTICE			1	1	
REJECTION LETTER (SCREENING)				1	1

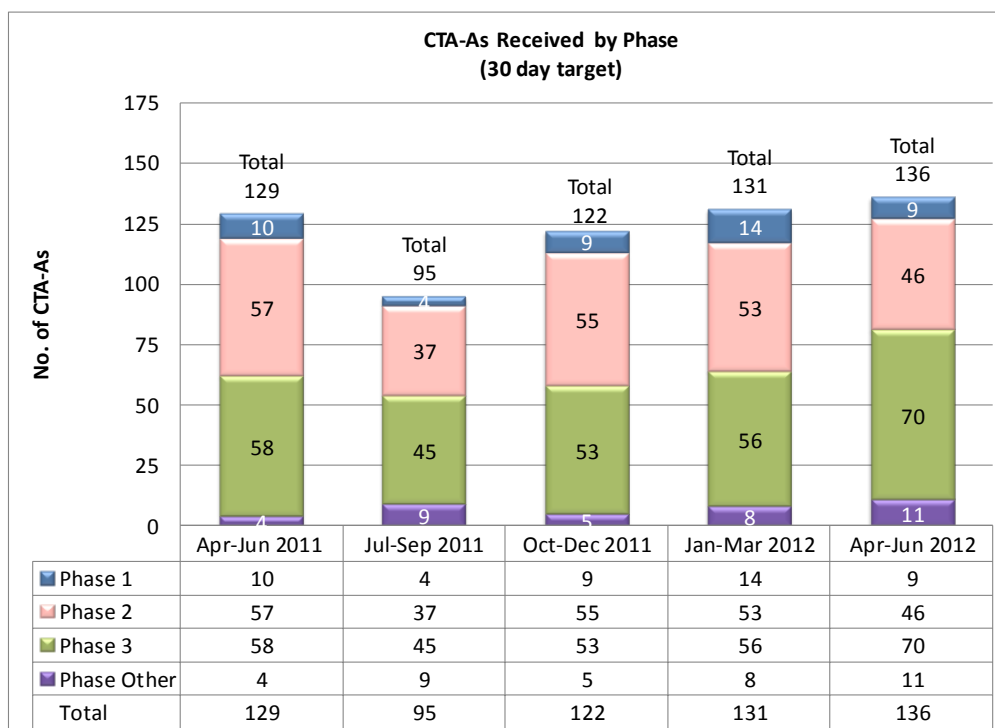
### Performance – Clinical Trial Applications (CTA) Reviews Meeting the 30 Day Target





## CLINICAL TRIAL APPLICATION AMENDMENTS

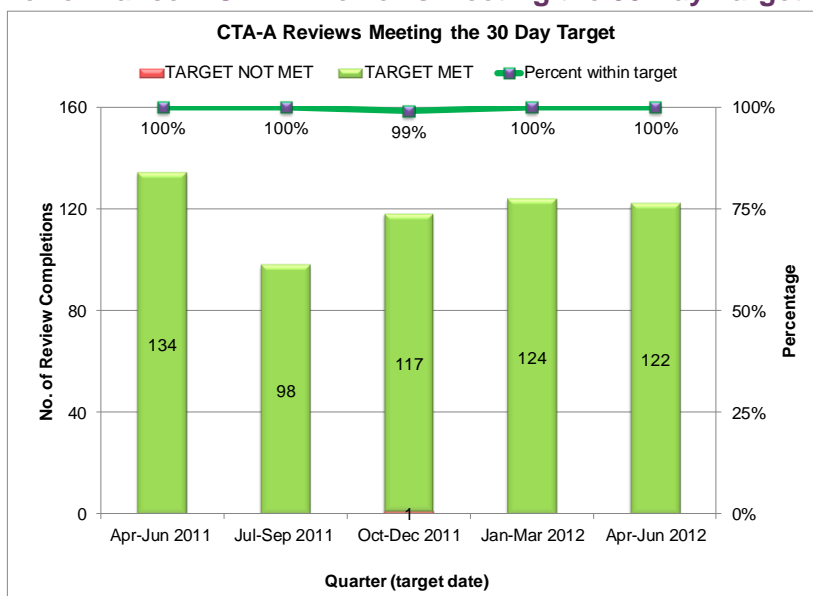
### Number Received - Clinical Trial Application Amendments (CTA-A)



### Decision Documents - Clinical Trial Application Amendments (CTA-A)

CTA-A					
DOCUMENT TYPE	Apr-Jun 2011	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012
NO OBJECTION LETTER	133	100	118	124	123
REJECTION LETTER (SCREENING)					3
CANCELLED BY COMPANY	3			2	2
NOT SATISFACTORY NOTICE				3	

### Performance – CTA-A Reviews Meeting the 30 Day Target



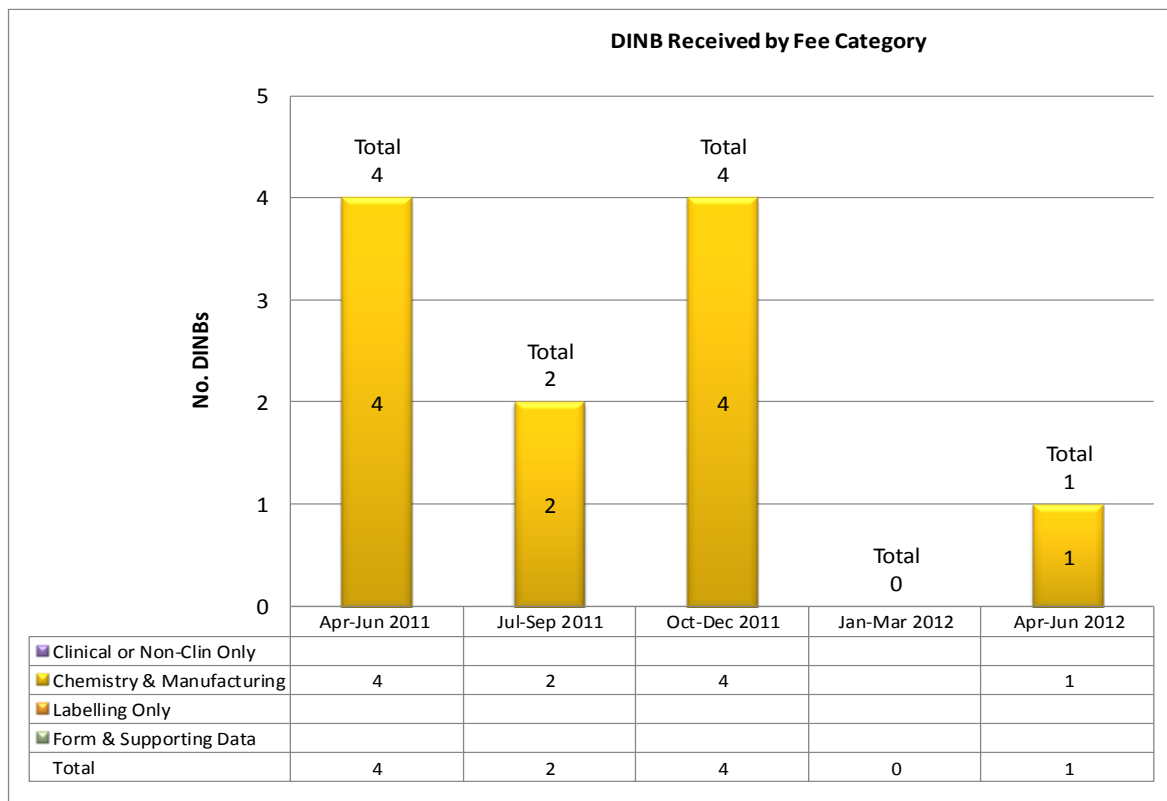
# **DINB**

## **Application for a Drug Identification Number**

### **Biological Product**

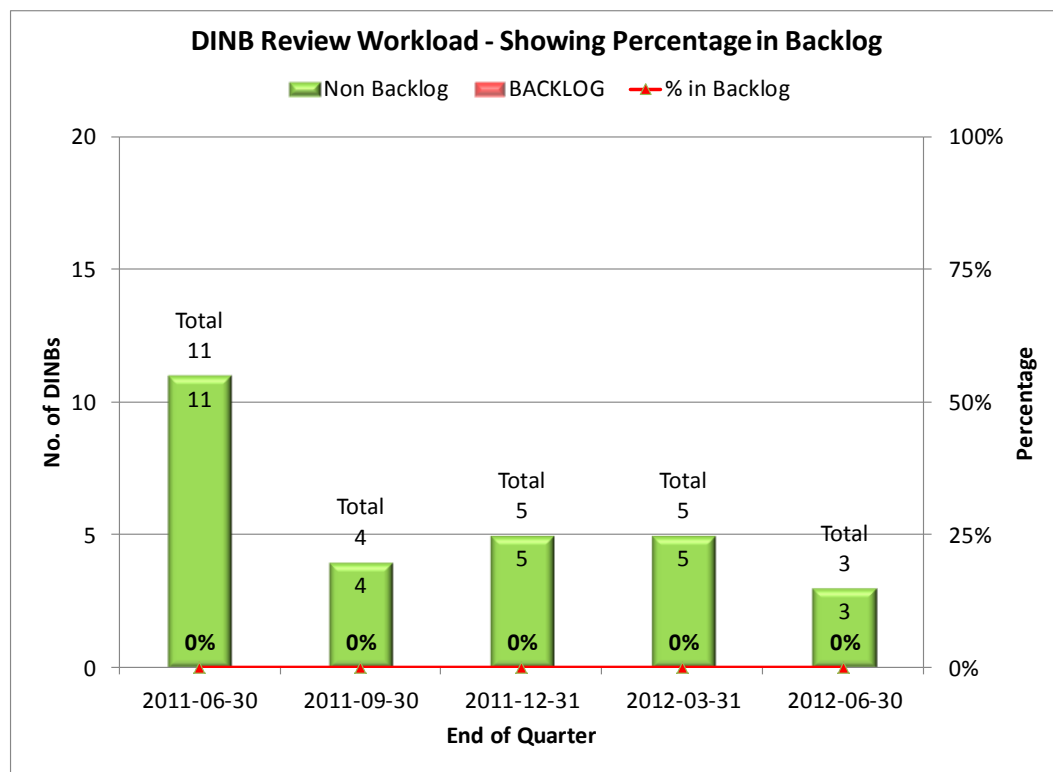
## DINB: APPLICATION FOR A DRUG IDENTIFICATION NUMBER – BIOLOGICAL PRODUCT

### Number Received - DINB



## REVIEW WORKLOAD

### Review Workload / Backlog - Showing Percentage in Backlog - DINB

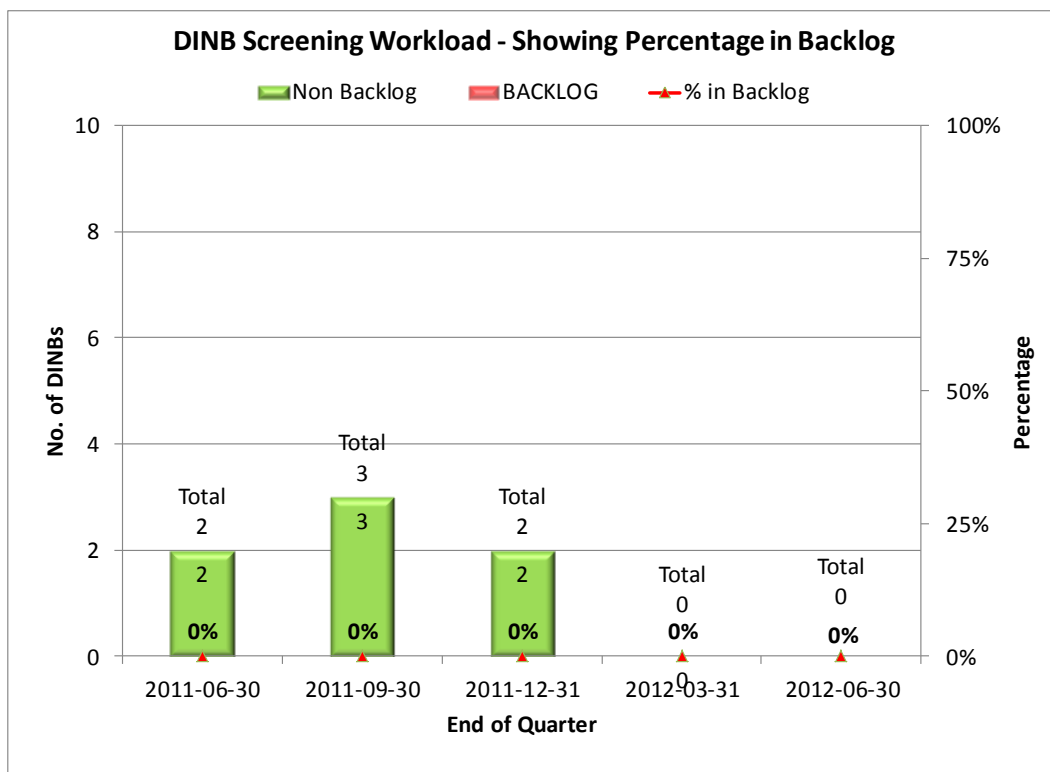


### Review Workload by Class - DINB

BGTD DINB All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2011-06-30	2011-09-30	2011-12-31	2012-03-31	2012-06-30
<b>FORM</b>	4	0	0	0	0
Backlog	0	0	0	0	0
<b>Form and Supporting Data</b>	4	2	1	1	0
Backlog	0	0	0	0	0
<b>Chemistry &amp; Manufacturing</b>	3	2	4	4	3
Backlog	0	0	0	0	0
<b>Total</b>	11	4	5	5	3
Non Backlog	11	4	5	5	3
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

## SCREENING WORKLOAD

### Screening Workload / Backlog - Showing Percentage in Backlog - DINB



### Screening Workload by Class - DINB

BGTD DINB ALL SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2011-06-30	2011-09-30	2011-12-31	2012-03-31	2012-06-30
<b>FORM</b>	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Form &amp; Supporting Data</b>	1	1	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Clinical or Non-Clin and C&amp;M</b>	1	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Chemistry &amp; Manufacturing</b>	0	2	2	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	2	3	2	0	0
<b>Non Backlog</b>	2	3	2	0	0
<b>BACKLOG</b>	0	0	0	0	0
<b>% in Backlog</b>	0%	0%	0%	0%	0%

## DECISION DOCUMENTS

### Decision Documents – DINB by Class

<b>DINB - FORM</b>					
<b>DOCUMENT TYPE</b>	<b>Apr-Jun 2011</b>	<b>Jul-Sep 2011</b>	<b>Oct-Dec 2011</b>	<b>Jan-Mar 2012</b>	<b>Apr-Jun 2012</b>
NO OBJECTION LETTER	1	4			

<b>DINB - FORM AND SUPPORTING DATA</b>					
<b>DOCUMENT TYPE</b>	<b>Apr-Jun 2011</b>	<b>Jul-Sep 2011</b>	<b>Oct-Dec 2011</b>	<b>Jan-Mar 2012</b>	<b>Apr-Jun 2012</b>
NO OBJECTION LETTER	8	1			
NOTICE OF DEFICIENCY	1				
NOTIFICATION FORM/DIN ISSUED			1		

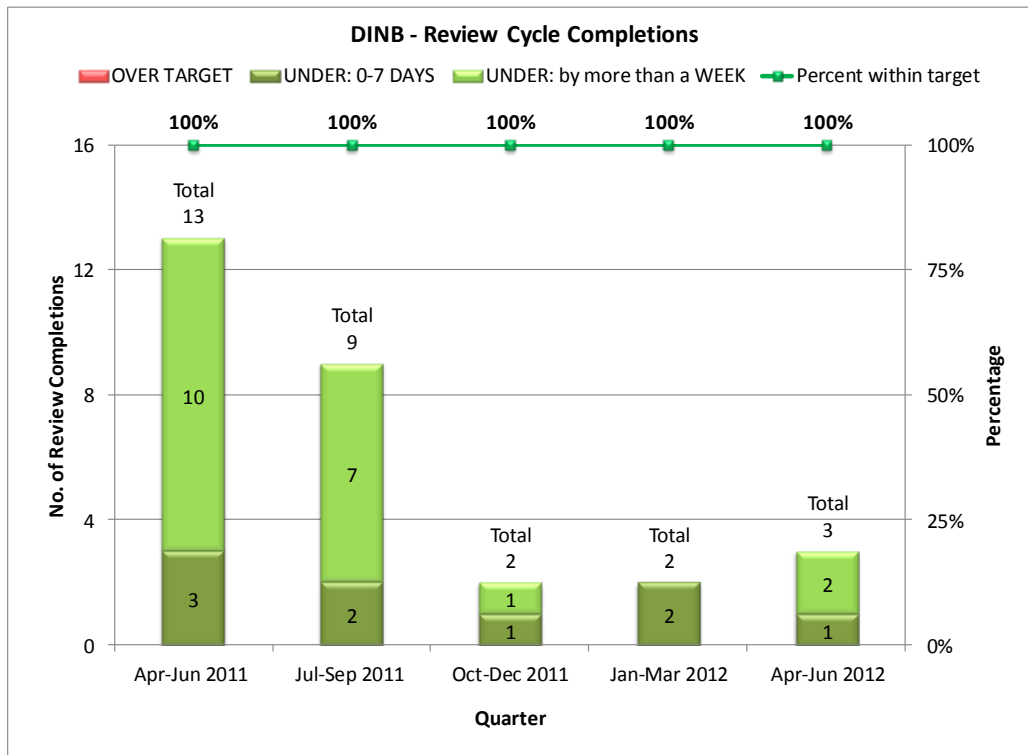
<b>DINB - CLIN ONLY</b>					
<b>DOCUMENT TYPE</b>	<b>Apr-Jun 2011</b>	<b>Jul-Sep 2011</b>	<b>Oct-Dec 2011</b>	<b>Jan-Mar 2012</b>	<b>Apr-Jun 2012</b>
NO OBJECTION LETTER	1				

<b>DINB - C&amp;M ONLY</b>					
<b>DOCUMENT TYPE</b>	<b>Apr-Jun 2011</b>	<b>Jul-Sep 2011</b>	<b>Oct-Dec 2011</b>	<b>Jan-Mar 2012</b>	<b>Apr-Jun 2012</b>
NO OBJECTION LETTER		2			
SCREENING DEFICIENCY NOTICE		1	3	2	
NOTICE OF DEFICIENCY				1	
CANCELLED BY COMPANY			2		

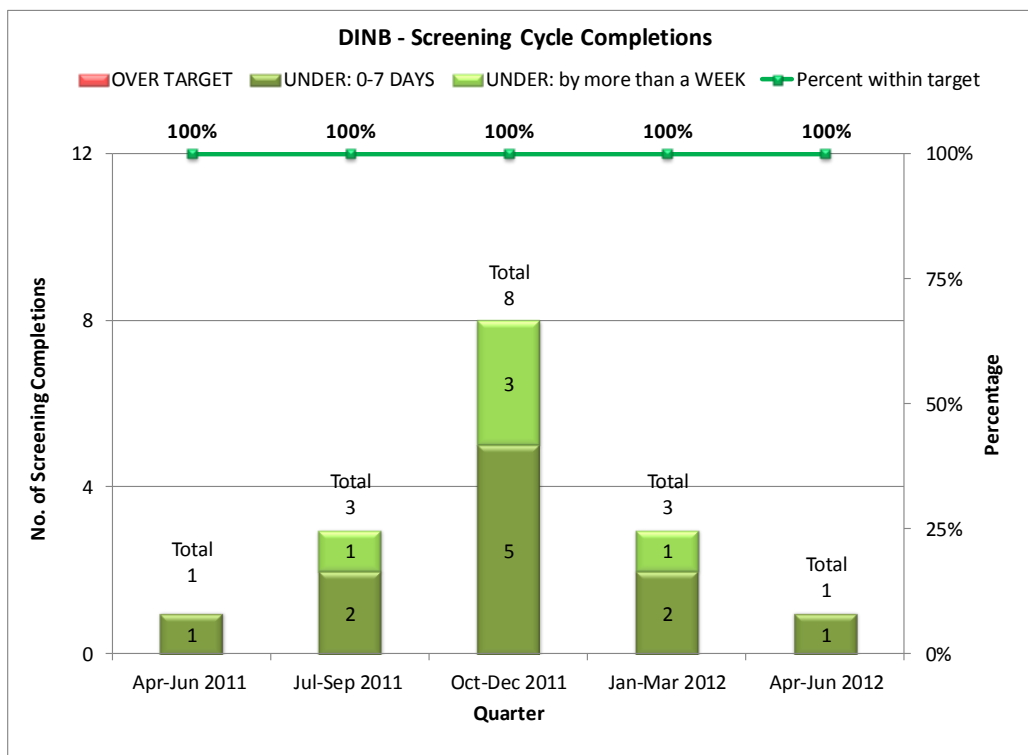
<b>DINB - ADMINISTRATIVE</b>					
<b>DOCUMENT TYPE</b>	<b>Apr-Jun 2011</b>	<b>Jul-Sep 2011</b>	<b>Oct-Dec 2011</b>	<b>Jan-Mar 2012</b>	<b>Apr-Jun 2012</b>
NOTIFICATION FORM/DIN ISSUED	2	4			

## PERFORMANCE

### Performance Review Cycle Completions Showing Percentage Within Target - DINB

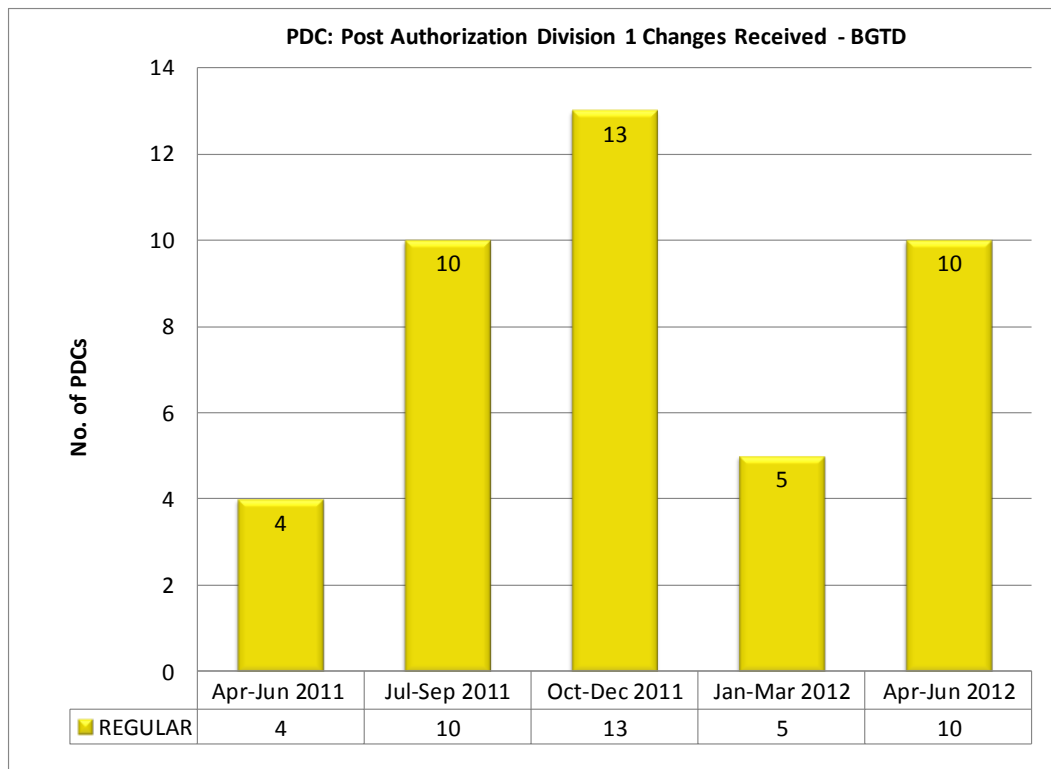


### Performance Screening Cycle Completions Showing Percentage Within Target - DINB



## Post –Authorization Division 1 Changes (PDC)

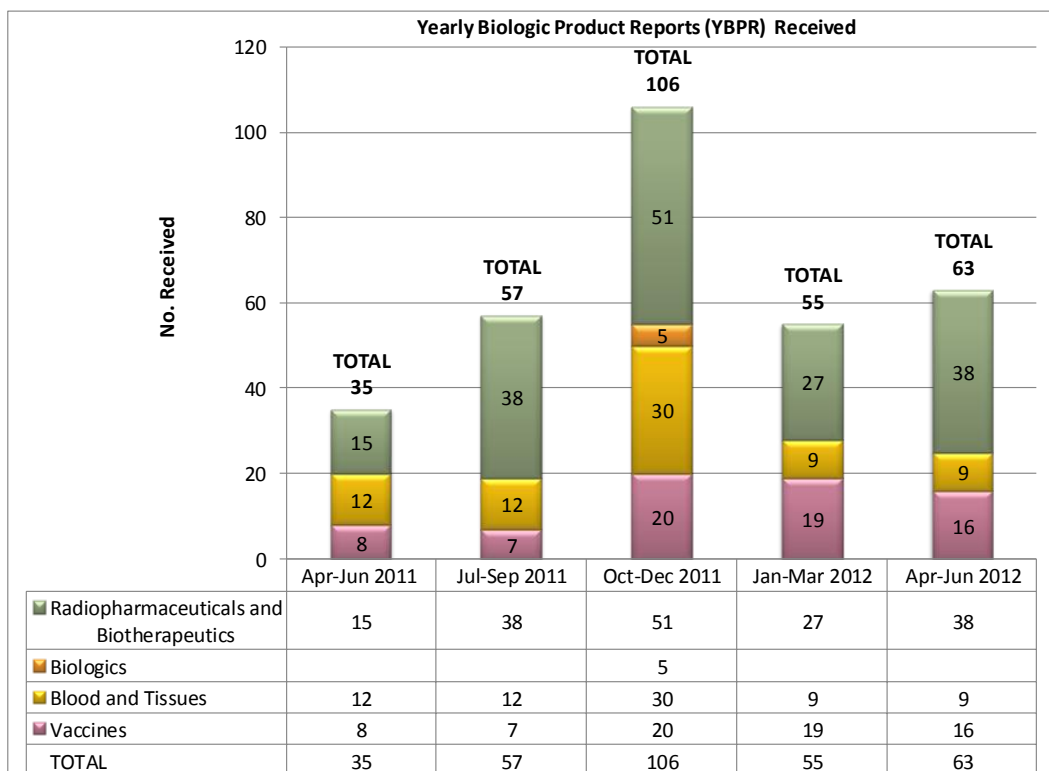
### Post –Authorization Division 1 Changes (PDC) Received





## Yearly Biologic Product Reports (YBPR)<sup>9</sup>

### Yearly Biologic Product Reports (YBPR) Received



<sup>9</sup> Yearly Biologic Product Report (YBPR) is a report that must be submitted annually by manufacturers of all Schedule D (Biologic) drugs. The report contains production information on both drug substance and drug product lots, including test methods and results, reasons for any recalls and corrective action taken, as well as other pertinent post-market information.

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