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**Biologics and Genetic Therapies  
Directorate  
Drug Submission Performance  
Quarterly Report  
January - March  
2011**



Canada 

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# Table of Contents

**OVERVIEW ..... 7**

**ACRONYMS ..... 8**

    Submission Types ..... 8

    Documents ..... 8

    Class ..... 9

**NDS & SNDS ..... 10**

**SUBMISSIONS RECEIVED ..... 11**

    New Drug Submissions (NDS) Received ..... 11

    Supplemental New Drug Submissions (SNDS) Received ..... 11

**WORKLOAD ..... 12**

    New Drug Submission (NDS) Review Workload / Backlog ..... 12

    Supplemental New Drug Submission (SNDS) Review Workload / Backlog ..... 12

    New Drug Submission (NDS) Review Workload by Class ..... 13

    Supplemental New Drug Submission (SNDS) Review Workload by Class ..... 13

**APPROVALS ..... 14**

    New Drug Submission (NDS) Approvals by Class ..... 14

    Supplemental New Drug Submission (SNDS) Approvals by Class ..... 14

**REVIEW CYCLE DECISIONS ..... 16**

    New Drug Submission (NDS) Review Decisions ..... 16

    NDS - Review Cycle Completions Showing Percentage Within Target ..... 16

    Supplemental New Drug Submission (SNDS) Review Decisions ..... 17

    SNDS - Review Cycle Completions Showing Percentage Within Target ..... 17

**SCREENING CYCLE DECISIONS ..... 18**

    New Drug Submission (NDS) Screening Decisions ..... 18

    NDS - Screening Cycle Completions Showing Percentage Within Target ..... 18

    Supplemental New Drug Submission (SNDS) Screening Decisions ..... 19

    SNDS - Screening Cycle Completions Showing Percentage Within Target ..... 19

<b>PRIORITY REVIEW STATUS REQUESTS (FOR NDS &amp; SNDS)</b> .....	<b>20</b>
Priority Review Status Requests: Received .....	20
Priority Review Status Requests: Decisions Rendered .....	20
Priority Review Status Request: Performance .....	20
<b>NOTIFIABLE CHANGES</b> .....	<b>23</b>
Notifiable Change (NC) Submissions Received .....	23
Notifiable Change (NC) Decision Documents by Type.....	23
<b>WORKLOAD</b> .....	<b>24</b>
Notifiable Change (NC) SAFETY - Review Workload / Backlog .....	24
Notifiable Change (NC) QUALITY: Review Workload / Backlog.....	24
Notifiable Change (NC) SAFETY: Review Workload by Class .....	25
Notifiable Change (NC) QUALITY: Review Workload by Class.....	25
<b>PERFORMANCE</b> .....	<b>26</b>
Notifiable Change - REVIEW Completions by Class .....	26
Notifiable Changes- SCREENING Completions by Class .....	26
<b>LABELLING ONLY AND ADMINISTRATIVE* REQUIRING A REVIEW</b> .....	<b>28</b>
Labelling Only & Administrative* Submissions Received .....	28
Labelling Only and Administrative* Submission Approvals .....	28
<b>ADMINISTRATIVE : PRODUCT &amp; MANUFACTURER NAME CHANGES</b> .....	<b>29</b>
SIPD Administrative Submissions Received by Submission Type .....	29
Administrative Submission Approvals (SIPD)- Product & Manufacturer Name Changes NDS, SNDS, ANDS and SANDS.....	29
<b>CLINICAL TRIAL APPLICATIONS</b> .....	<b>30</b>
Clinical Trial Application (CTA) Received.....	30
Clinical Trail Application (CTA) Decision Documents .....	30
CTA Reviews Meeting 30 Day Target .....	30
<b>CLINICAL TRIAL APPLICATION AMENDMENTS</b> .....	<b>31</b>
Clinical Trial Application-Amendments (CTA-A) Received .....	31
Clinical Trial Application-Amendments (CTA-A) Decision Documents.....	31

CTA-A Reviews Meeting 30 Day Target .....31

**DINB: APPLICATION FOR A DRUG IDENTIFICATION NUMBER – BIOLOGICAL PRODUCT ..... 33**

DINB Received.....33

DINB -DECISION DOCUMENTS –by CLASS .....33

DINB Review Workload / Backlog .....34

DINB Review Workload by Class.....34

DINB Screening Workload / Backlog .....35

DINB Screening Workload by Class .....35

DINB Review Cycle Completions Showing Proportion Within Target .....36

DINB Screening Cycle Completions Showing Proportion Within Target .....36

**YEARLY BIOLOGIC PRODUCT REPORTS (YBPR) ..... 37**

Yearly Biologic Product Report s (YBPR) Received .....37

**REQUESTS FOR RECONSIDERATION OF FINAL DECISION..... 38**

Requests for Reconsideration of Final Decision: NDS & SNDS .....38

Requests for Reconsideration of Final Decision: Request for Advance Consideration under the Notice of Compliance with Conditions Policy .....38

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# OVERVIEW

This Biologics and Genetic Therapies Directorate (BGTD) Quarterly Drug Submission Performance Report reflects activity related to biologics and radiopharmaceutical drug review for five quarters: from the 1<sup>st</sup> Quarter (Jan – Mar) 2010 to the 1<sup>st</sup> Quarter (Jan –Mar) 2011. Statistics are provided by submission type<sup>1</sup> and show the number received, the number in workload, the number of decisions and the number of approvals.

There are several steps involved in the drug submission review 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 a given day. “**Backlog**” is the proportion of the workload that is over target. Comparisons of quarter-end workload/backlog are reported to show the reduction or increase in the backlog. 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** 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 and the type of cycle. For instance, in the case of a Priority NDS, there is a 180 calendar day target for the “Review 1” cycle. Health Canada has set a goal of 90% of review cycle completions to be rendered within performance standards.<sup>3</sup>

**“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” submissions.

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

Submission Information Policy Division  
Therapeutic Products Directorate  
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

<sup>1</sup> For NDS and SNDS, the submission classes “Labelling Only” and “Administrative” are reported separately as they have a much shorter performance target in comparison to the other submission classes.

<sup>2</sup>For further clarification refer to the Guidance for Industry - Management of Drug Submission posted at:[http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/mgmt-gest/mands\\_gespd-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/mgmt-gest/mands_gespd-eng.php)

<sup>3</sup> 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.

# 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
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

## Class

Admin	-	Administrative
Comp/C&M	-	Comparative Bio, Clinical, or Pharmacodynamic/Chemistry & Manufacturing
C&M/Labelling	-	Chemistry & Manufacturing/Labelling
Clin/C&M	-	Clinical/Chemistry & Manufacturing
Clin Only	-	Clinical Only
Labelling Only	-	Labelling Only
NAS	-	New Active Substance
NOC-c/NAS	-	Notice of Compliance with conditions/New Active Substance
NOC-c/Clin/C&M	-	Notice of Compliance with conditions/Clinical/Chemistry & Manufacturing
NOC-c/Clin Only	-	Notice of Compliance with conditions/Clinical Only
Priority-NAS	-	Priority-New Active Substance
Priority-Clin/C&M	-	Priority-Clinical/Chemistry & Manufacturing
Priority-Clin Only	-	Priority-Clinical Only
Priority-C&M Labelling	-	Priority-Chemistry & Manufacturing/Labelling
Priority-Comp/C&M	-	Priority-comparative Bio., Clinical or Pharmacodynamic/Chemistry & Manufacturing
Priority-Rx to OTC-No New	-	Priority Rx to Over the Counter – No New Indication
Quality (90)		Notifiable Change – Quality (90)
Rx to OTC-New	-	Rx to Over the Counter – New Indication
Safety (90)		Notifiable Change- Safety (90)
Safety (120)		Notifiable Change – Safety (120)

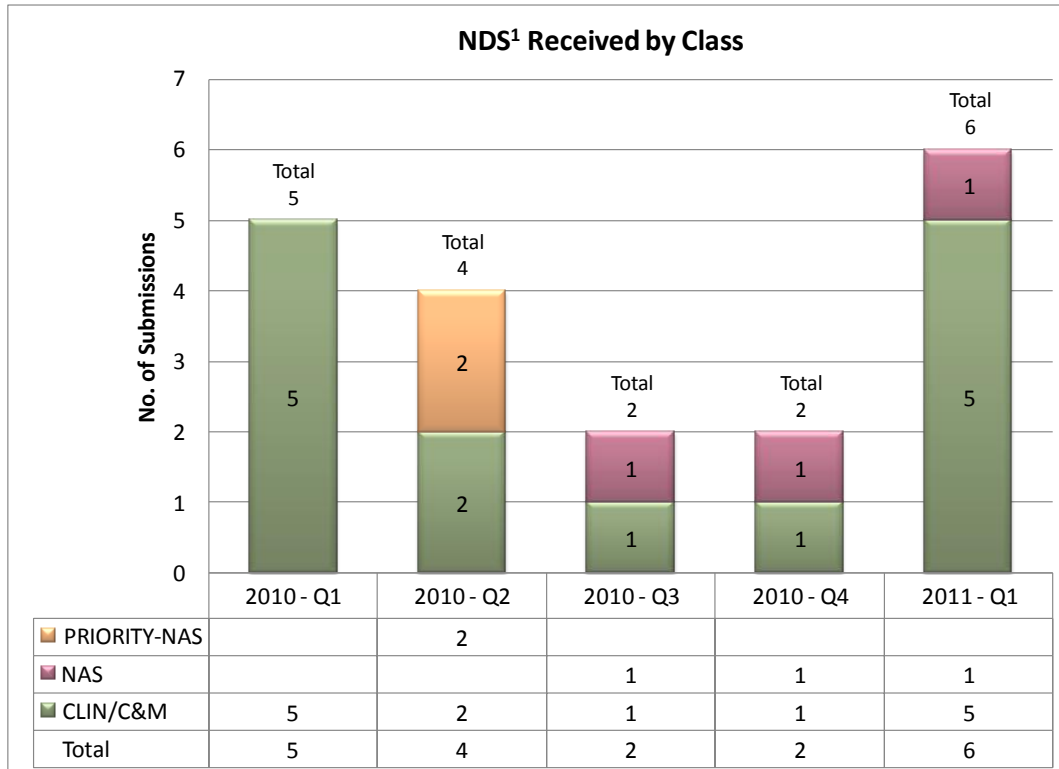
For further clarification refer to the Guidance to Industry - Management of Drug Submissions posted at:

[http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/mgmt-gest/mands\\_gespd-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/mgmt-gest/mands_gespd-eng.php)

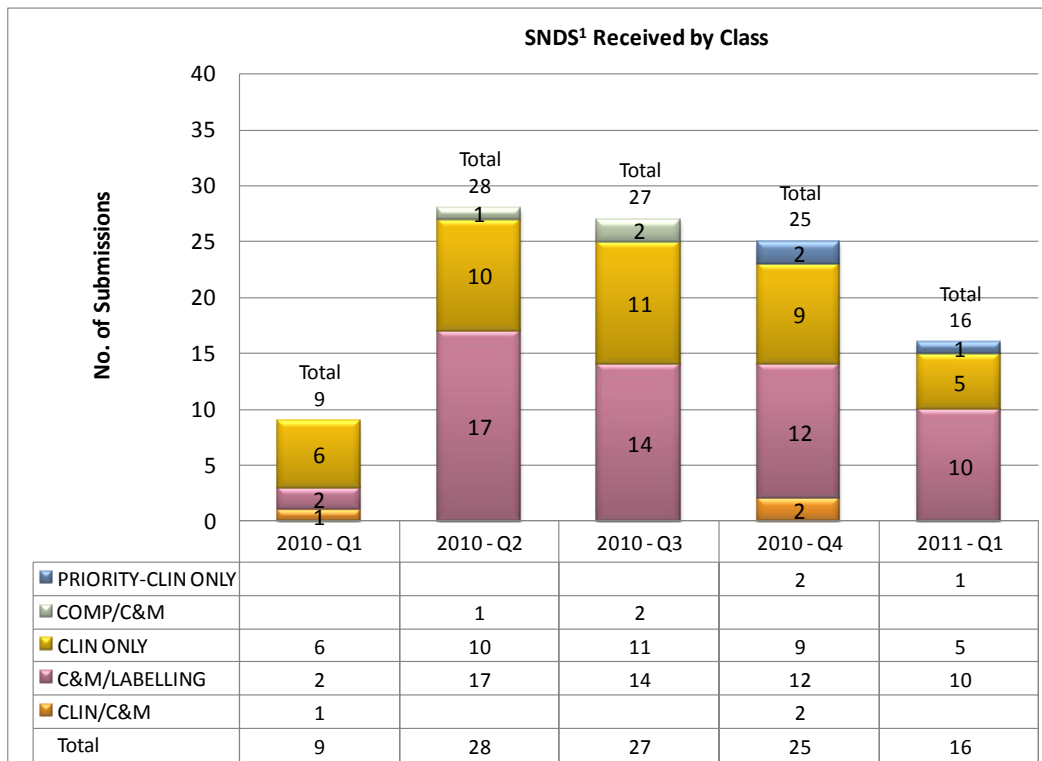
New Drug Submissions  
(NDS)  
  
and  
  
Supplemental New Drug Submissions  
(SNDS)

## SUBMISSIONS RECEIVED

### New Drug Submissions (NDS) Received

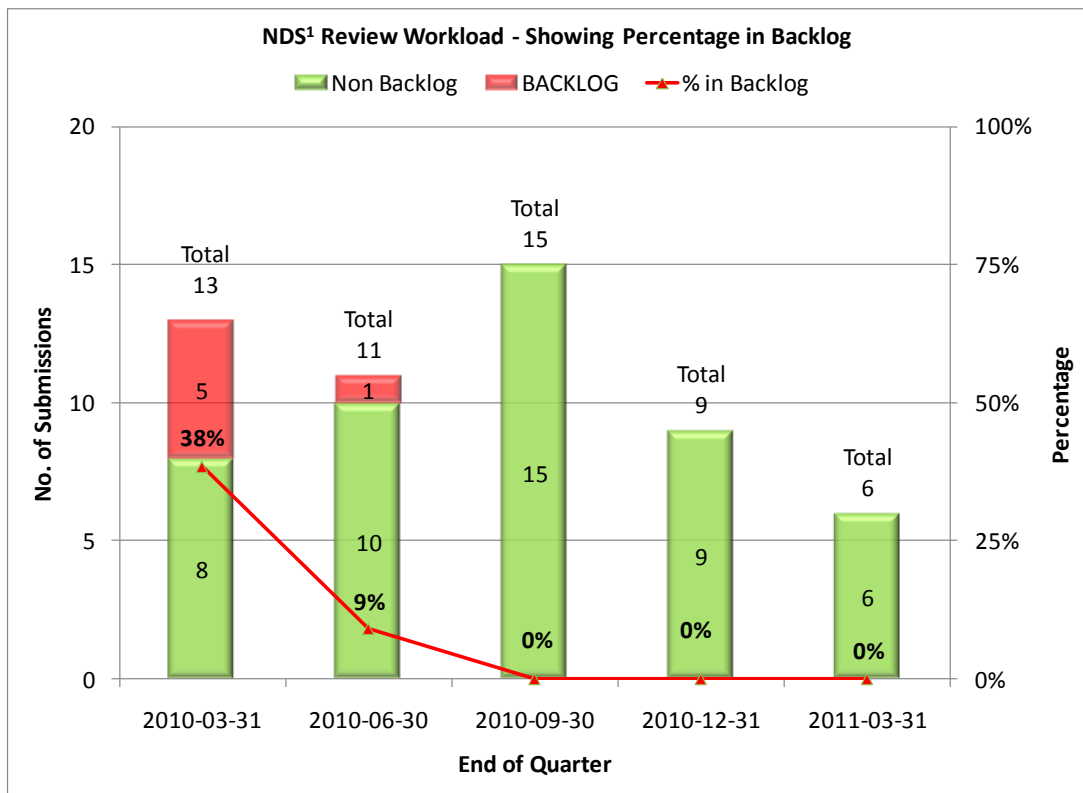


### Supplemental New Drug Submissions (SNDS) Received

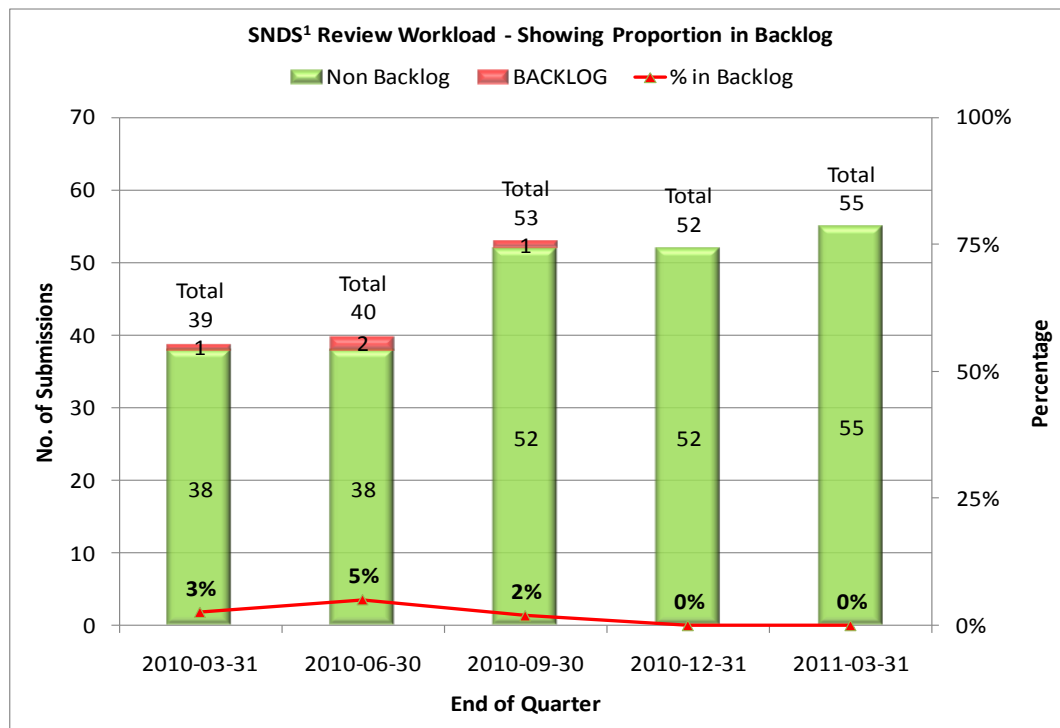


## WORKLOAD

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



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



## WORKLOAD

### New Drug Submission (NDS) Review Workload by Class

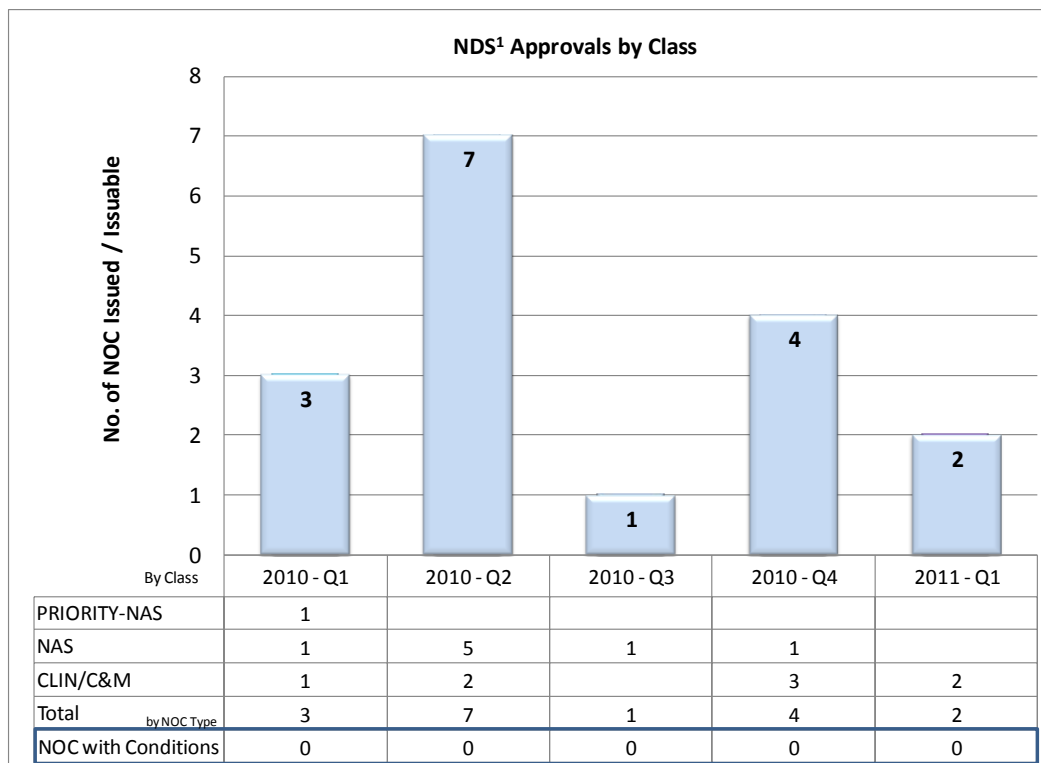
BGTD NDS REVIEW WORKLOAD BY CLASS AND END OF QUARTER					
CLASS	2010-03-31	2010-06-30	2010-09-30	2010-12-31	2011-03-31
<b>CLIN/C&amp;M</b>	<b>6</b>	<b>6</b>	<b>9</b>	<b>6</b>	<b>2</b>
Backlog	2	0	0	0	0
<b>NAS</b>	<b>7</b>	<b>4</b>	<b>4</b>	<b>2</b>	<b>3</b>
Backlog	3	1	0	0	0
<b>PRIORITY-NAS</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>1</b>	<b>1</b>
Backlog	0	0	0	0	0
<b>Total</b>	<b>13</b>	<b>11</b>	<b>15</b>	<b>9</b>	<b>6</b>
<b>Non Backlog</b>	<b>8</b>	<b>10</b>	<b>15</b>	<b>9</b>	<b>6</b>
<b>BACKLOG</b>	<b>5</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>38%</b>	<b>9%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

### Supplemental New Drug Submission (SNDS) Review Workload by Class

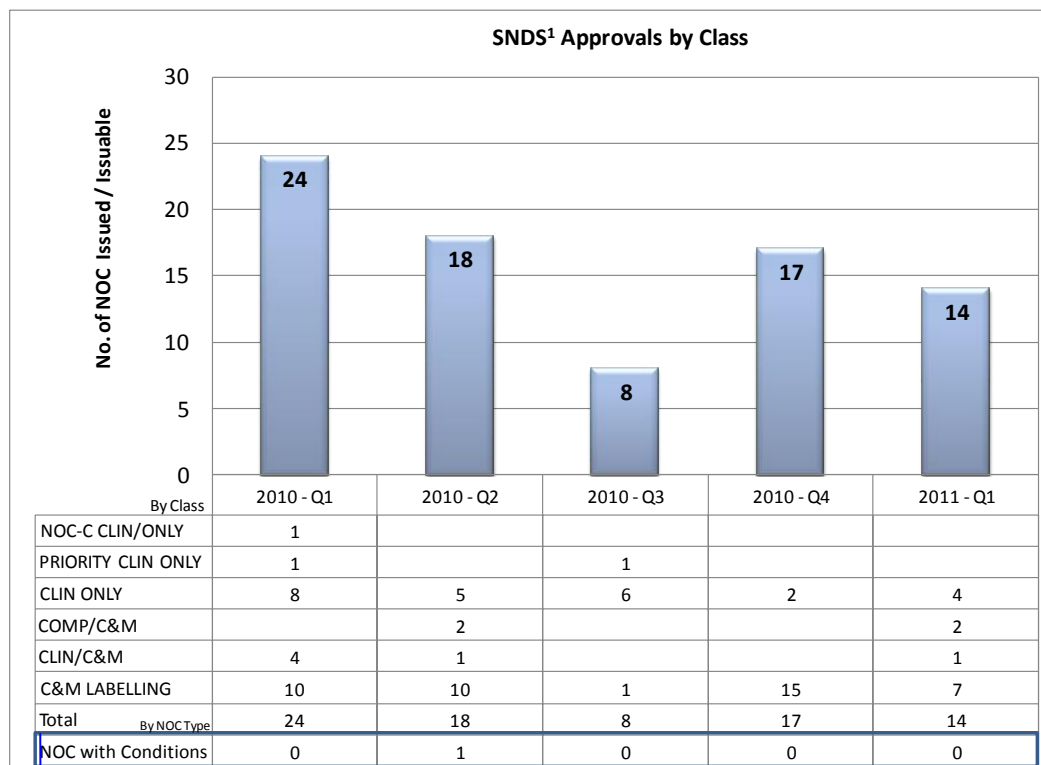
BGTD SNDS REVIEW WORKLOAD BY CLASS AND END OF QUARTER					
CLASS	2010-03-31	2010-06-30	2010-09-30	2010-12-31	2011-03-31
<b>C&amp;M/LABELLING</b>	<b>11</b>	<b>16</b>	<b>23</b>	<b>15</b>	<b>17</b>
Backlog	1	1	1	0	0
<b>CLIN/C&amp;M</b>	<b>1</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>
Backlog	0	0	0	0	0
<b>CLIN ONLY</b>	<b>23</b>	<b>20</b>	<b>26</b>	<b>31</b>	<b>31</b>
Backlog	0	1	0	0	0
<b>COMP/C&amp;M</b>	<b>3</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>2</b>
Backlog	0	0	0	0	0
<b>PRIORITY-CLIN ONLY</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>3</b>
Backlog	0	0	0	0	0
<b>Total</b>	<b>39</b>	<b>40</b>	<b>53</b>	<b>52</b>	<b>55</b>
<b>Non Backlog</b>	<b>38</b>	<b>38</b>	<b>52</b>	<b>52</b>	<b>55</b>
<b>BACKLOG</b>	<b>1</b>	<b>2</b>	<b>1</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>3%</b>	<b>5%</b>	<b>2%</b>	<b>0%</b>	<b>0%</b>

## APPROVALS

### New Drug Submission (NDS) Approvals by Class



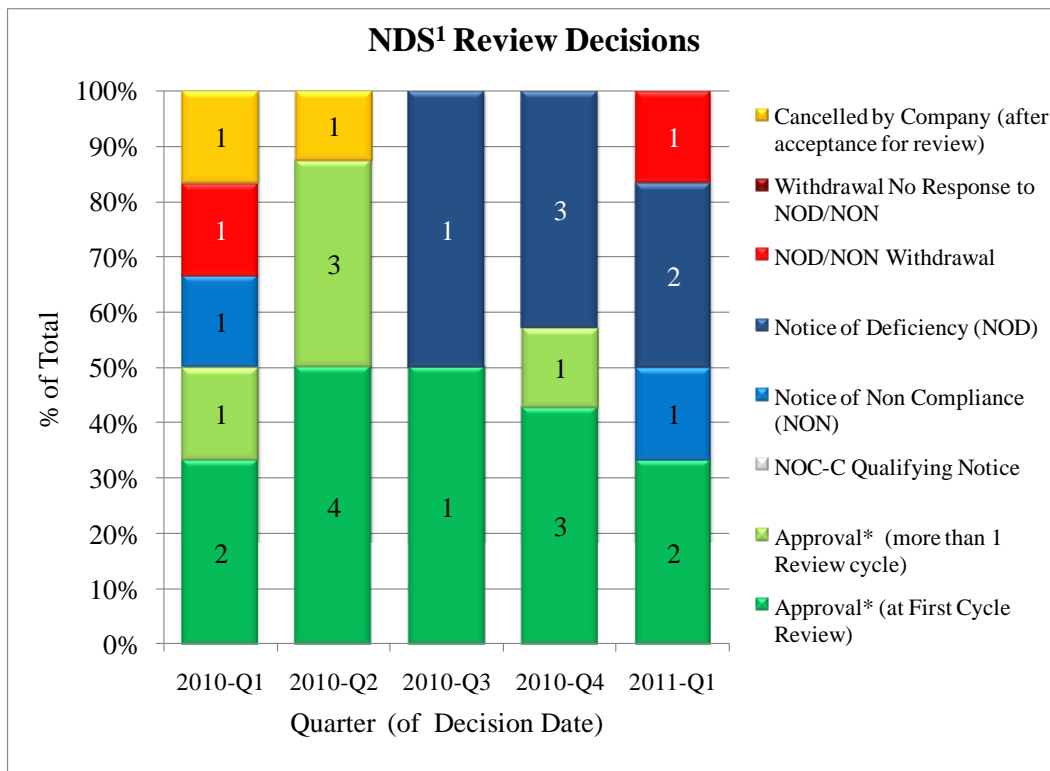
### Supplemental New Drug Submission (SNDS) Approvals by Class



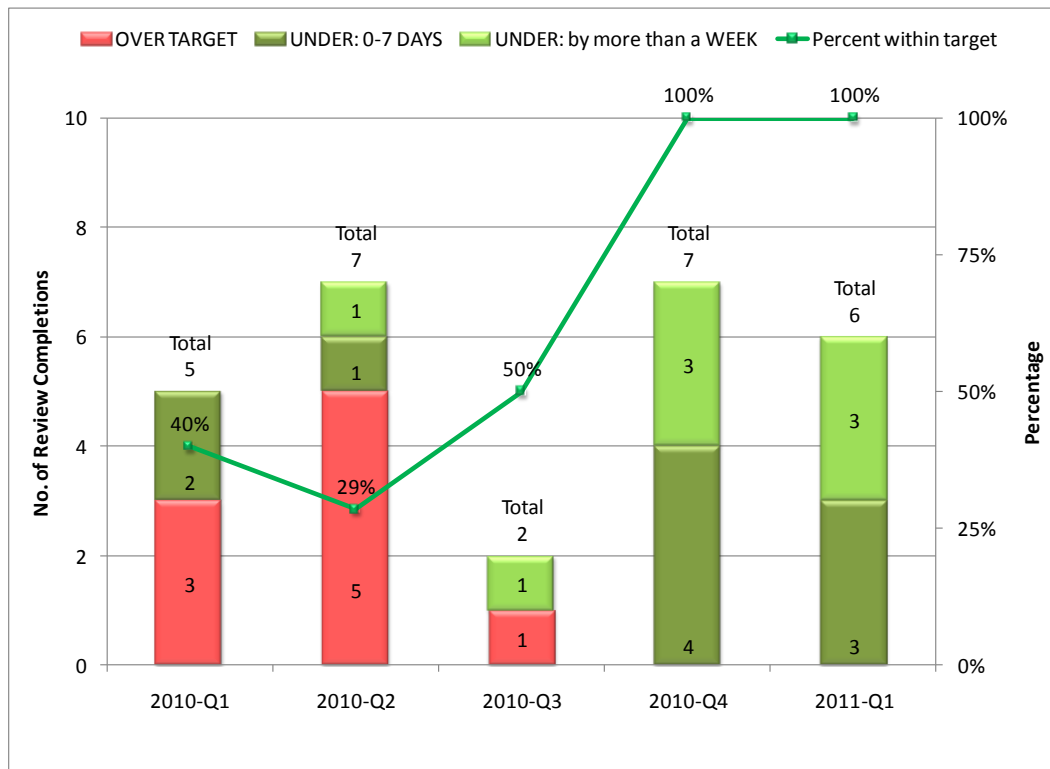
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## REVIEW CYCLE DECISIONS

### New Drug Submission (NDS) Review Decisions

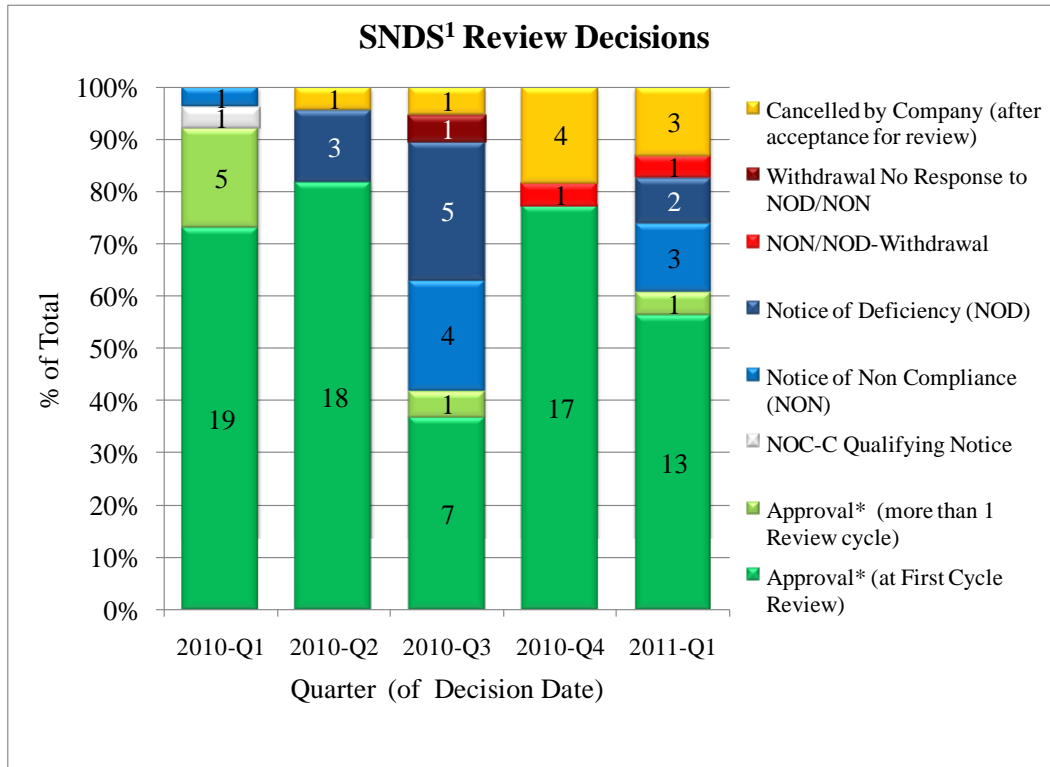


### NDS - Review Cycle Completions Showing Percentage Within Target

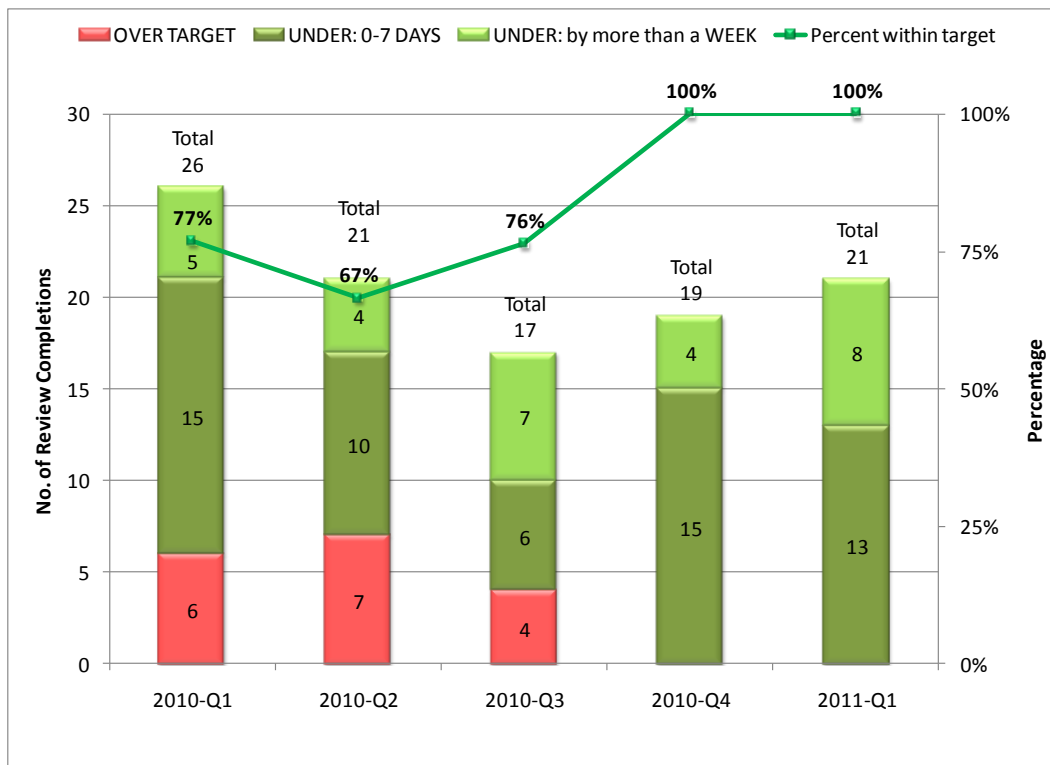


## REVIEW CYCLE DECISIONS

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

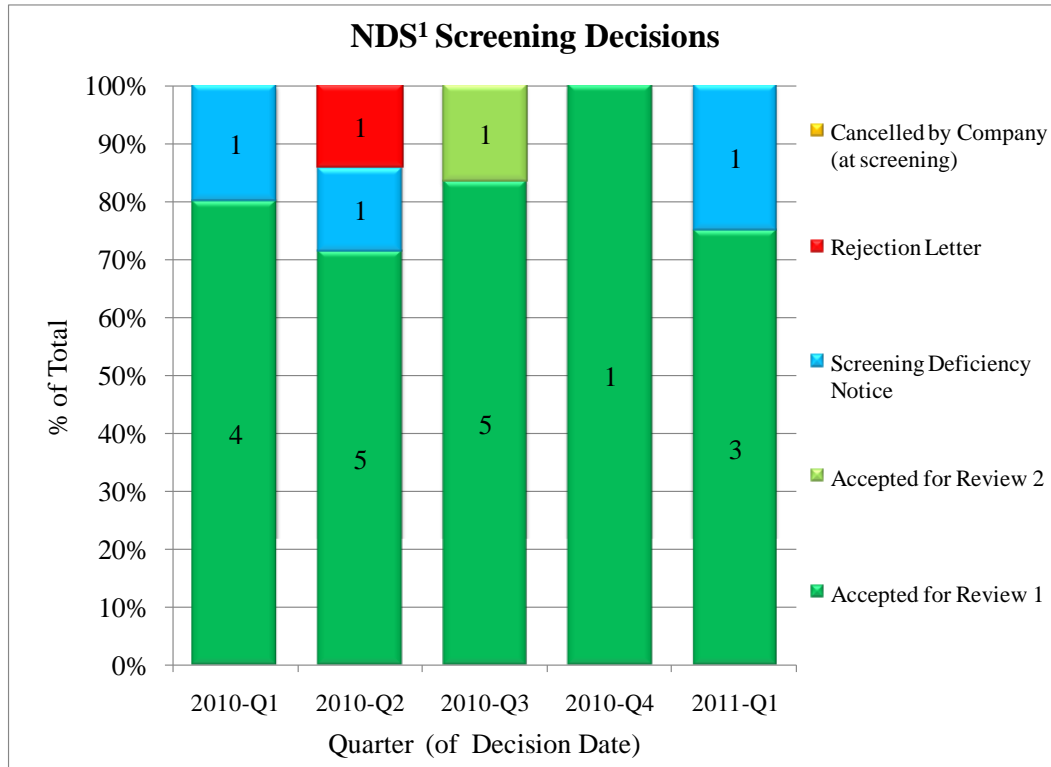


### SNDS - Review Cycle Completions Showing Percentage Within Target

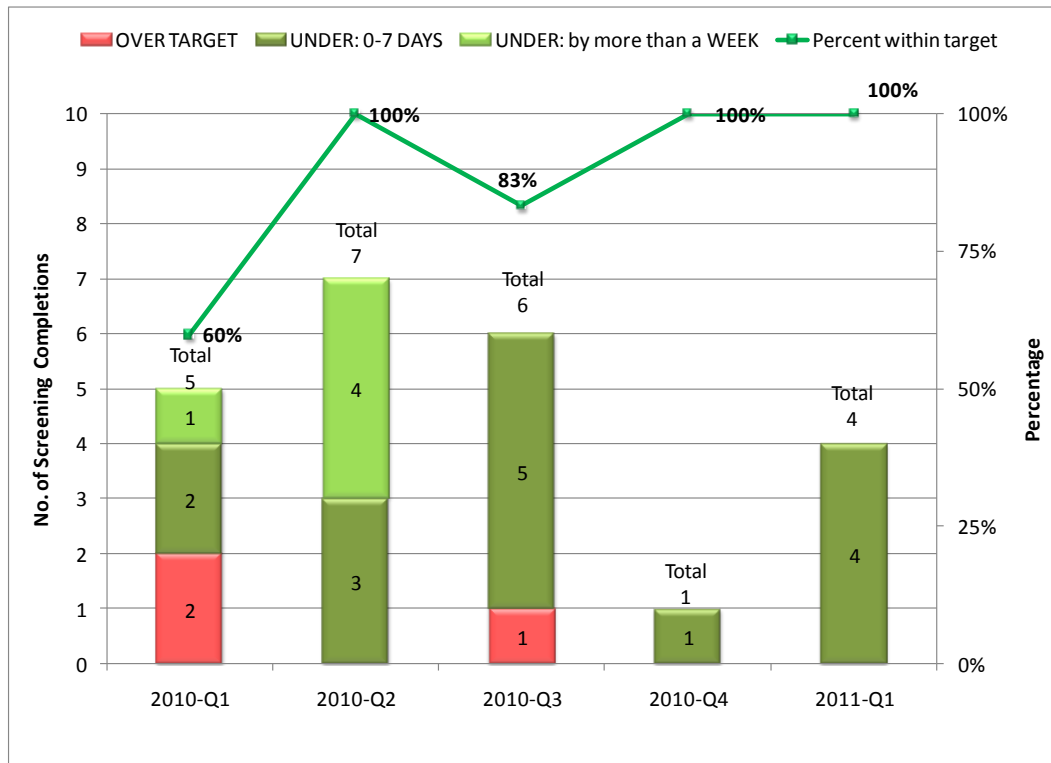


## SCREENING CYCLE DECISIONS

### New Drug Submission (NDS) Screening Decisions

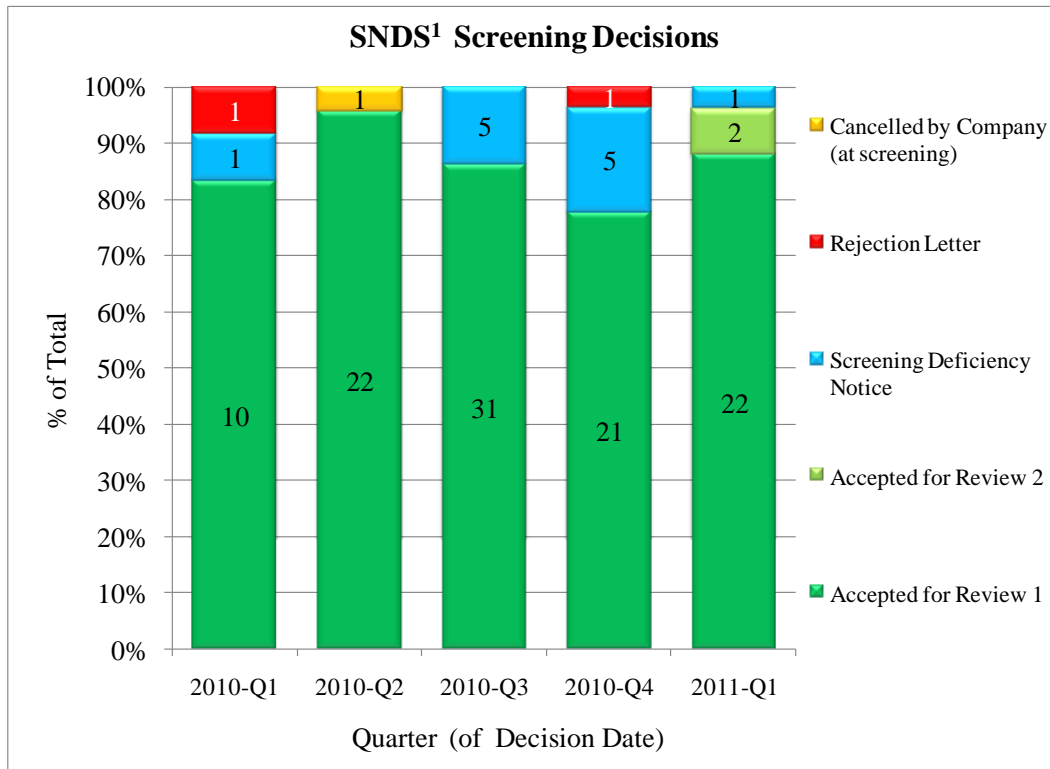


### NDS - Screening Cycle Completions Showing Percentage Within Target

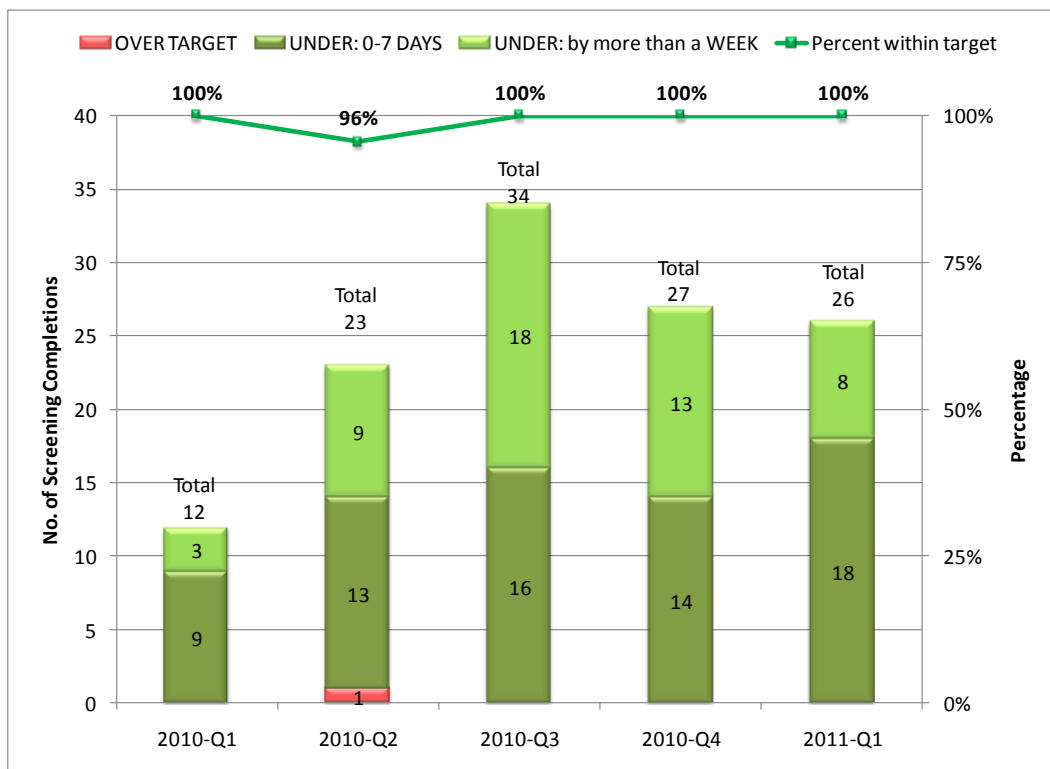


### SCREENING CYCLE DECISIONS

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

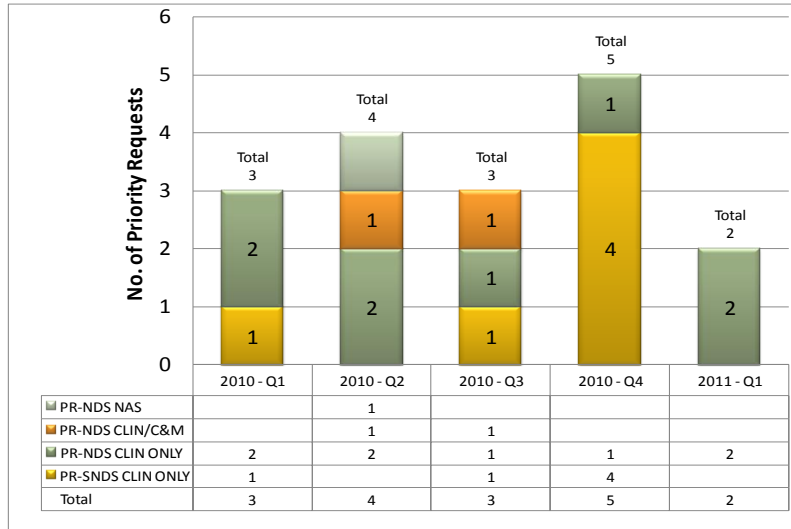


#### SNDS - Screening Cycle Completions Showing Percentage Within Target

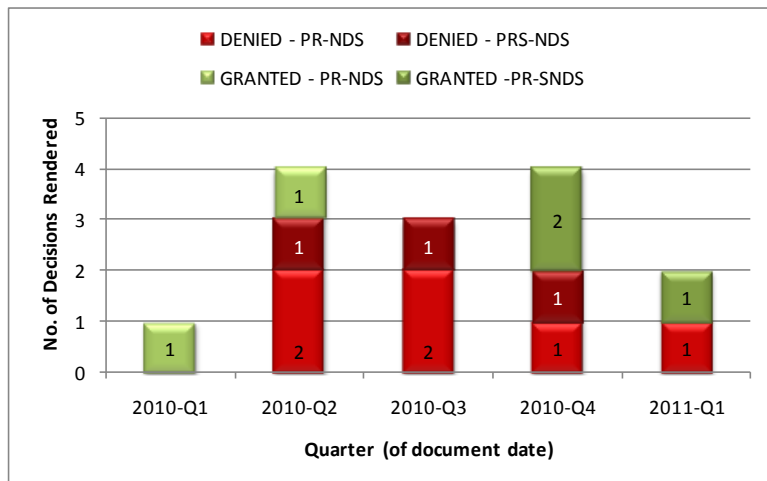


## PRIORITY REVIEW STATUS REQUESTS (FOR NDS & SNDS)

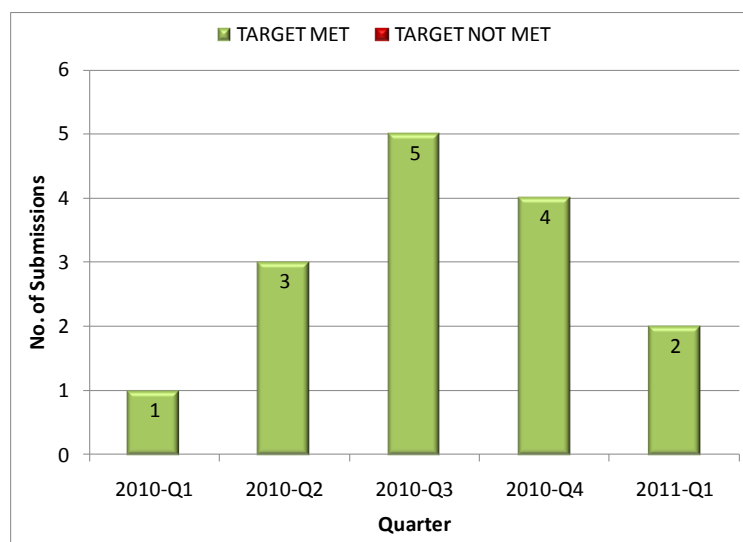
### Priority Review Status Requests: Received



### Priority Review Status Requests: Decisions Rendered



### Priority Review Status Request: Performance



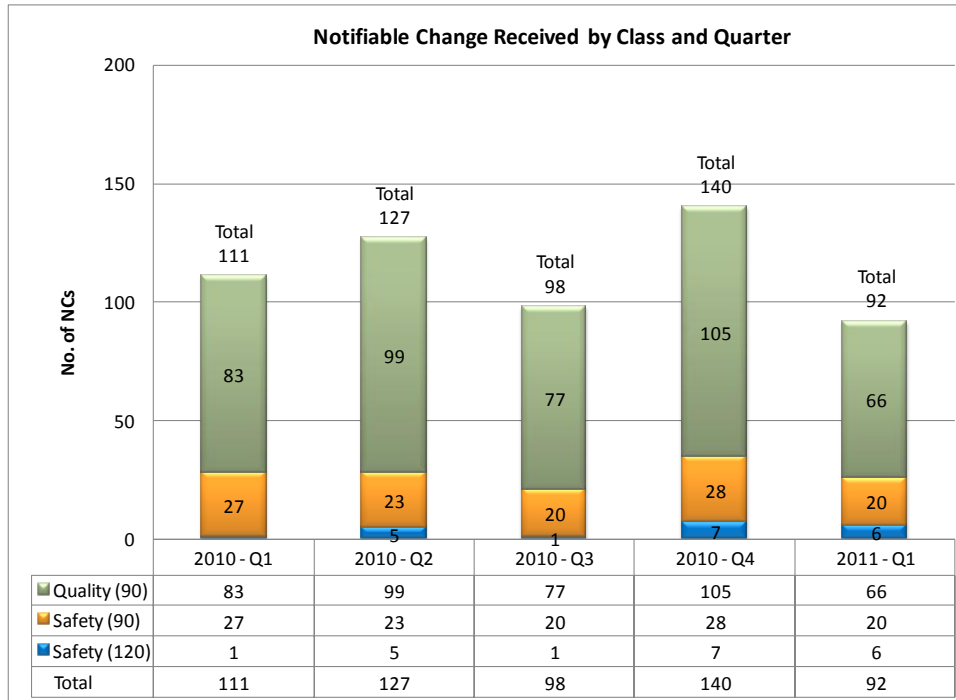
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## **NOTIFIABLE CHANGES**

**(NC)**

## NOTIFIABLE CHANGES<sup>4</sup>

### Notifiable Change (NC) Submissions Received



### Notifiable Change (NC) Decision Documents by Type

<b>NC - SAFETY (90)</b>					
<b>DOCUMENT TYPE</b>	<b>2010-Q1</b>	<b>2010-Q2</b>	<b>2010-Q3</b>	<b>2010-Q4</b>	<b>2011-Q1</b>
NO OBJECTION LETTER	21	27	26	8	25
REJECTION LETTER (SCREENING)			2	1	
CANCELLED BY COMPANY		3	3		1

<b>NC - QUALITY (90)</b>					
<b>DOCUMENT TYPE</b>	<b>2010-Q1</b>	<b>2010-Q2</b>	<b>2010-Q3</b>	<b>2010-Q4</b>	<b>2011-Q1</b>
NO OBJECTION LETTER	72	79	101	59	88
NOT SATISFACTORY NOTICE		2	1		1
REJECTION LETTER (SCREENING)	4	3	7	8	8
SCREENING DEFICIENCY NOTICE			6	7	2
CANCELLED BY COMPANY	1	2		3	4

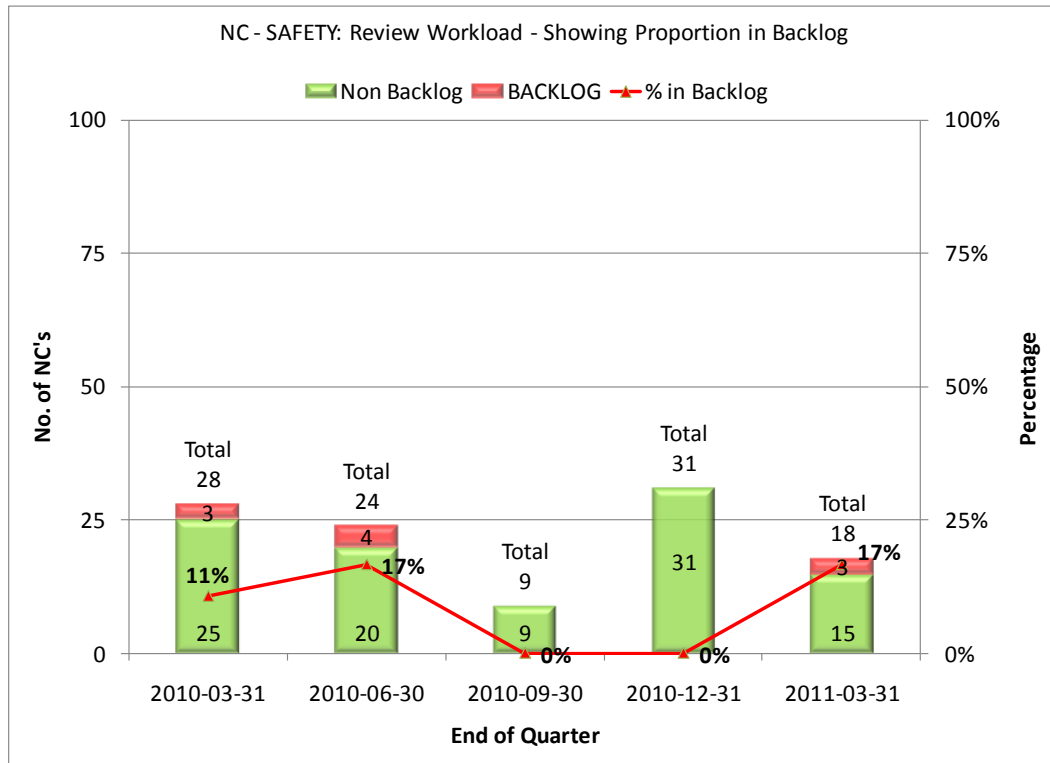
<b>NC - SAFETY (120)</b>					
<b>DOCUMENT TYPE</b>	<b>2010-Q1</b>	<b>2010-Q2</b>	<b>2010-Q3</b>	<b>2010-Q4</b>	<b>2011-Q1</b>
NO OBJECTION LETTER	1	1	4	2	6
NOT SATISFACTORY NOTICE				1	

<sup>4</sup> [Post-Notice of Compliance \(NOC\) Changes Guidance Documents.](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld-postnoc_change_apresac/noc_postnotice_ac_apresavis_change-eng.php)

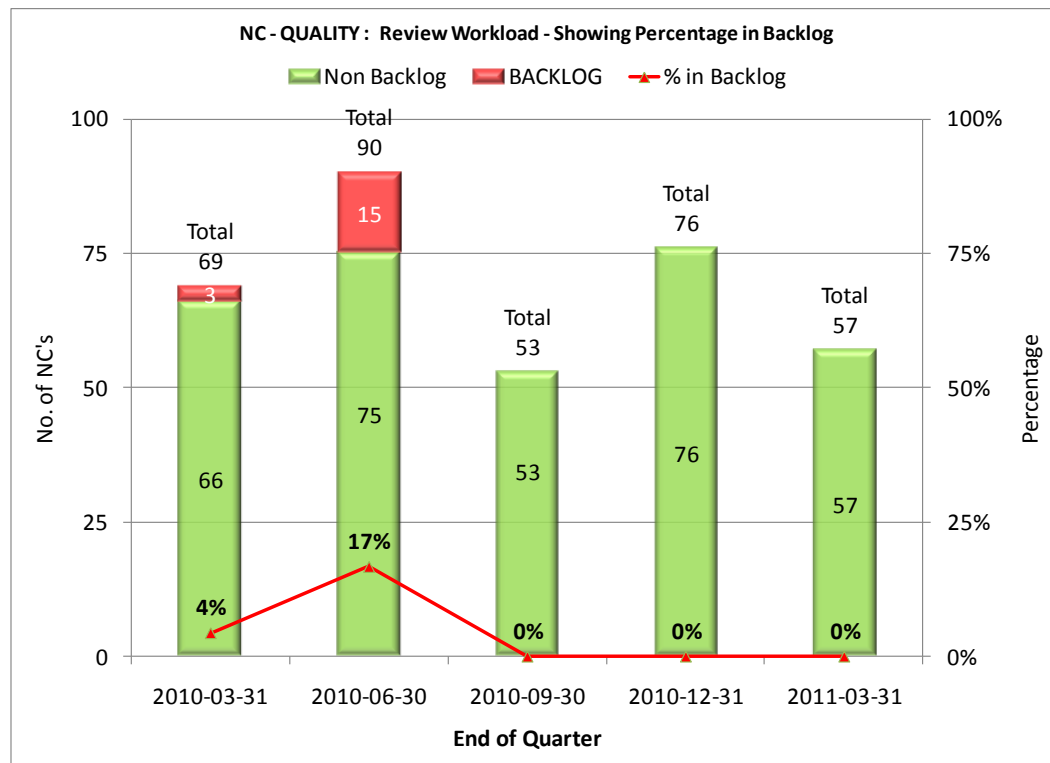
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld-postnoc\_change\_apresac/noc\_postnotice\_ac\_apresavis\_change-eng.php  
The Guidance documents were effective as of September 30, 2009

## WORKLOAD

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



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



**WORKLOAD****Notifiable Change (NC) SAFETY: Review Workload by Class**

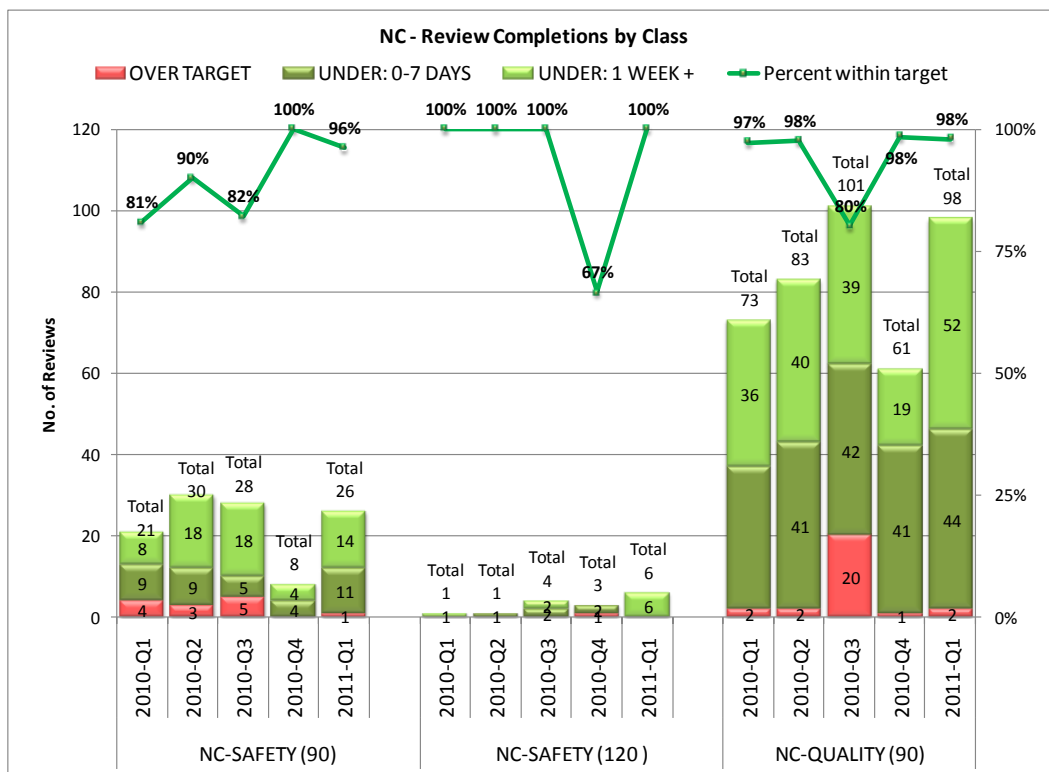
<b>BGTD NC- SAFETY: REVIEW WORKLOAD AT END OF QUARTER</b>					
<b>CLASS</b>	<b>2010-03-31</b>	<b>2010-06-30</b>	<b>2010-09-30</b>	<b>2010-12-31</b>	<b>2011-03-31</b>
<b>SAFETY - 90 day</b>	<b>25</b>	<b>21</b>	<b>6</b>	<b>25</b>	<b>15</b>
<b>Backlog</b>	<b>3</b>	<b>4</b>	<b>0</b>	<b>0</b>	<b>3</b>
<b>SAFETY - 120 day</b>	<b>3</b>	<b>3</b>	<b>3</b>	<b>6</b>	<b>3</b>
	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Total</b>	<b>28</b>	<b>24</b>	<b>9</b>	<b>31</b>	<b>18</b>
<b>Non Backlog</b>	<b>25</b>	<b>20</b>	<b>9</b>	<b>31</b>	<b>15</b>
<b>BACKLOG</b>	<b>3</b>	<b>4</b>	<b>0</b>	<b>0</b>	<b>3</b>
<b>% in Backlog</b>	<b>11%</b>	<b>17%</b>	<b>0%</b>	<b>0%</b>	<b>17%</b>

**Notifiable Change (NC) QUALITY: Review Workload by Class**

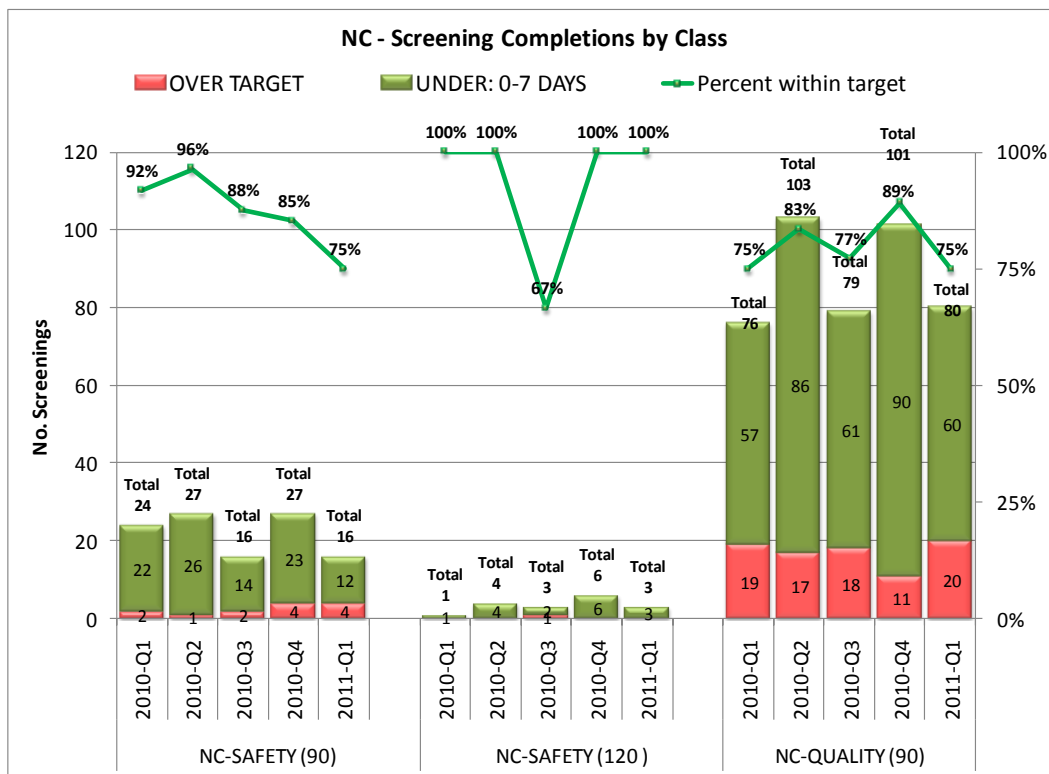
<b>BGTD NC- QUALITY: REVIEW WORKLOAD AT END OF QUARTER</b>					
<b>CLASS</b>	<b>2010-03-31</b>	<b>2010-06-30</b>	<b>2010-09-30</b>	<b>2010-12-31</b>	<b>2011-03-31</b>
<b>QUALITY - 90 day</b>	<b>69</b>	<b>87</b>	<b>53</b>	<b>76</b>	<b>57</b>
<b>Backlog</b>	<b>3</b>	<b>15</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Total</b>	<b>69</b>	<b>90</b>	<b>53</b>	<b>76</b>	<b>57</b>
<b>Non Backlog</b>	<b>66</b>	<b>75</b>	<b>53</b>	<b>76</b>	<b>57</b>
<b>BACKLOG</b>	<b>3</b>	<b>15</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>4%</b>	<b>17%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

### PERFORMANCE

#### Notifiable Change - REVIEW Completions by Class



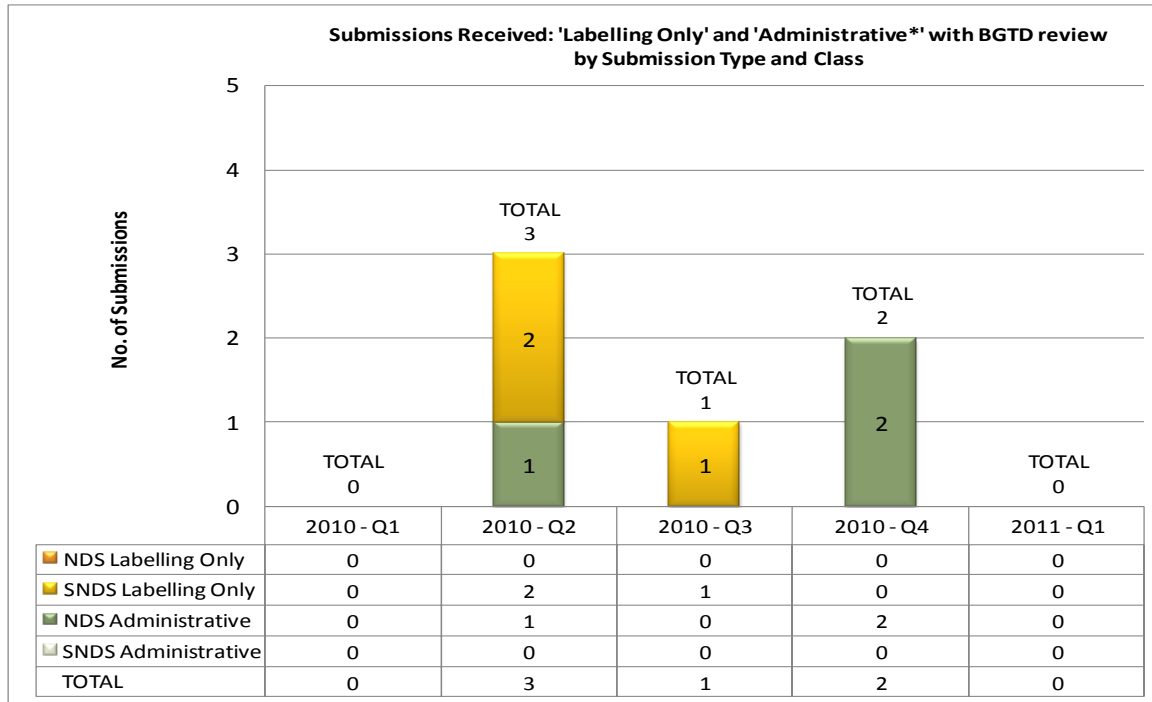
#### Notifiable Changes- SCREENING Completions by Class



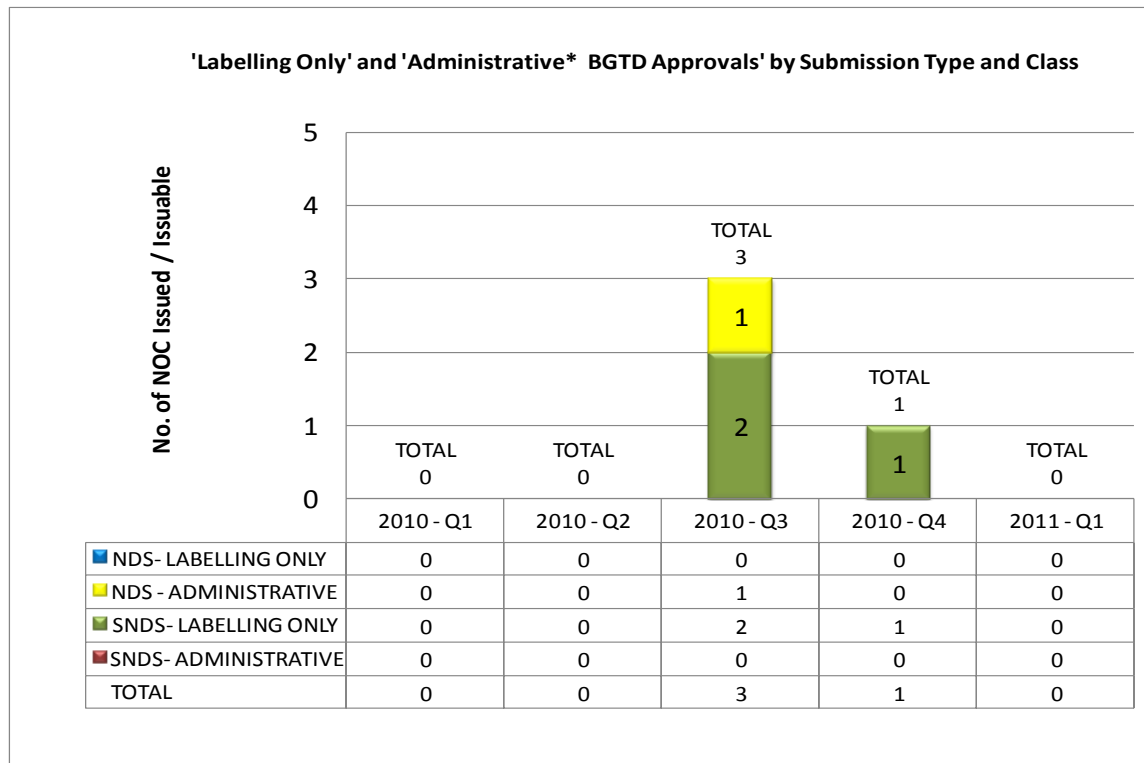
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## Labelling Only and Administrative\* Requiring a Review (\*such as product name change that requires a drug name review)

### Labelling Only & Administrative\* Submissions Received

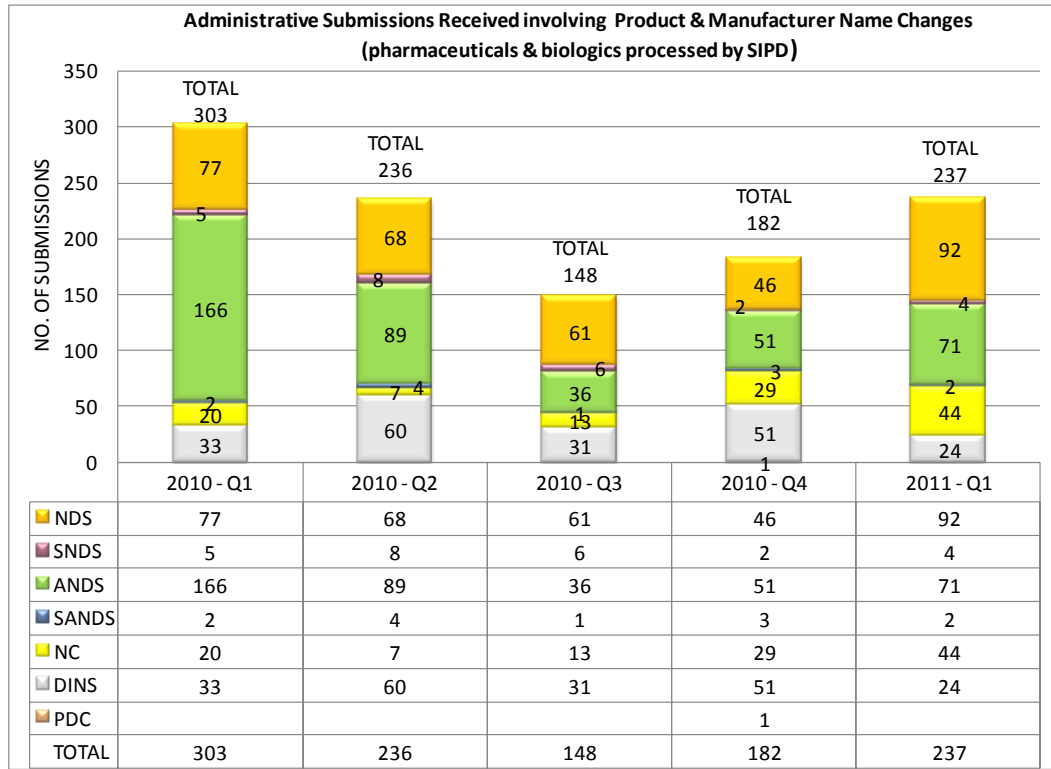


### Labelling Only and Administrative\* Submission Approvals

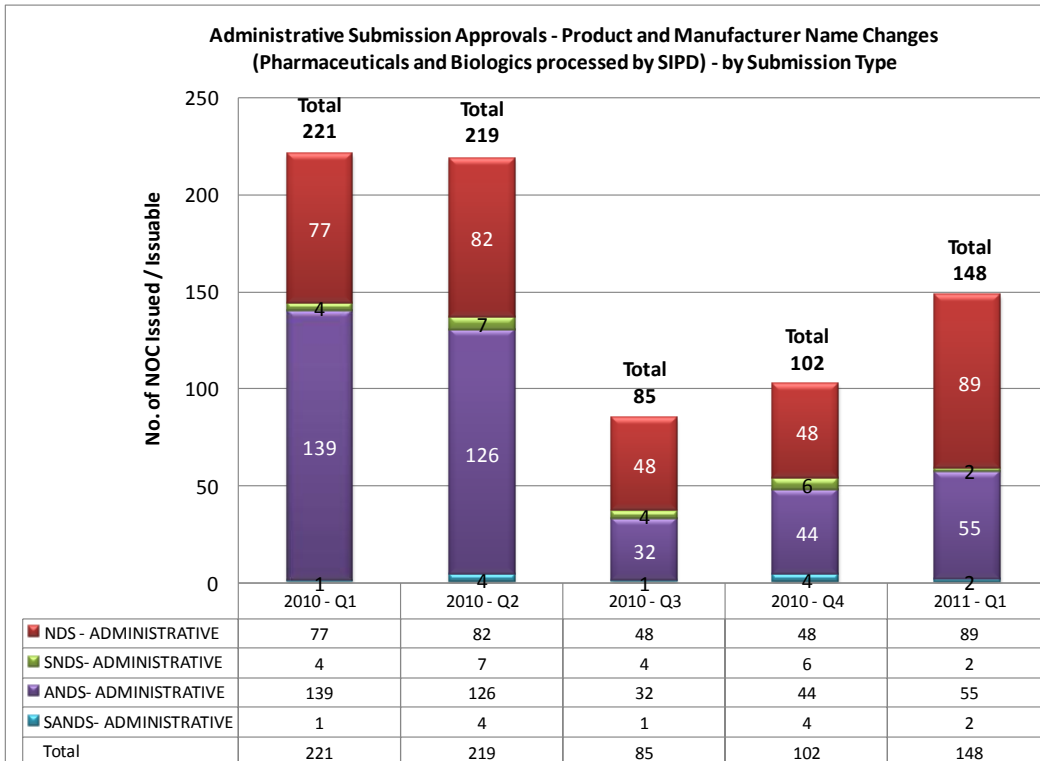


### Administrative : Product & Manufacturer Name Changes

#### SIPD Administrative Submissions Received by Submission Type

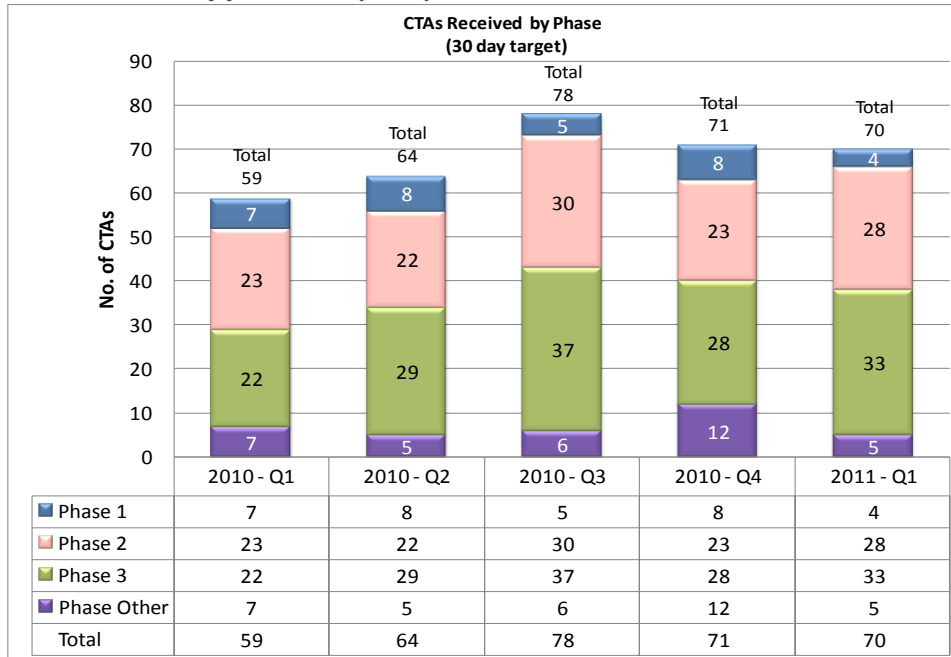


#### Administrative Submission Approvals (SIPD)- Product & Manufacturer Name Changes NDS, SNDS, ANDS and SANDS



## CLINICAL TRIAL APPLICATIONS

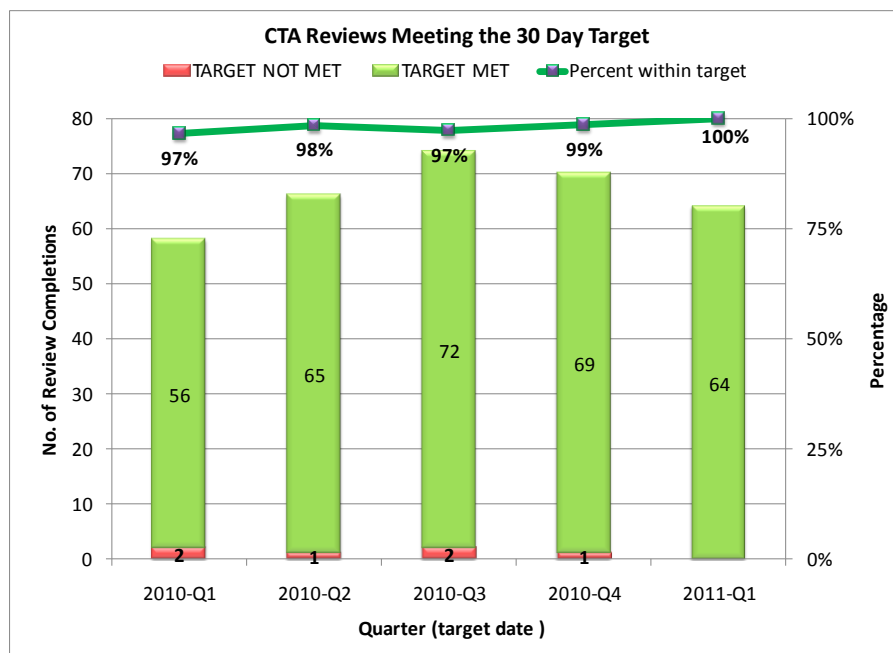
### Clinical Trial Application (CTA) Received



### Clinical Trail Application (CTA) Decision Documents

CTA	2010-Q1	2010-Q2	2010-Q3	2010-Q4	2011-Q1
<b>DOCUMENT TYPE</b>					
NO OBJECTION LETTER	54	73	69	67	64
CANCELLED BY COMPANY	6	3		5	
NOT SATISFACTORY NOTICE			2		1
REJECTION LETTER (SCREENING)					1

### CTA Reviews Meeting 30 Day Target



## CLINICAL TRIAL APPLICATION AMENDMENTS

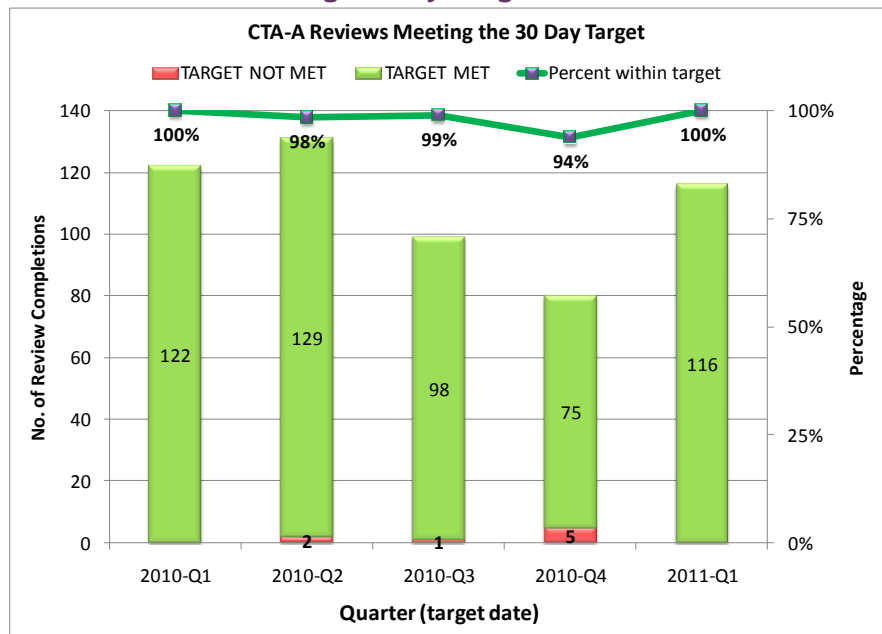
### Clinical Trial Application-Amendments (CTA-A) Received



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

CTA-A					
DOCUMENT TYPE	2010-Q1	2010-Q2	2010-Q3	2010-Q4	2011-Q1
NO OBJECTION LETTER	119	131	99	83	119
REJECTION LETTER (SCREENING)	1	2	1	2	1
CANCELLED BY COMPANY	3	1	2	2	1
NOT SATISFACTORY NOTICE				1	1

### CTA-A Reviews Meeting 30 Day Target



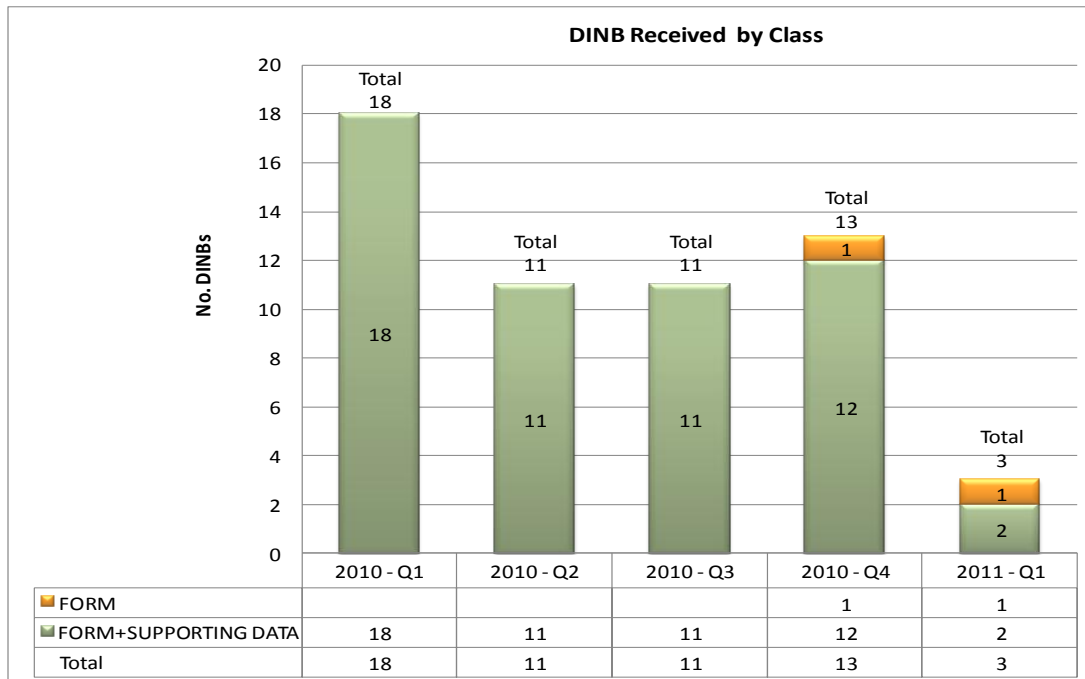
**DINB**

**APPLICATION FOR A DRUG IDENTIFICATION NUMBER**

**BIOLOGICAL PRODUCT**

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

### DINB Received



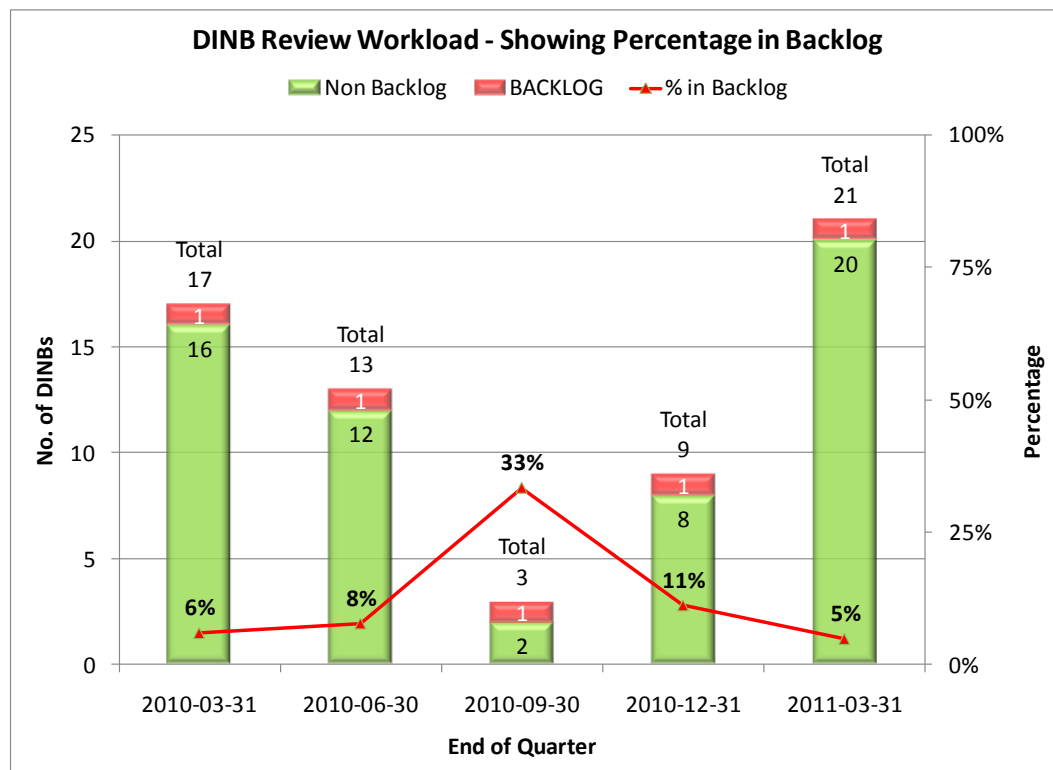
### DINB -DECISION DOCUMENTS –by CLASS

<b>DINB - FORM</b>					
<b>DOCUMENT TYPE</b>	<b>2010-Q1</b>	<b>2010-Q2</b>	<b>2010-Q3</b>	<b>2010-Q4</b>	<b>2011-Q1</b>
NO OBJECTION LETTER					1

<b>DINB - FORM AND SUPPORTING DATA</b>					
<b>DOCUMENT TYPE</b>	<b>2010-Q1</b>	<b>2010-Q2</b>	<b>2010-Q3</b>	<b>2010-Q4</b>	<b>2011-Q1</b>
NO OBJECTION LETTER	7	18	12	2	1
NOT SATISFACTORY NOTICE			4		
NOTICE OF DEFICIENCY			1		
REJECTION LETTER (SCREENING)	1				
SCREENING DEFICIENCY NOTICE		1		8	

## REVIEW WORKLOAD

### DINB Review Workload / Backlog

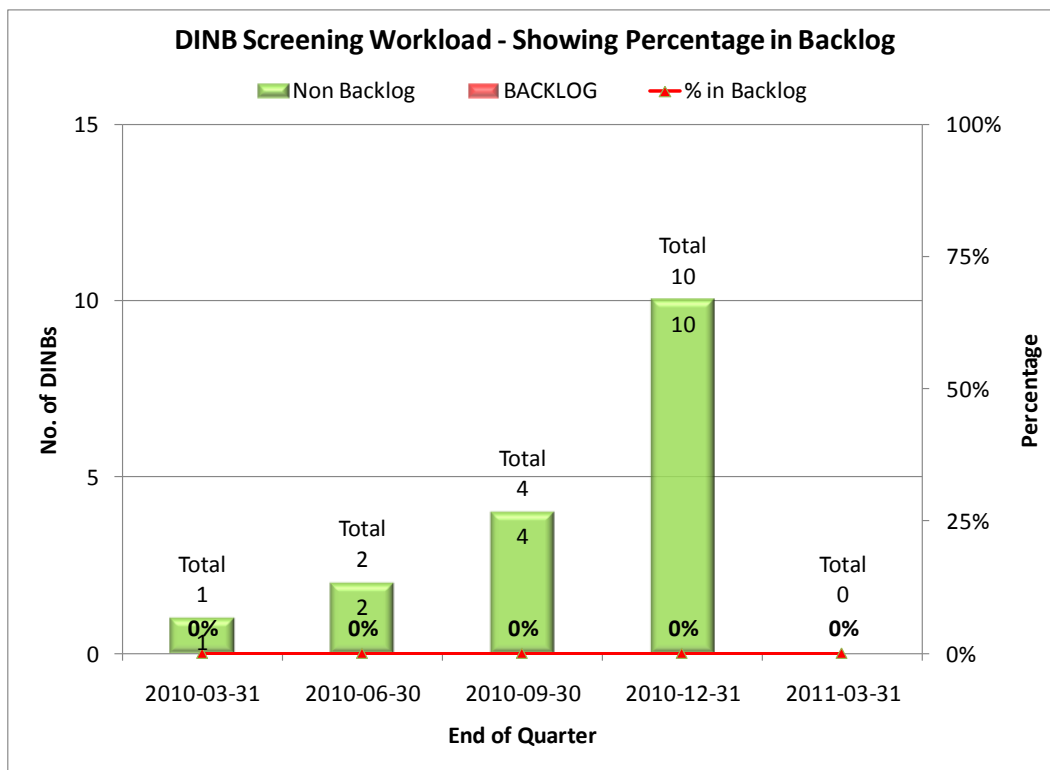


### DINB Review Workload by Class

BGTD DINB REVIEW WORKLOAD BY CLASS AND END OF QUARTER					
CLASS	2010-03-31	2010-06-30	2010-09-30	2010-12-31	2011-03-31
FORM	0	0	0	1	5
	0	0	0	0	0
<b>Form and Supporting Data</b>	<b>17</b>	<b>13</b>	<b>3</b>	<b>8</b>	<b>16</b>
Backlog	1	1	1	1	1
<b>Total</b>	<b>17</b>	<b>13</b>	<b>3</b>	<b>9</b>	<b>21</b>
<b>Non Backlog</b>	<b>16</b>	<b>12</b>	<b>2</b>	<b>8</b>	<b>20</b>
<b>BACKLOG</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>
<b>% in Backlog</b>	<b>6%</b>	<b>8%</b>	<b>33%</b>	<b>11%</b>	<b>5%</b>

### SCREENING WORKLOAD

#### DINB Screening Workload / Backlog

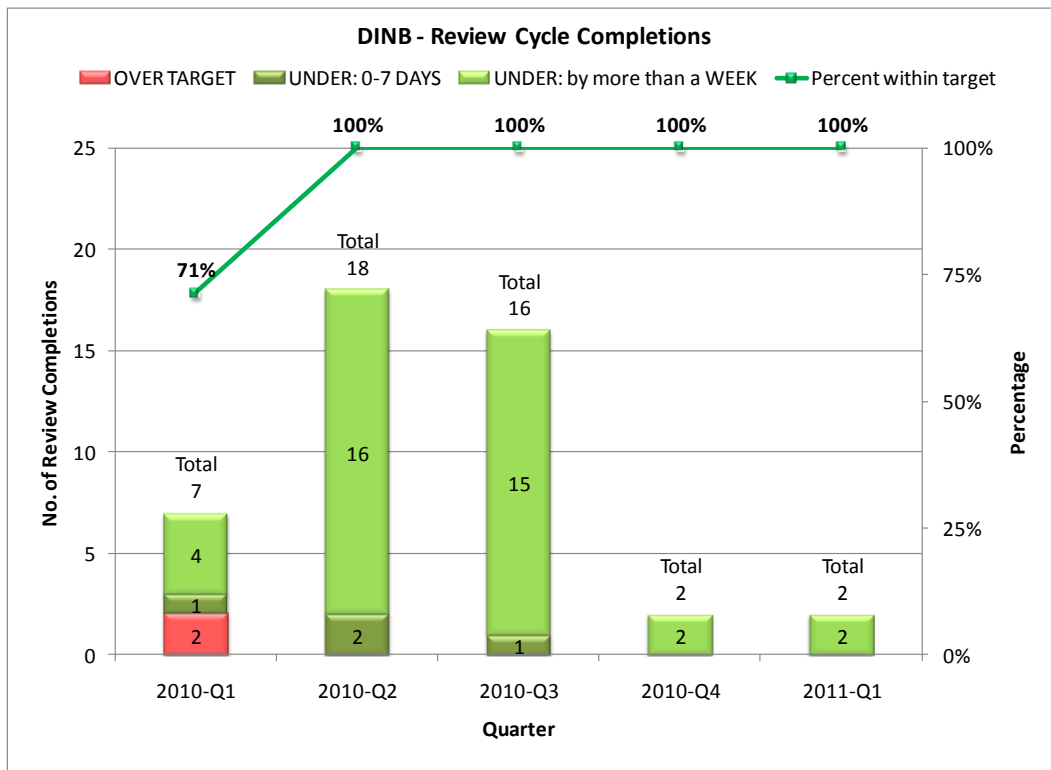


#### DINB Screening Workload by Class

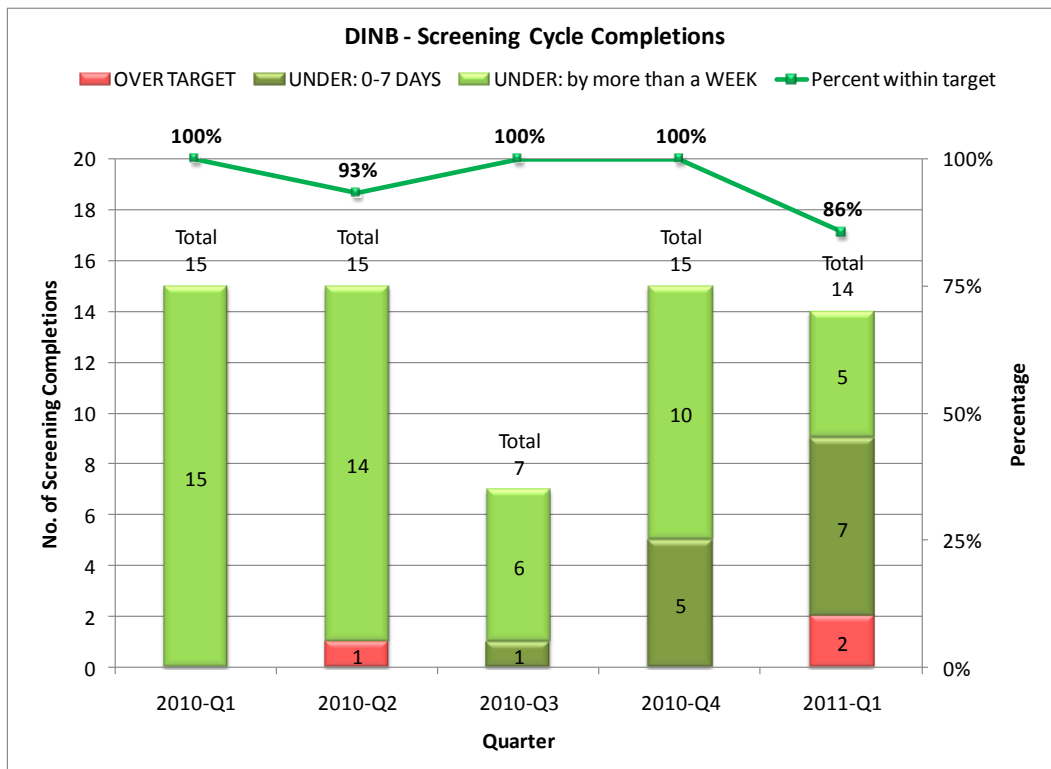
BGTD DINB SCREENING WORKLOAD BY CLASS AND END OF QUARTER					
CLASS	2010-03-31	2010-06-30	2010-09-30	2010-12-31	2011-03-31
FORM	0	0	3	0	0
	0	0	0	0	0
FORM+SUPPORTING DATA	1	2	1	10	0
	0	0	0	0	0
<b>Total</b>	<b>1</b>	<b>2</b>	<b>4</b>	<b>10</b>	<b>0</b>
<b>Non Backlog</b>	<b>1</b>	<b>2</b>	<b>4</b>	<b>10</b>	<b>0</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>

### REVIEW & SCREENING CYCLE DECISIONS

#### DINB Review Cycle Completions Showing Proportion Within Target

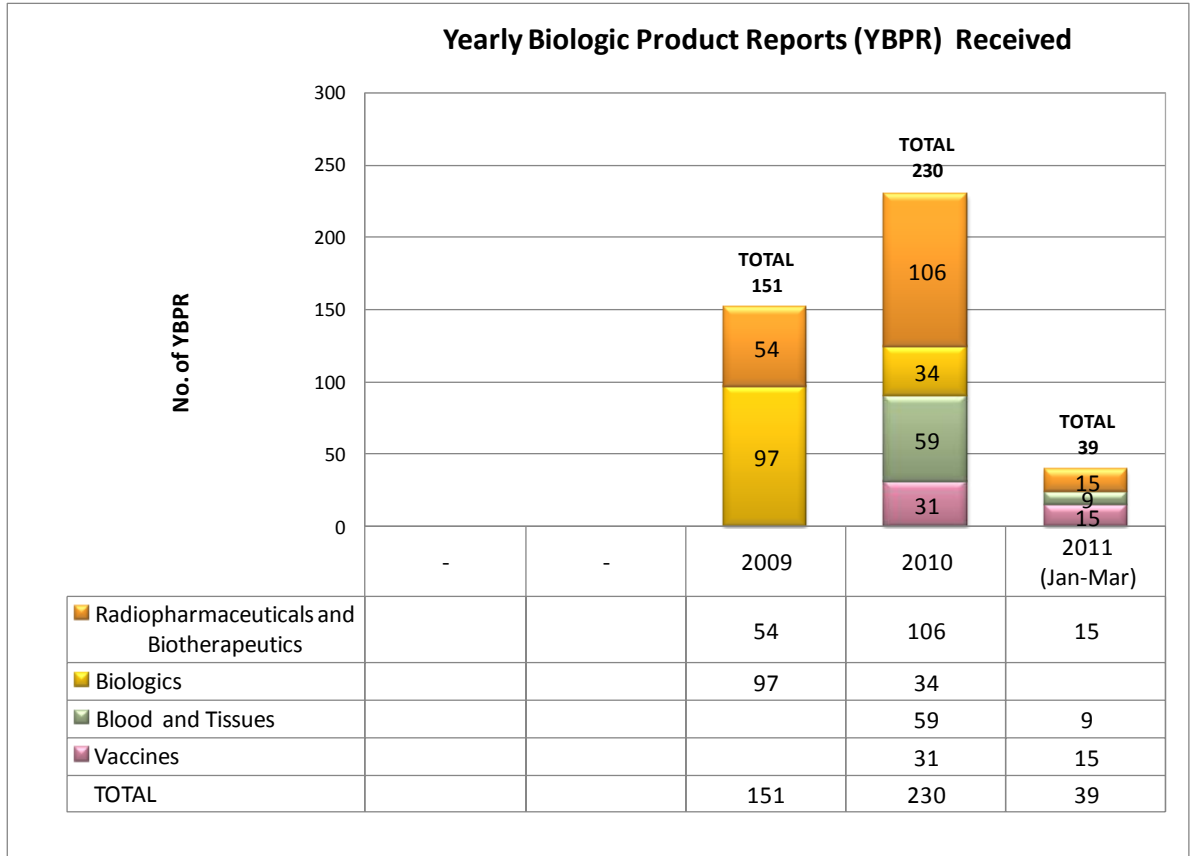


#### DINB Screening Cycle Completions Showing Proportion Within Target



## Yearly Biologic Product Reports (YBPR<sup>5</sup>)

### Yearly Biologic Product Reports (YBPR) Received



<sup>5</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.

## REQUESTS FOR RECONSIDERATION OF FINAL DECISION

### Requests for Reconsideration of Final Decision: NDS & SNDS<sup>6</sup>

NDS & SNDS - Reconsideration of Final Decisions by Year Requested							
Year of Reconsideration Request							
Final Decision in Dispute	2007	2008	2009	2010	2011	Reconsideration Decision	NDS's Status as of March 31, 2011
<b>NDS Total</b>	0	0	0	0	0		
<b>SNDS Total</b>	0	0	0	0	0		

### Requests for Reconsideration of Final Decision: Request for Advance Consideration under the Notice of Compliance with Conditions Policy

Request for Advance Consideration under the Notice of Compliance with Conditions Policy (NOC/c): Reconsideration of Final Decisions by Year Requested							
Year of Reconsideration Request							
Final Decision in Dispute	2007	2008	2009	2010	2011	Reconsideration Decision	Submission Status as of March 31, 2011
<b>Total</b>	0	0	0	0	0		

<sup>6</sup> As of March 1, 2006, the *Appeals Procedures for Drug Submissions Policy* has been replaced by the [guidance Reconsideration of Final Decisions Issued for Human Drug Submissions](#)

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