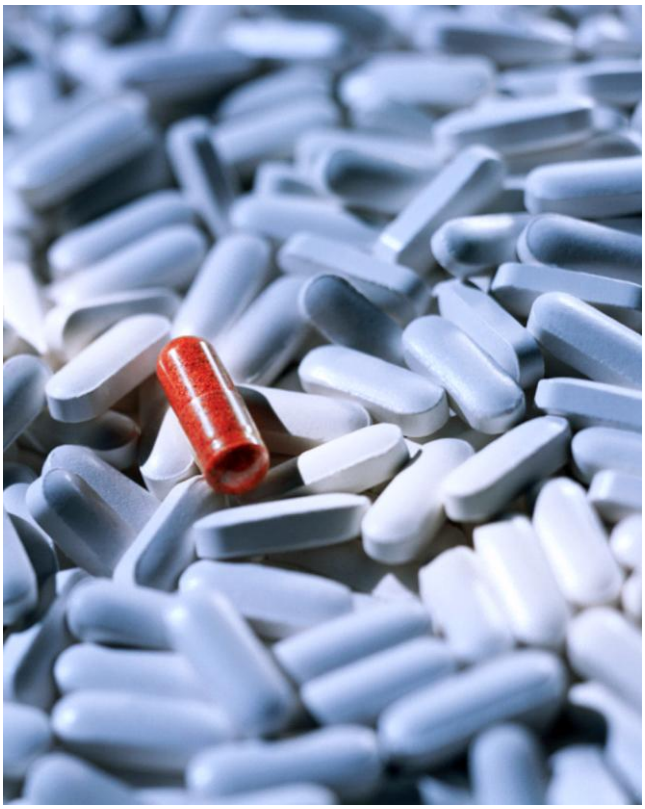
Biologics and Genetic Therapies Directorate
Drug Submission Performance Annual Report

Fiscal Year
2011 – 2012

Apr 1 2011 – Mar 31 2012



Canada

This page is left blank intentionally.

Table of Contents

OVERVIEW

The Biologics and Genetic Therapies Directorate's (BGTD) Annual Drug Submission Performance Report reflects biologic and radiopharmaceutical drug submission review activity over five consecutive fiscal years (April 1 to March 31) from 2007-08 to 2011-12. Statistics are provided by submission type and show the number received, the number in workload, the number of decisions, the number of approvals and approval times. The report lists details of Priority Submissions and New Active Substances approved during the fiscal year Apr 1 2011 to March 31 2012.

What's New

- The Annual report is now based on Fiscal Year (Apr 1- Mar 31).
- The new Cost Recovery Fee Categories[1] introduced on April 1st 2011 have been incorporated into the report.
- 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[2].
- '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[3] are now included in the SNDS Received, Workload and Performance figures. SNDS-C are not included in the SNDS Approval figures.

General Information

There are several steps involved in the drug submission review[4] 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, which is the date the submission is considered administratively complete by Health Canada.

[1] 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.

[2] 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)

[3] 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

[4] 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).

Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, (including any time awaiting a response from the sponsor.)

A **review cycle completion**[5]. 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[2] 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"[6] submissions.

Any questions or comments on this report should be forwarded to:
Submission Information Policy Division, Biologics and Genetic Therapies 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

[5] 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.

[6] 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

ACRONYMS

Submission Types

CTA	-	Clinical Trial Application
CTA-A	-	Clinical Trial Application-Amendment
DINB	-	Application for a DIN – Biological Product
NDS	-	New Drug Submission
NC	-	Notifiable Change – New Drug
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
YBPR		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
New Active Substance (NAS)* *This new NAS definition came into effect on April 1 2011*	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.
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 non-clinical 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, pharmacokinetic and pharmacodynamic data) 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.
Published data only	Submissions based only on published clinical or non-clinical data for a drug that does not include a new active substance.
Switch from prescription to nonprescription status	Submissions based only on data that support the modification or removal of a medicinal ingredient listed in Schedule F to the *Food and Drug Regulations* (i.e. identical claim for existing drug).
Labelling only	Submissions of labelling material (i.e. does not include supporting clinical or non-clinical data or chemistry and manufacturing data).
Administrative submission	Submissions in support of a manufacturer or product name change.
Disinfectants	Submissions and applications that include data in support of a disinfectant.
Drug identification number application - labelling standards	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**

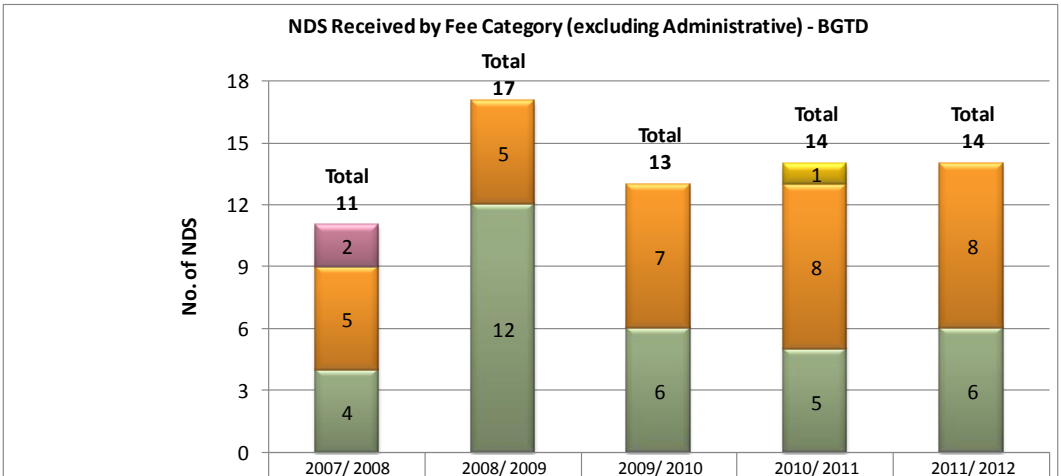
New Drug Submission (NDS)

&

Supplemental New Drug Submission (SNDS)

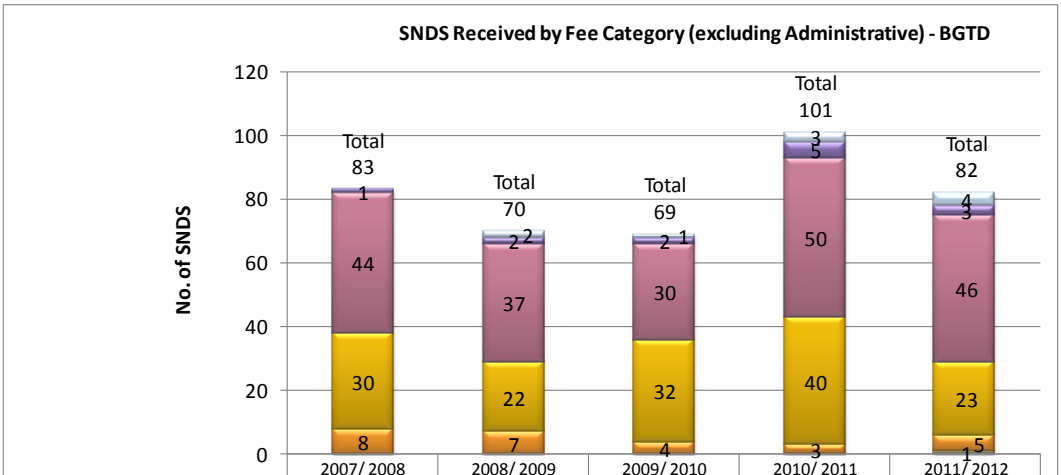
SUBMISSIONS RECEIVED

New Drug Submissions (NDS) Received by Fee Category



	2007/ 2008	2008/ 2009	2009/ 2010	2010/ 2011	2011/ 2012
Labelling Only	0	0	0	0	0
Disinfectants	0	0	0	0	0
Comparative Studies	0	0	0	0	0
Chemistry & Manufacturing	2	0	0	0	0
Clinical or Non-Clin Only	0	0	0	1	0
Clinical or Non-Clin and C&M	5	5	7	8	8
New Active Substance*	4	12	6	5	6
Total	11	17	13	14	14
Priority (subset)	2	2	1	2	3
Emergency Use NDS	0	0	0	1	0

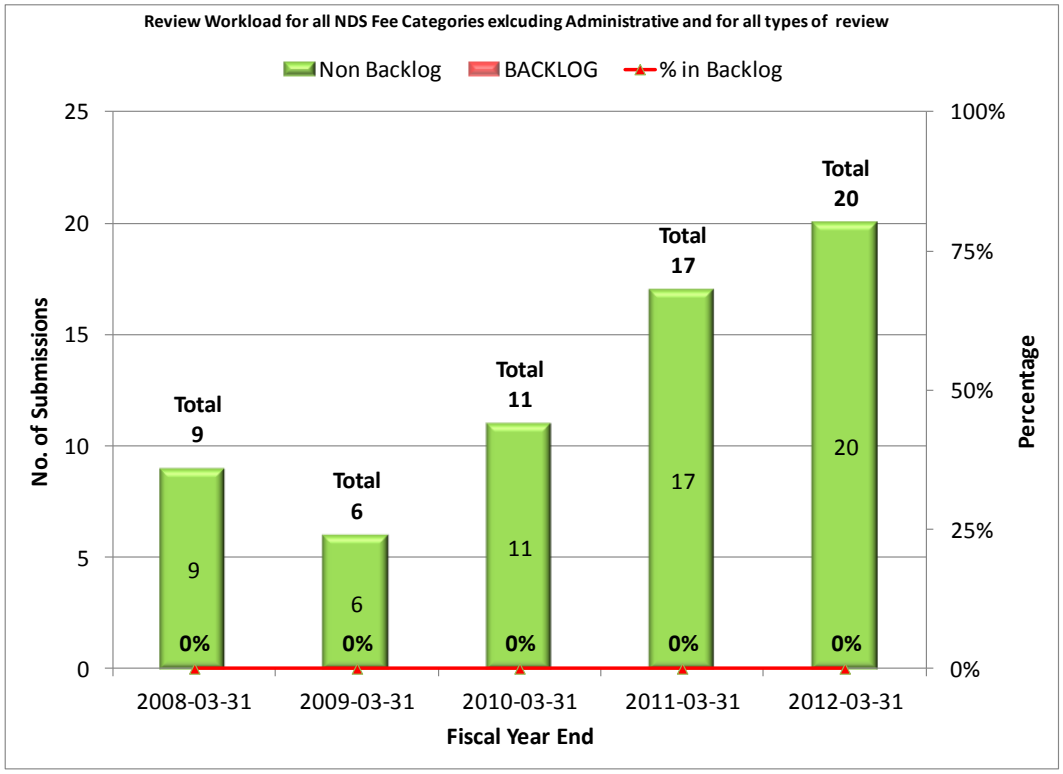
Supplemental New Drug Submissions (SNDS) Received by Fee Category



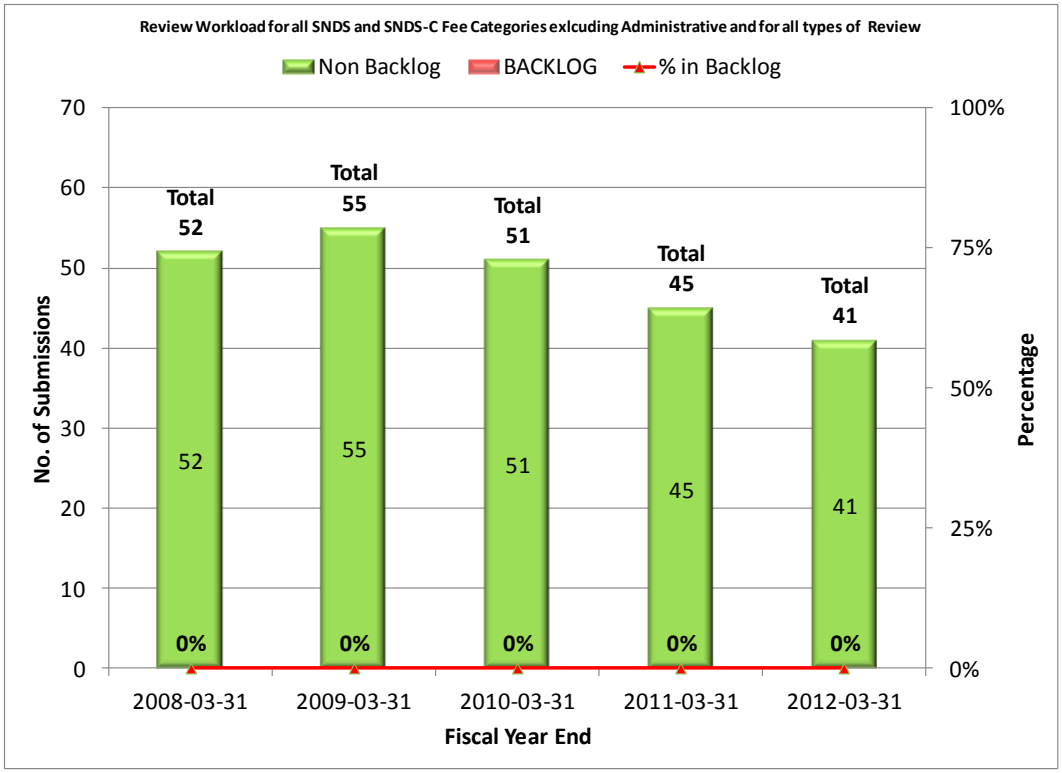
	2007/ 2008	2008/ 2009	2009/ 2010	2010/ 2011	2011/ 2012
Labelling Only		2	1	3	4
Comparative Studies	1	2	2	5	3
Chemistry & Manufacturing	44	37	30	50	46
Clinical or Non-Clin Only*	30	22	32	40	23
Clinical or Non-Clin and C&M	8	7	4	3	5
Published Data Only					1
Switch from Rx to OTC	0	0	0	0	0
Total	83	70	69	101	82
Priority (subset)	3	2	2	3	1
*SNDS Confirmatory	0	0	0	3	0

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

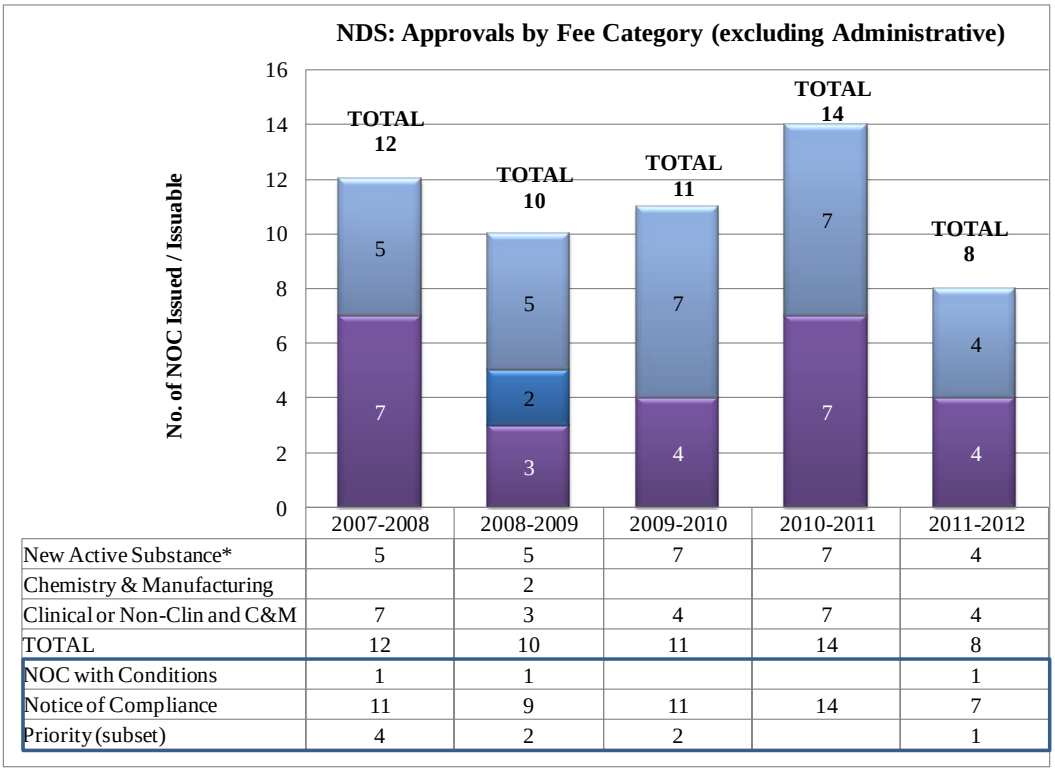
BGTD NDS All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2008-03-31	2009-03-31	2010-03-31	2011-03-31	2012-03-31
Comparative Studies	0	0	0	0	0
Backlog	0	0	0	0	0
Chemistry & Manufacturing	1	0	0	0	0
Backlog	0	0	0	0	0
Clinical or Non-Clin Only	0	0	0	0	1
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	4	6	5	2	9
Backlog	1	0	2	0	0
New Active Substance	4	7	8	4	5
Backlog	0	1	3	0	0
Total	**9**	**13**	**13**	**6**	**15**
Non Backlog	**8**	**12**	**8**	**6**	**15**
Backlog	**1**	**1**	**5**	0	0
% in Backlog	**11%**	**8%**	**38%**	0%	0%
Priority (subset)	1	0	0	1	1
Non Backlog	1	0	0	1	1
Backlog	0	0	0	0	0

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

BGTD SNDS and SNDS-C All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2008-03-31	2009-03-31	2010-03-31	2011-03-31	2012-03-31
Comparative Studies	1	0	3	2	1
Backlog	0	0	0	0	0
Chemistry & Manufacturing	18	14	11	17	24
Backlog	0	0	1	0	0
Clinical or Non-Clin Only	21	16	24	35	18
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	7	7	1	2	3
Backlog	0	0	0	0	0
Total	**47**	**37**	**39**	**56**	**46**
Non Backlog	**47**	**37**	**38**	**56**	**46**
Backlog	0	0	**1**	0	0
% in Backlog	0%	0%	**3%**	0%	0%
Priority (subset)	2	2	1	3	0
Non Backlog	2	2	1	3	0
Backlog	0	0	0	0	0
SNDS-C (Confirmatory)	0	0	0	1	0
Backlog	0	0	0	0	0

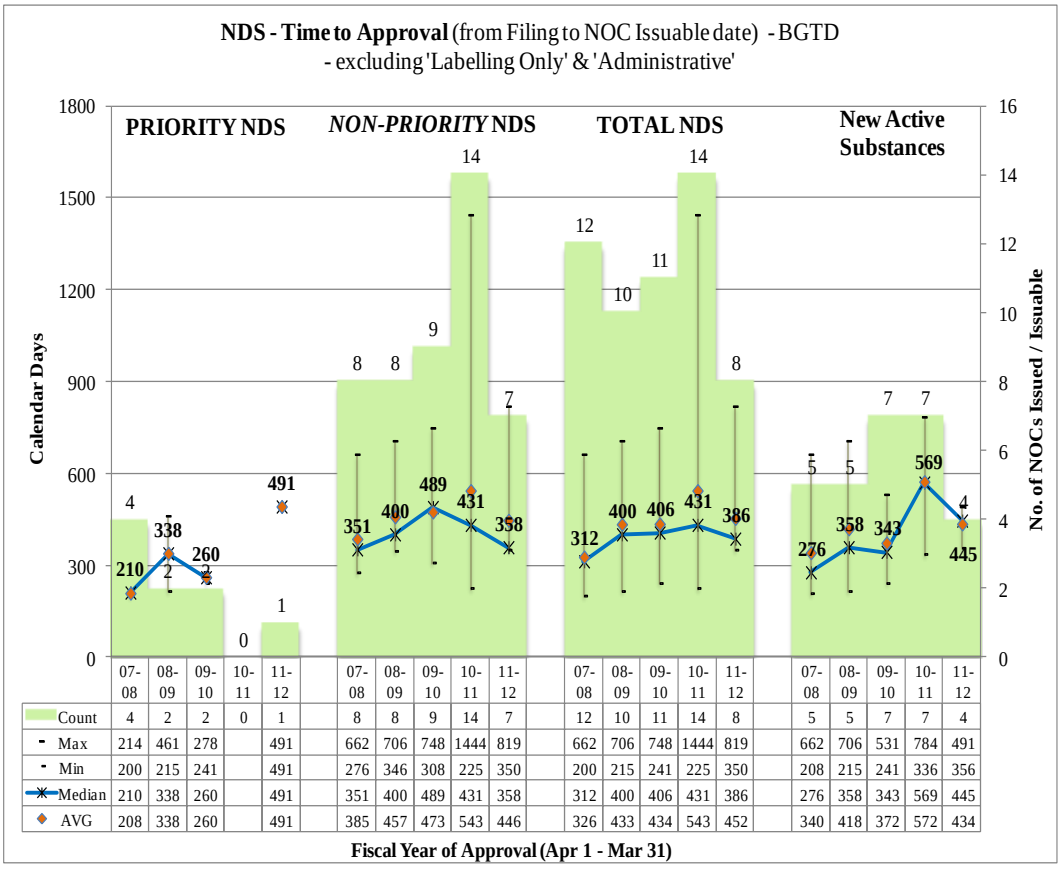
APPROVALS

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



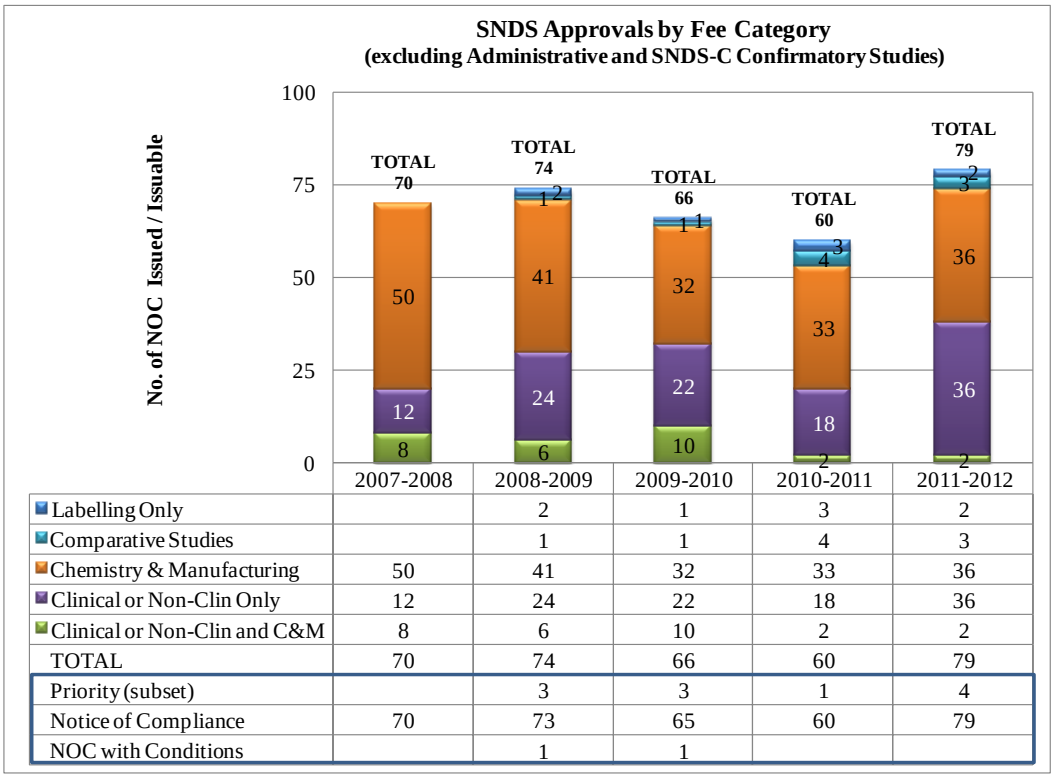
	2007-2008	2008-2009	2009-2010	2010-2011	2011-2012
New Active Substance*	5	5	7	7	4
Chemistry & Manufacturing		2			
Clinical or Non-Clin and C&M	7	3	4	7	4
TOTAL	12	10	11	14	8
NOC with Conditions	1	1			1
Notice of Compliance	11	9	11	14	7
Priority (subset)	4	2	2		1

NDS Approval Times



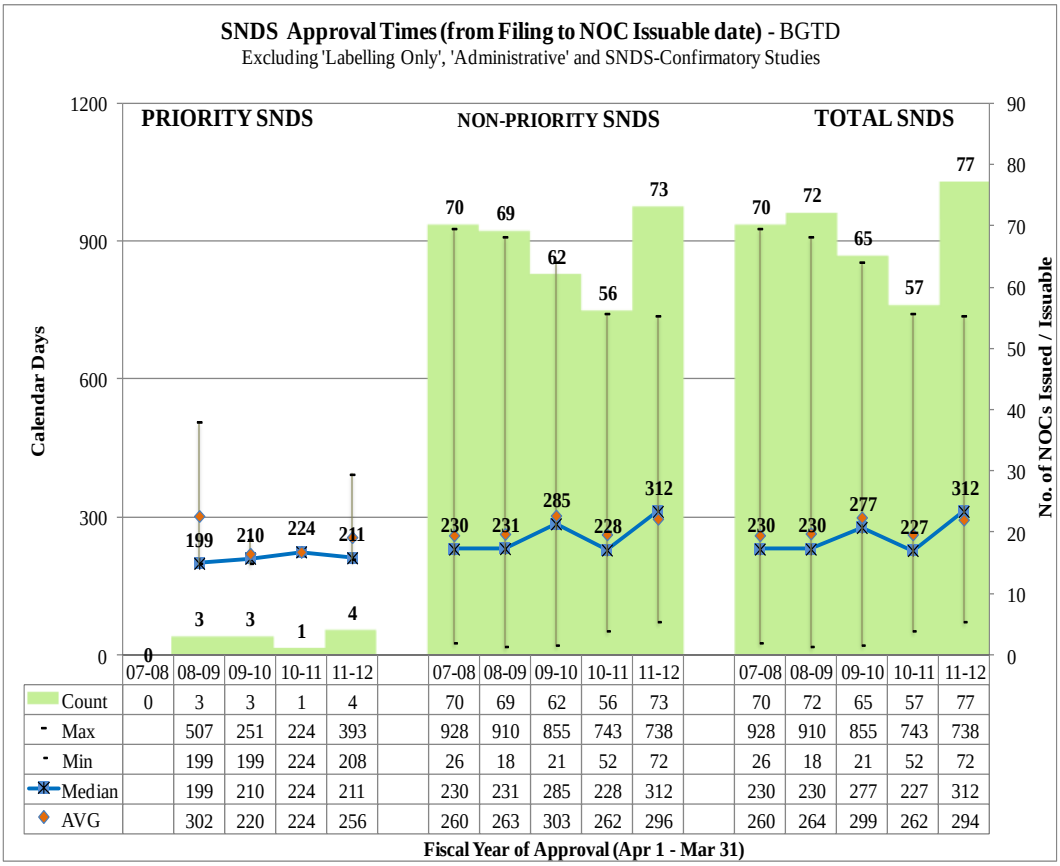
	07-08	08-09	09-10	10-11	11-12	07-08	08-09	09-10	10-11	11-12	07-08	08-09	09-10	10-11	11-12	07-08	08-09	09-10	10-11	11-12
Count	4	2	2	0	1	8	8	9	14	7	12	10	11	14	8	5	5	7	7	4
Max	214	461	278		491	662	706	748	1444	819	662	706	748	1444	819	662	706	531	784	491
Min	200	215	241		491	276	346	308	225	350	200	215	241	225	350	208	215	241	336	356
Median	210	338	260		491	351	400	489	431	358	312	400	406	431	386	276	358	343	569	445
AVG	208	338	260		491	385	457	473	543	446	326	433	434	543	452	340	418	372	572	434

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



	2007-2008	2008-2009	2009-2010	2010-2011	2011-2012
Labelling Only		2	1	3	2
Comparative Studies		1	1	4	3
Chemistry & Manufacturing	50	41	32	33	36
Clinical or Non-Clin Only	12	24	22	18	36
Clinical or Non-Clin and C&M	8	6	10	2	2
TOTAL	70	74	66	60	79
Priority (subset)		3	3	1	4
Notice of Compliance	70	73	65	60	79
NOC with Conditions		1	1		

SNDS Approval Times



	07-08	08-09	09-10	10-11	11-12		07-08	08-09	09-10	10-11	11-12		07-08	08-09	09-10	10-11	11-12
Count	0	3	3	1	4		70	69	62	56	73		70	72	65	57	77
Max		507	251	224	393		928	910	855	743	738		928	910	855	743	738
Min		199	199	224	208		26	18	21	52	72		26	18	21	52	72
Median		199	210	224	211		230	231	285	228	312		230	230	277	227	312
AVG		302	220	224	256		260	263	303	262	296		260	264	299	262	294

New Active Substance Approvals (NAS) – BGTD - Fiscal Year 2011-2012

New Active Substance Approvals (NAS) – BGTD Fiscal Year 2011-2012 (April 1 2011 to March 31 2012)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[7])**	**Approval Date**
ARZERRA (ofatumumab) - is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) refractory to fludarabine and alemtuzumab.	NAS	GlaxoSmithKline Inc.	21-Jan-11	9-Mar-12
BENLYSTA (belimumab) - is indicated in addition to standard therapy for reducing disease activity in adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE).	NAS	GlaxoSmithKline Inc.	15-Jul-10	6-Jul-11
RUBY-FILL (rubidium chloride rb 82) - is indicated as an accessory to positron emission tomography (PET) for imaging of the myocardium, to evaluate regional myocardial perfusion in adult patients, as an aid in the diagnosis or assessment of suspected or known coronary artery disease.	Priority NAS	Jubilant Draximage Inc.	17-May-10	20-Sep-11
YERVOY (ipilimumab) - is indicated for the treatment of unresectable or metastatic melanoma in patients who have failed or do not tolerate other systemic therapy for advanced disease.	NAS	Bristol Myers Squibb	13-Oct-10	1-Feb-12

[7] The CR Date is the date the submission is received and considered administratively complete by Health Canada

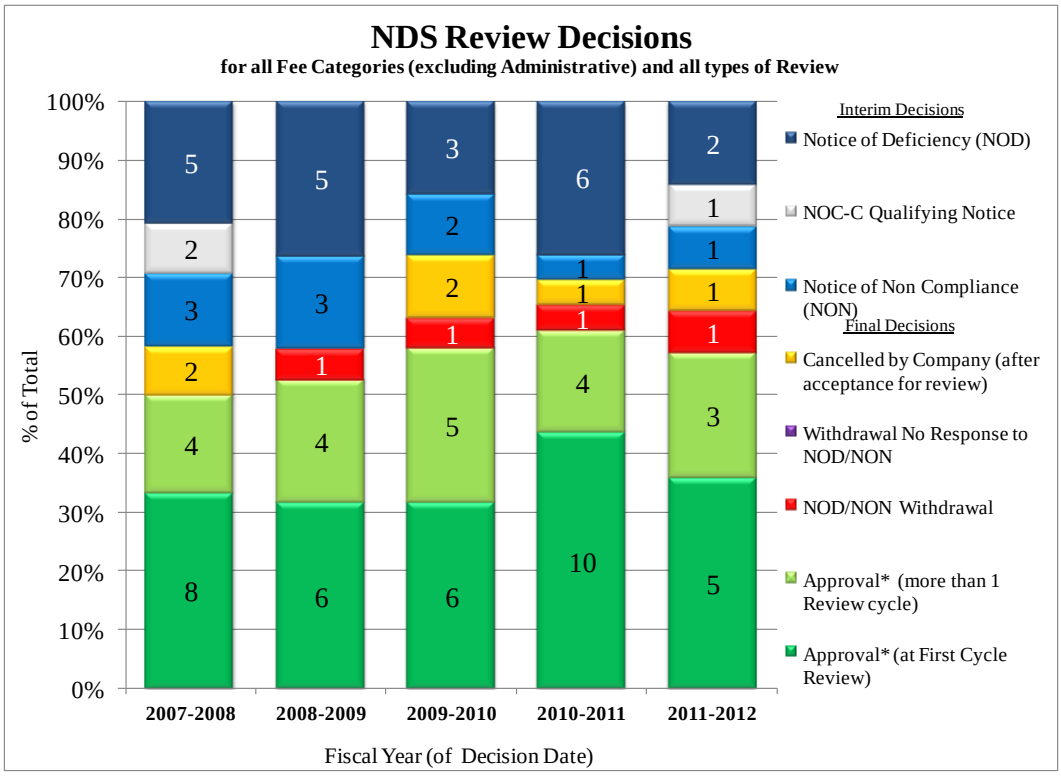
PRIORITY SUBMISSION APPROVALS – BGTD - Fiscal Year 2011-2012

Priority Submission Approvals – BGTD Fiscal Year 2011-2012 (April 1 2011 to March 31 2012)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[8])**	**Approval Date**
BOTOX (botulinum toxin type A) - is indicated: **Neurogenic Detrusor Overactivity associated with a neurological condition** - for the treatment of urinary incontinence due to neurogenic detrusor overactivity resulting from neurogenic bladder associated with multiple sclerosis or subcervical spinal cord injury in adults who had an inadequate response to or are intolerant of anticholinergic medications.	Priority Clin Only	Allergan Inc.	23-Nov-10	21-Dec-11
LUCENTIS (ranibizumab) - is indicated for the treatment of visual impairment due to macular edema secondary to retinal vein occlusion (RVO).	Priority Clin Only	Novartis Pharmaceuticals Canada Inc.	29-Dec-10	25-Jul-11
REMICADE (infliximab) - is indicated for: reduction of signs and symptoms, induction and maintenance of clinical remission, and induction of mucosal healing in pediatric patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy (i.e.,aminosalicylate and/or corticosteroid and/or an immunosuppressant).	Priority Clin Only	Janssen Inc	31-Jan-11	31-Aug-11
RITUXAN (rituximab) - RITUXAN in combination with glucocorticoids is indicated for the induction of remission in adult patients with severely active Granulomatosis with Polyangiitis (GPA, also known as Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA). Consideration should be given to current treatment guidelines for vasculitis.	Priority Clin Only	Hoffmann La Roche Limited	17-May-11	12-Dec-11
RUBY-FILL (rubidium chloride rb 82) - is indicated as an accessory to positron emission tomography (PET) for imaging of the myocardium, to evaluate regional myocardial perfusion in adult patients, as an aid in the diagnosis or assessment of suspected or known coronary artery disease.	Priority -NAS	Jubilant Draximage Inc.	17-May-10	20-Sep-11

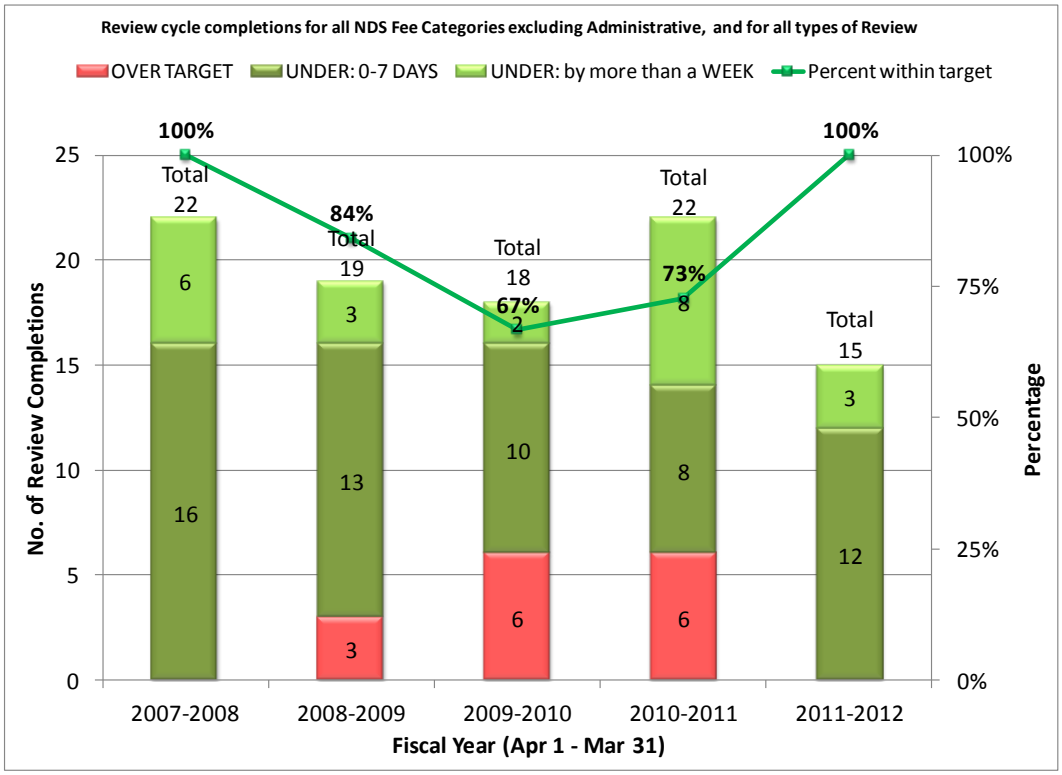
[8] The CR Date is the date the submission is received and considered administratively complete by Health Canada

REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

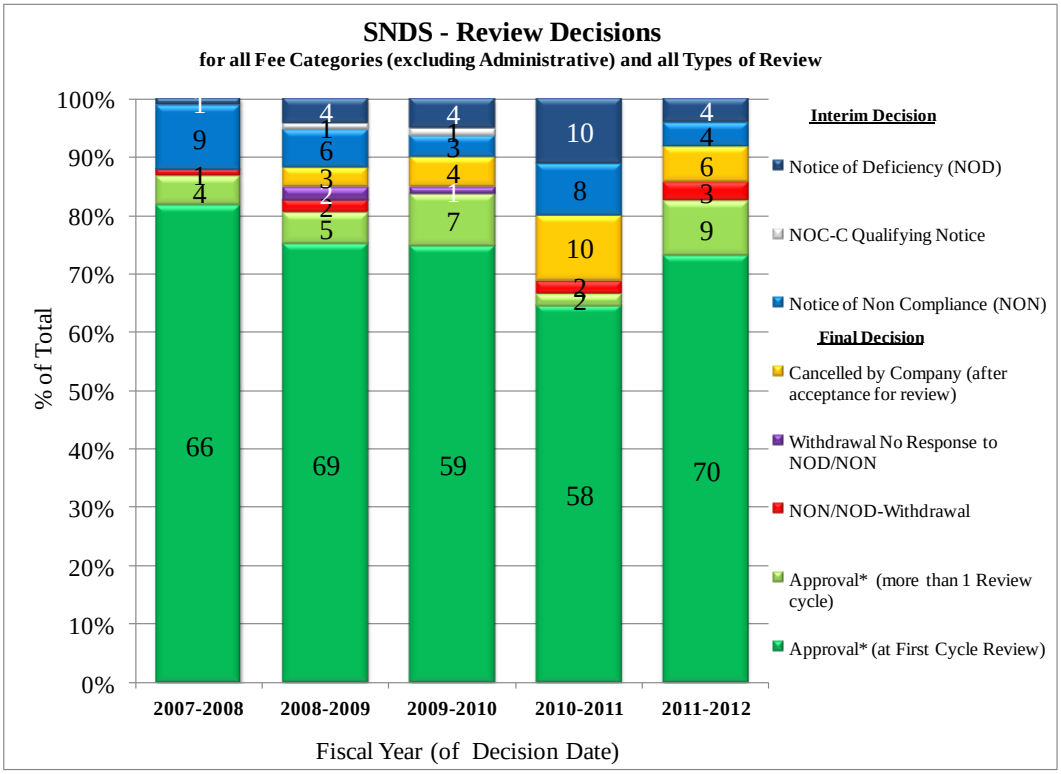


NDS - Review Cycle Completions Showing Percentage Within Target

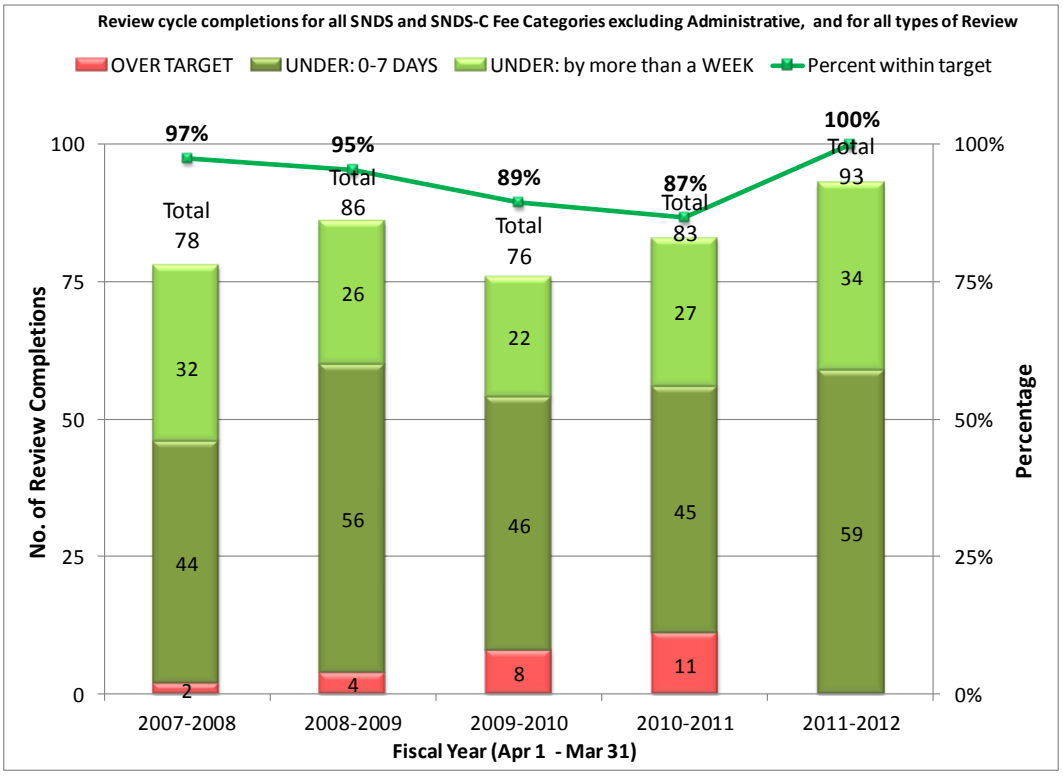


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

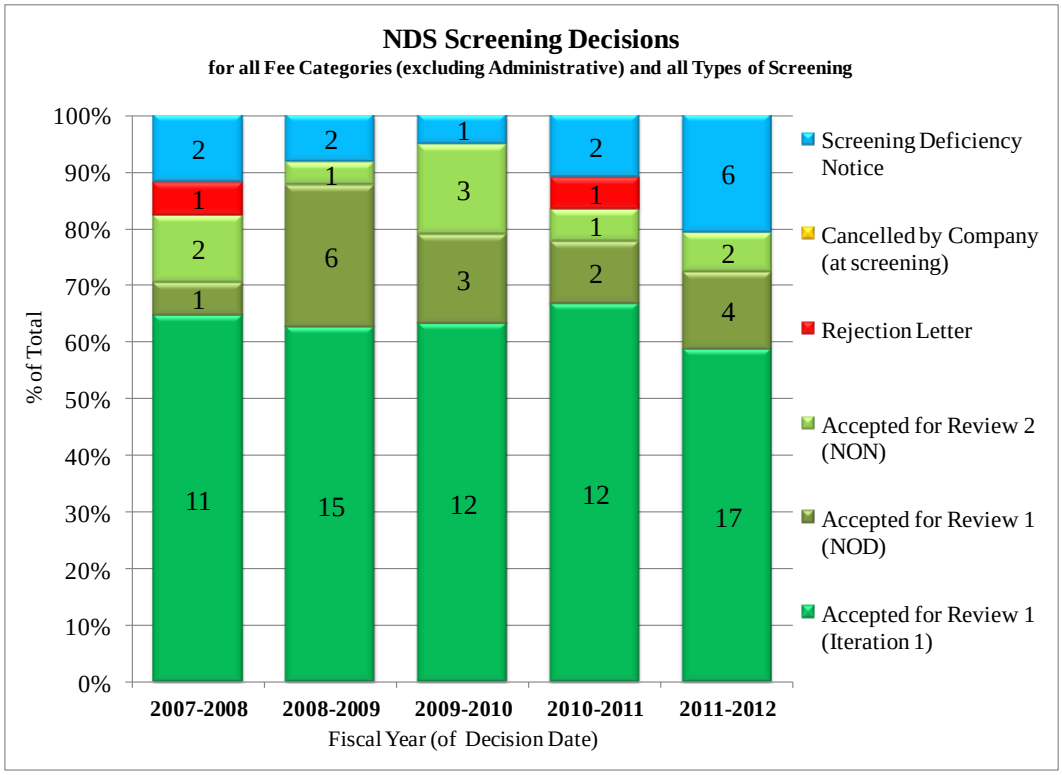


SNDS - Review Cycle Completions Showing Percentage Within Target

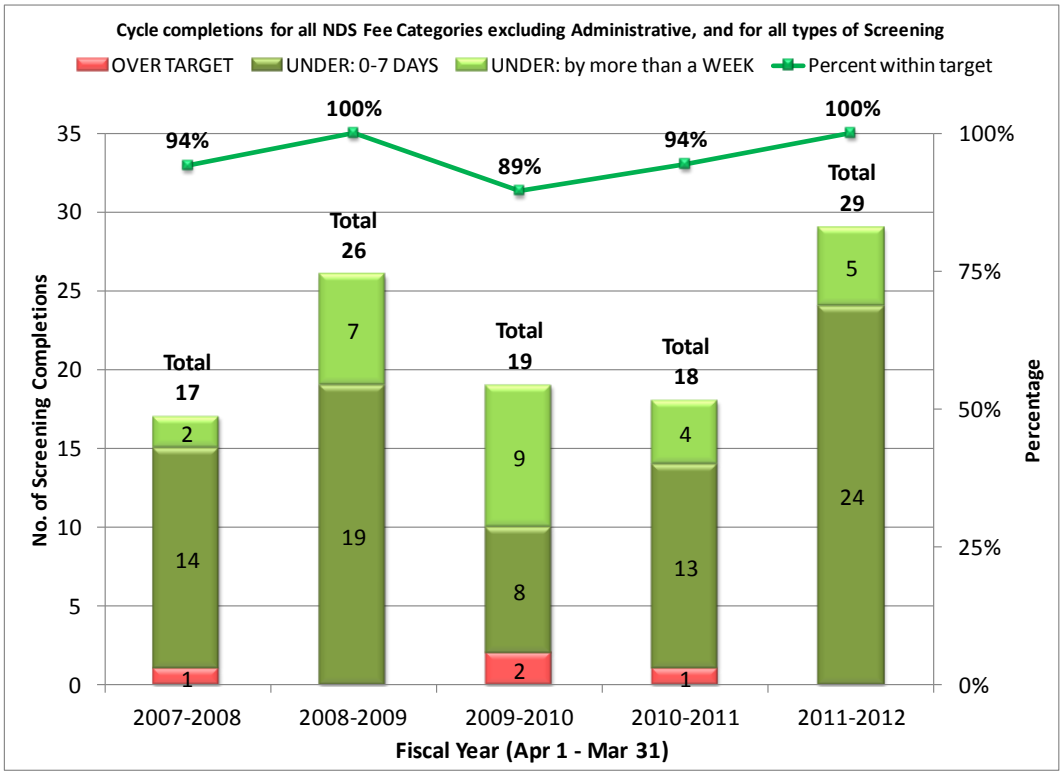


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

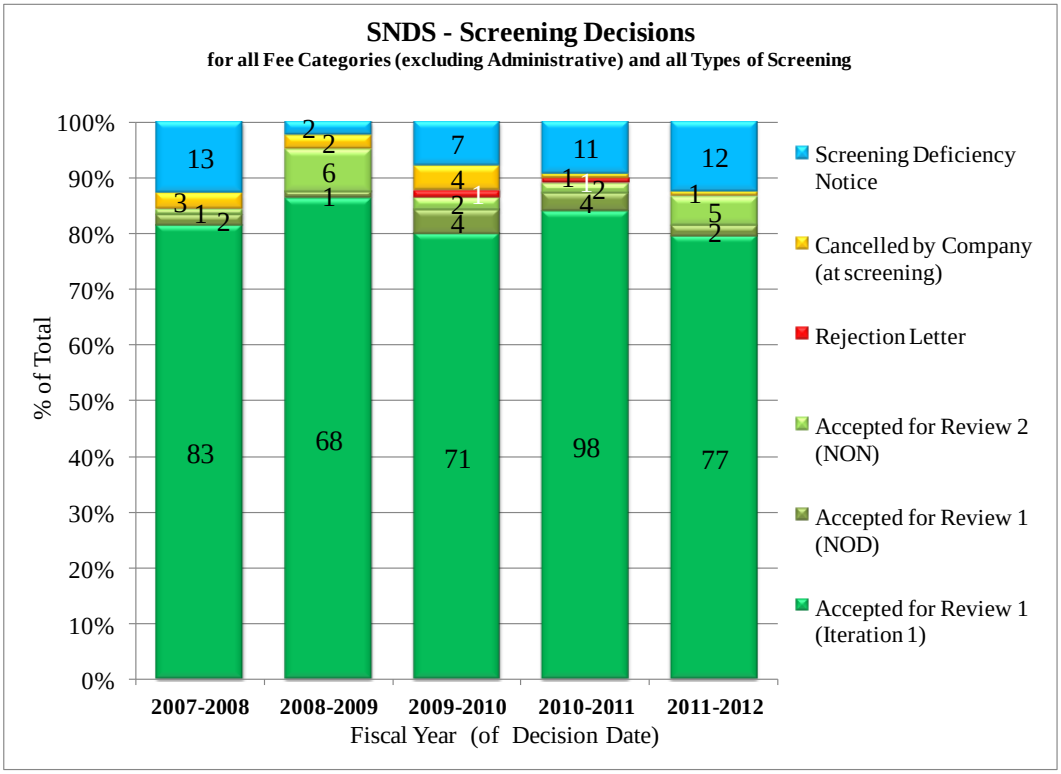


NDS - Screening Cycle Completions Showing Percentage Within Target

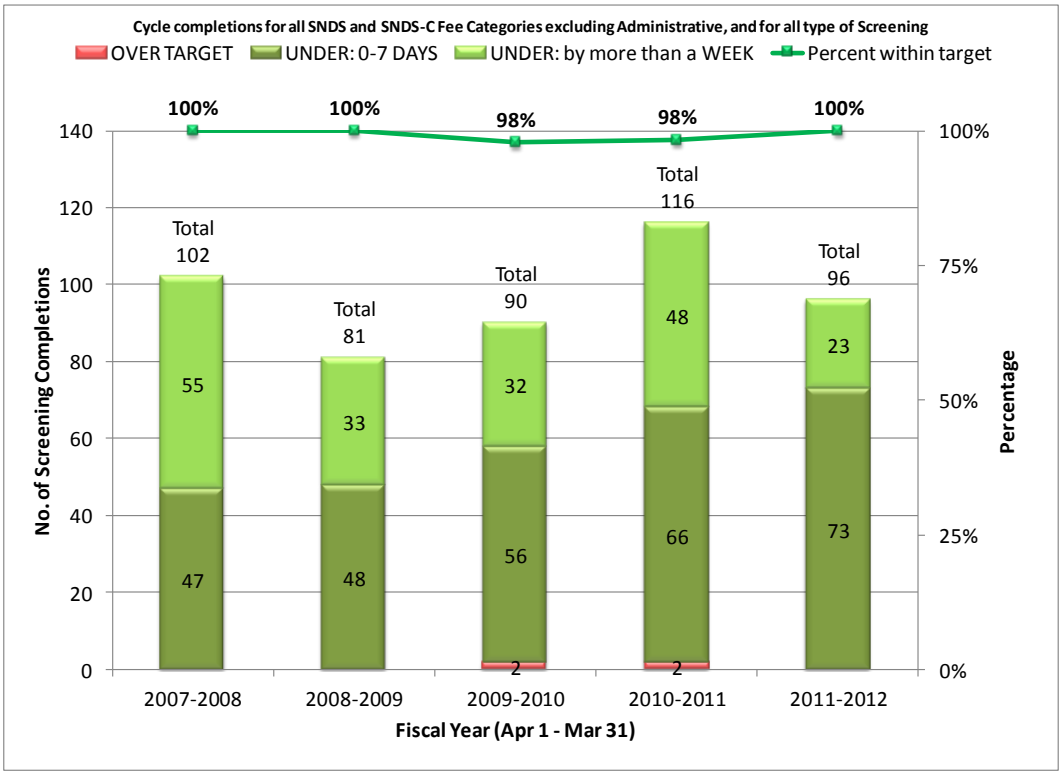


SCREENING CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Screening Decisions



SNDS - Screening Cycle Completions Showing Percentage Within Target



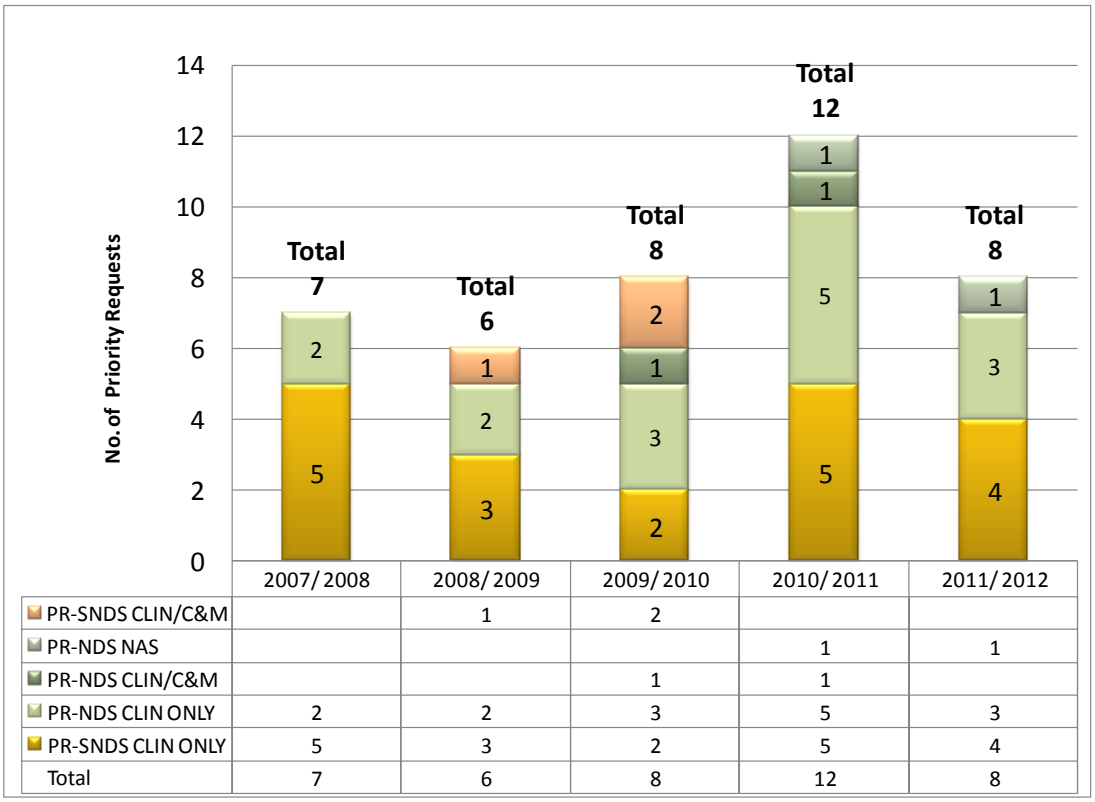
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – New Drug Submissions & Supplemental New Drug Submissions (NDS & SNDS)

NDS & SNDS					
	Year of Reconsideration Request				
	07-08	08-09	09-10	10-11	11-12
NDS Total	0	0	0	0	0
SNDS Total	0	0	0	0	0

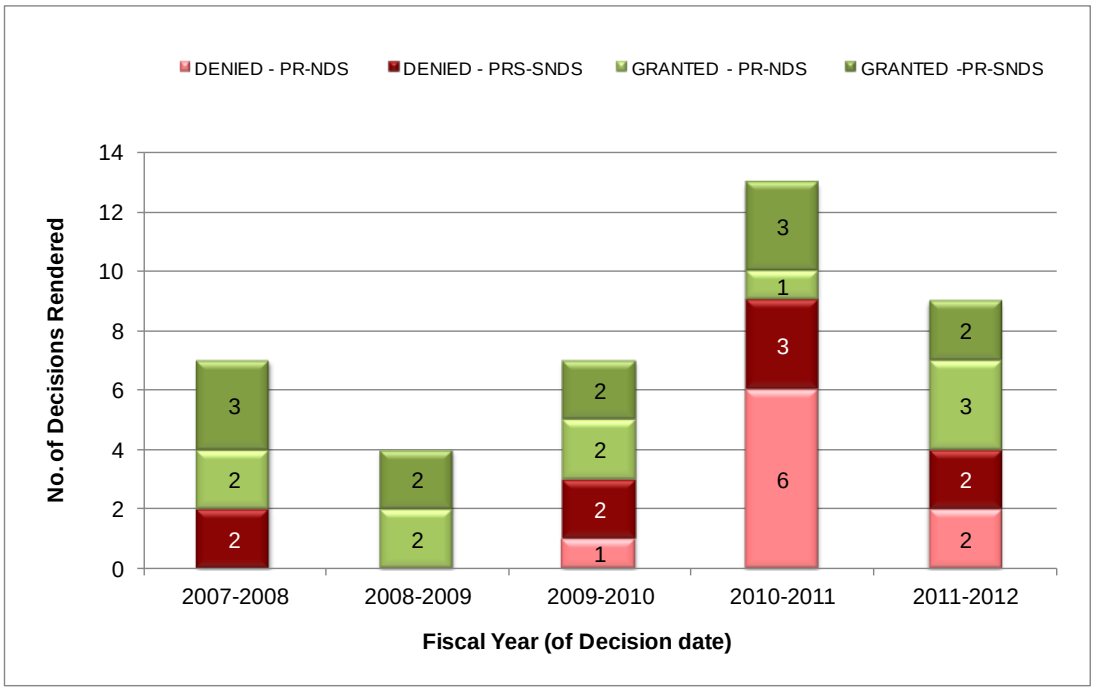
PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests Received



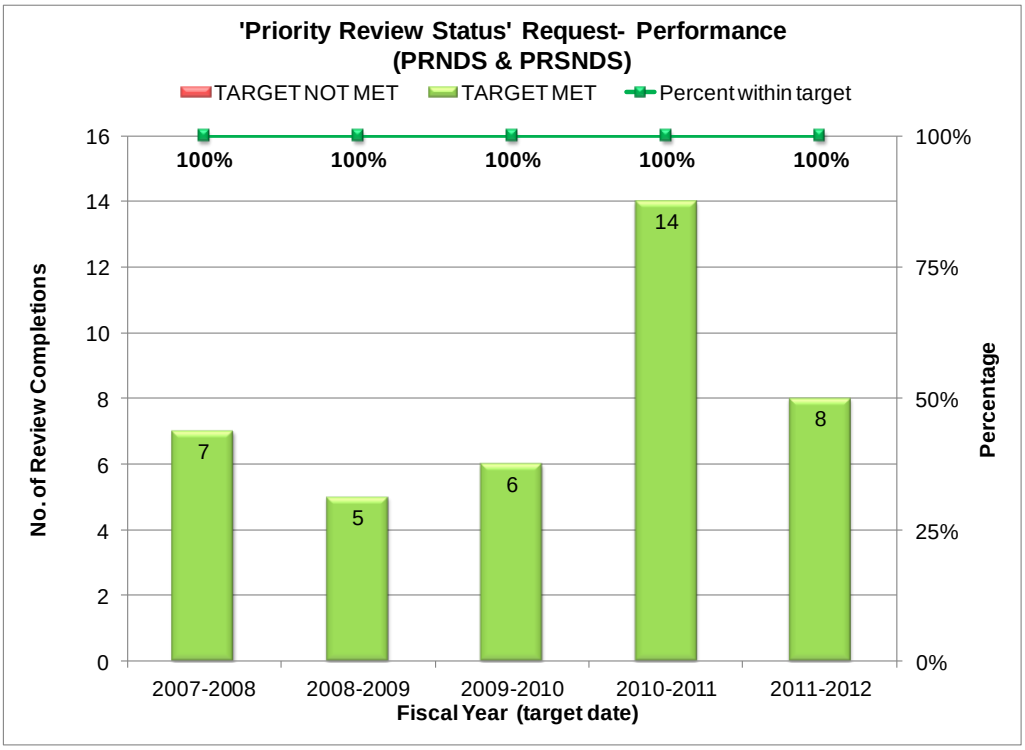
	2007/2008	2008/2009	2009/2010	2010/2011	2011/2012
PR-SNDS CLIN/C&M		1	2		
PR-NDS NAS				1	1
PR-NDS CLIN/C&M			1	1	
PR-NDS CLIN ONLY	2	2	3	5	3
PR-SNDS CLIN ONLY	5	3	2	5	4
Total	7	6	8	12	8

Priority Review Status Requests: Decisions Rendered



PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests: Performance



REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

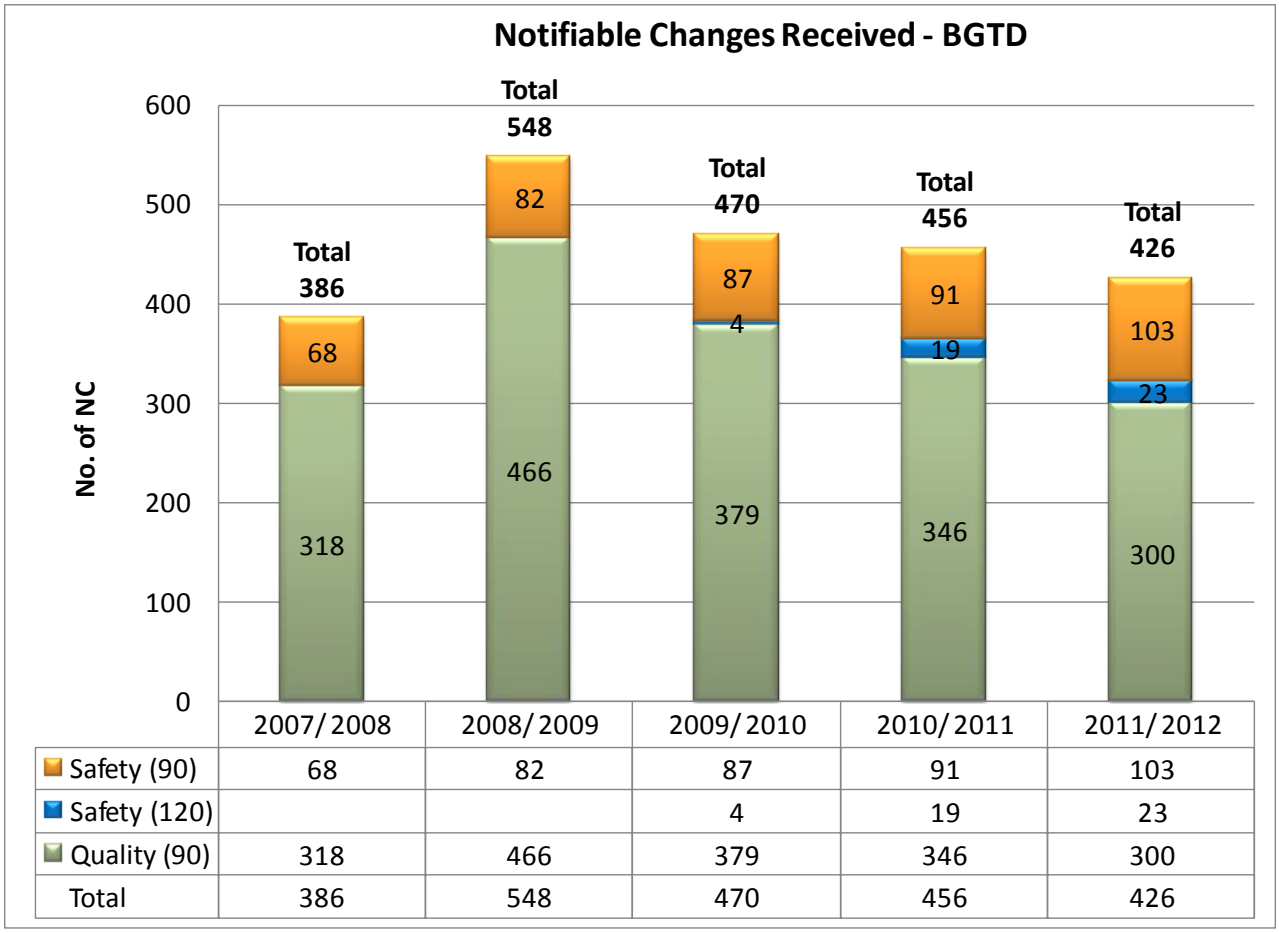
Requests for Reconsideration of Final Decisions – Priority Review Requests (for NDS and SNDS)

Priority Review Requests (for NDS and SNDS)					
	Year of Reconsideration Request				
	07-08	08-09	09-10	10-11	11-12
Total	0	0	0	0	0

NOTIFIABLE CHANGES (NC)

NOTIFIABLE CHANGES[9,10]

Number Received - Notifiable Changes (NC)



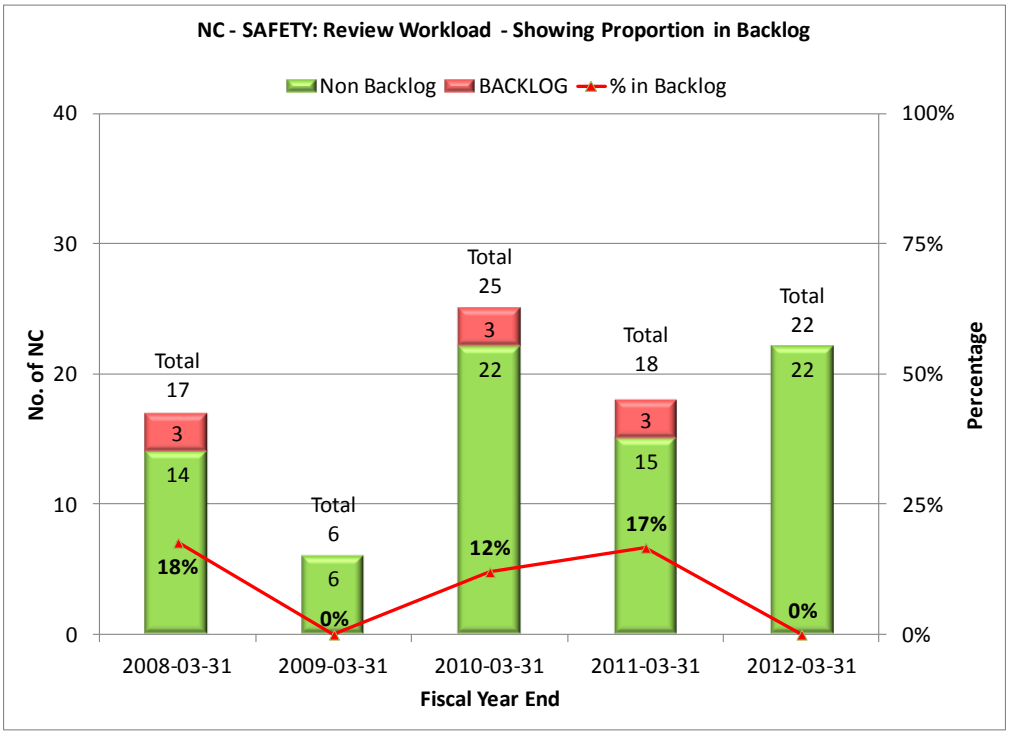
	2007/2008	2008/2009	2009/2010	2010/2011	2011/2012
Safety (90)	68	82	87	91	103
Safety (120)			4	19	23
Quality (90)	318	466	379	346	300
Total	386	548	470	456	426

9 Post-Notice of Compliance (NOC) Changes Guidance Documents became effective as of September 30, 2009. http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/postnoc_change_apresac/noc_postnotice_ac_apresavis_change-eng.php

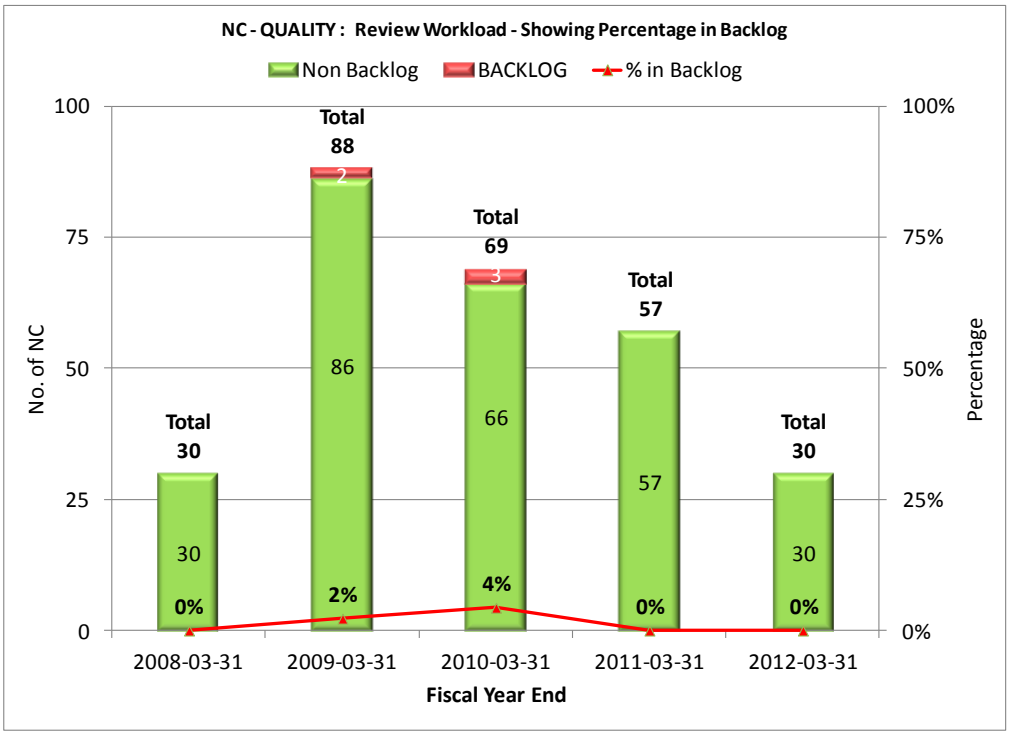
10 Post-Notice of Compliance (NOC) Changes - Quality Guidance Appendix 1 for Human Pharmaceuticals became effective October 17, 2011.

WORKLOAD

Notifiable Change (NC) SAFETY: Review Workload / Backlog



Notifiable Change (NC) QUALITY: Review Workload / Backlog



Post-Notice of Compliance (NOC) Changes Guidance Documents became effective as of September 30, 2009.
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/postnoc_change_apresac/noc_postnotice_ac_apresavis_change-eng.php
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 by Class

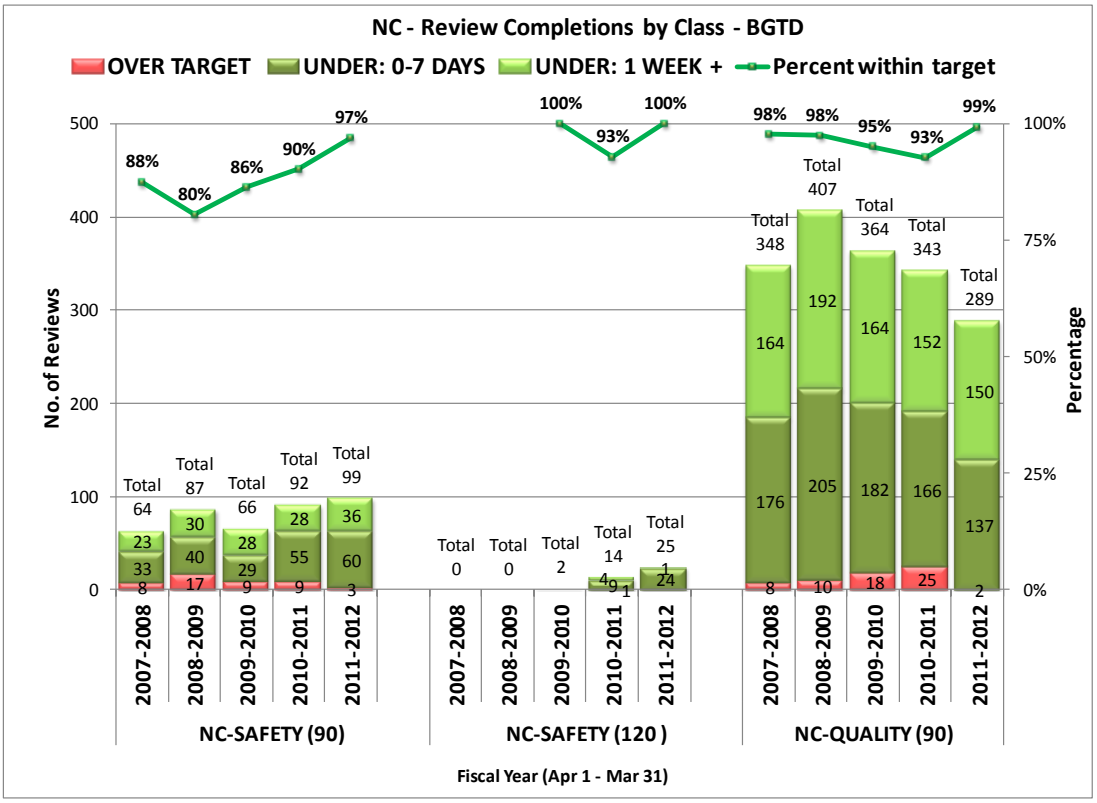
BGTD NC- SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2008-03-31	2009-03-31	2010-03-31	2011-03-31	2012-03-31
SAFETY - 90 day	17	6	24	15	20
Backlog	3	0	3	3	0
SAFETY - 120 day	0	0	1	3	2
	0	0	0	0	0
Total	17	6	25	18	22
Non Backlog	14	6	22	15	22
BACKLOG	3	0	3	3	0
% in Backlog	18%	0%	12%	17%	0%

Notifiable Change (NC) QUALITY: Review Workload by Class

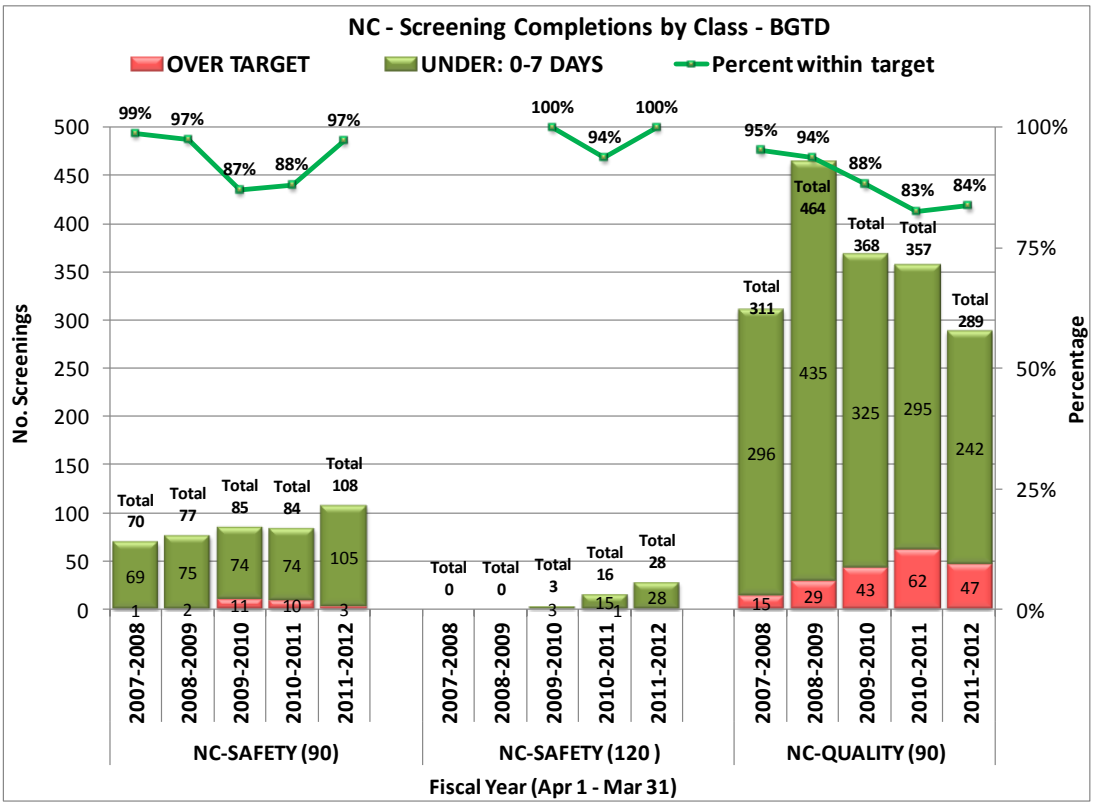
BGTD NC- QUALITY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2008-03-31	2009-03-31	2010-03-31	2011-03-31	2012-03-31
QUALITY - 90 day	30	88	69	57	30
Backlog	0	2	3	0	0
Total	30	88	69	57	30
Non Backlog	30	86	66	57	30
BACKLOG	0	2	3	0	0
% in Backlog	0%	2%	4%	0%	0%

PERFORMANCE

REVIEW Completions by Class - Notifiable Changes (NC)



SCREENING Completions by Class - Notifiable Changes (NC)



Decision Documents by Class - Notifiable Change (NC)

NC - QUALITY (90)					
DOCUMENT TYPE	**2007-2008**	**2008-2009**	**2009-2010**	**2010-2011**	**2011-2012**
NO OBJECTION LETTER	343	405	368	330	315
NOT SATISFACTORY NOTICE	1		17	26	27
REJECTION LETTER (SCREENING)		1		3	5
CANCELLED BY COMPANY	3	11	11	9	7
SCREENING DEFICIENCY NOTICE	3	1	10	15	7

NC - SAFETY (90)					
DOCUMENT TYPE	**2007-2008**	**2008-2009**	**2009-2010**	**2010-2011**	**2011-2012**
NO OBJECTION LETTER	61	83	66	89	98
NOT SATISFACTORY NOTICE	2	2	1		
REJECTION LETTER (SCREENING)		1		3	5
CANCELLED BY COMPANY		3	1	7	4
SCREENING DEFICIENCY NOTICE	1				2

NC - SAFETY (120)					
DOCUMENT TYPE	**2007-2008**	**2008-2009**	**2009-2010**	**2010-2011**	**2011-2012**
NO OBJECTION LETTER			2	13	25
NOT SATISFACTORY NOTICE				1	
REJECTION LETTER (SCREENING)					3
SCREENING DEFICIENCY NOTICE					1

REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – Notifiable Changes (NC)

NC					
	Year of Reconsideration Request				
	07-08	**08-09**	**09-10**	**10-11**	**11-12**
Total	**0**	**0**	**0**	**0**	**0**

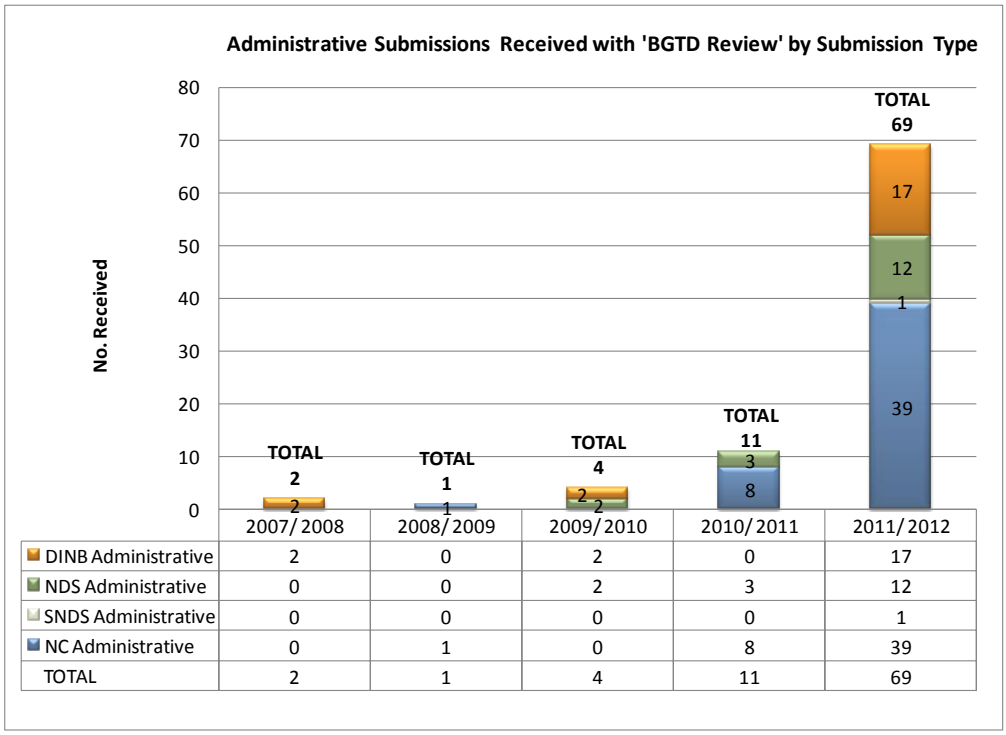
Administrative Submissions

Submissions in support of a manufacturer or product name change.

ADMINISTRATIVE SUBMISSIONS with BGTD review

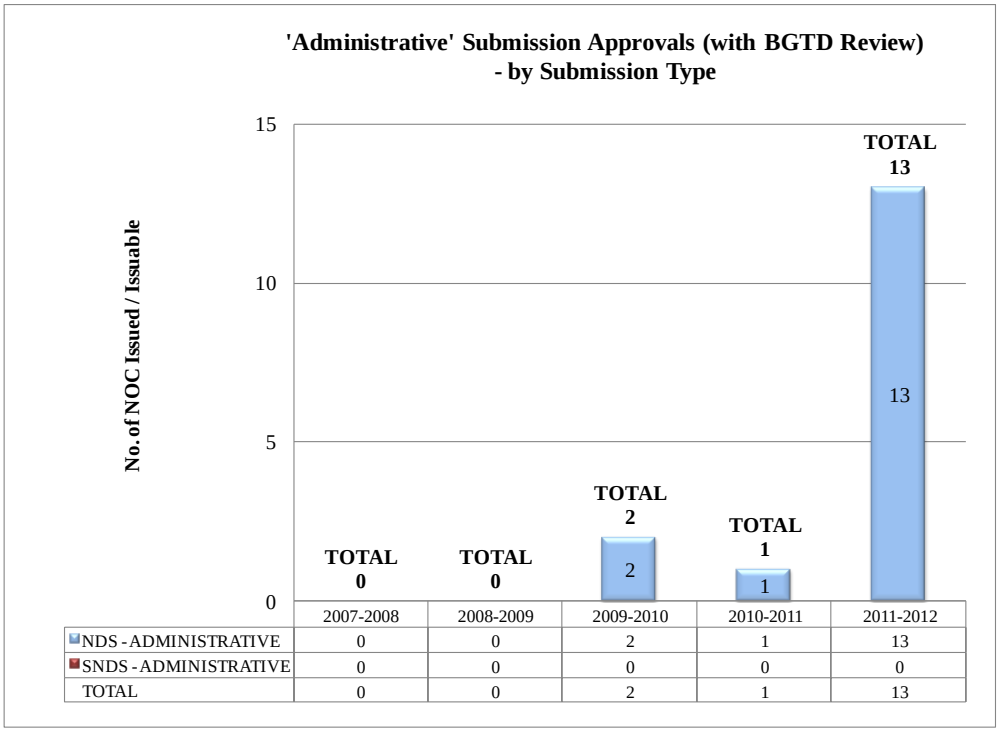
(such as product name change that requires a drug name review)

Administrative Submissions Received (with BGTD review)



	2007/2008	2008/2009	2009/2010	2010/2011	2011/2012
DINB Administrative	2	0	2	0	17
NDS Administrative	0	0	2	3	12
SNDS Administrative	0	0	0	0	1
NC Administrative	0	1	0	8	39
TOTAL	2	1	4	11	69

Administrative Submission Approvals (with BGTD Review)

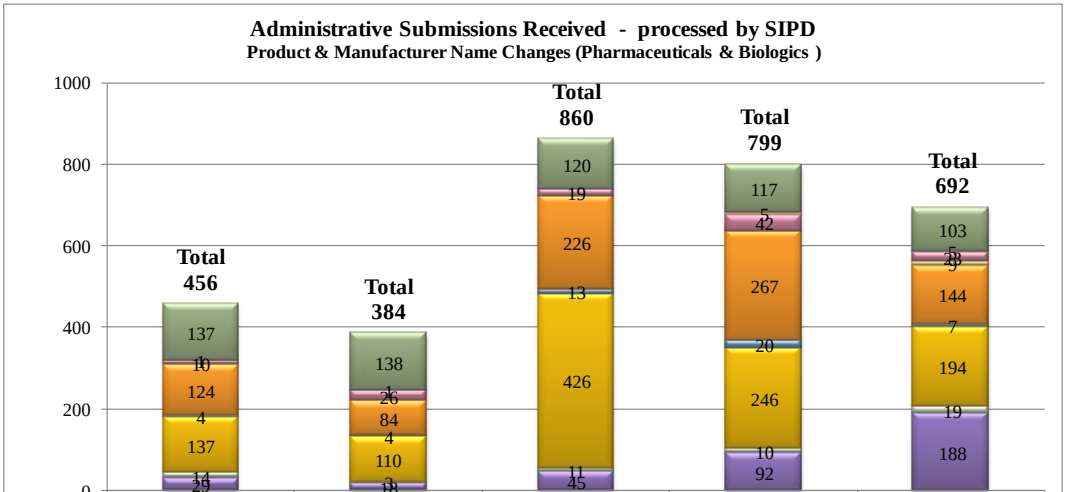


	2007-2008	2008-2009	2009-2010	2010-2011	2011-2012
NDS - ADMINISTRATIVE	0	0	2	1	13
SNDS - ADMINISTRATIVE	0	0	0	0	0
TOTAL	0	0	2	1	13

ADMINISTRATIVE SUBMISSIONS (Processed by SIPD)

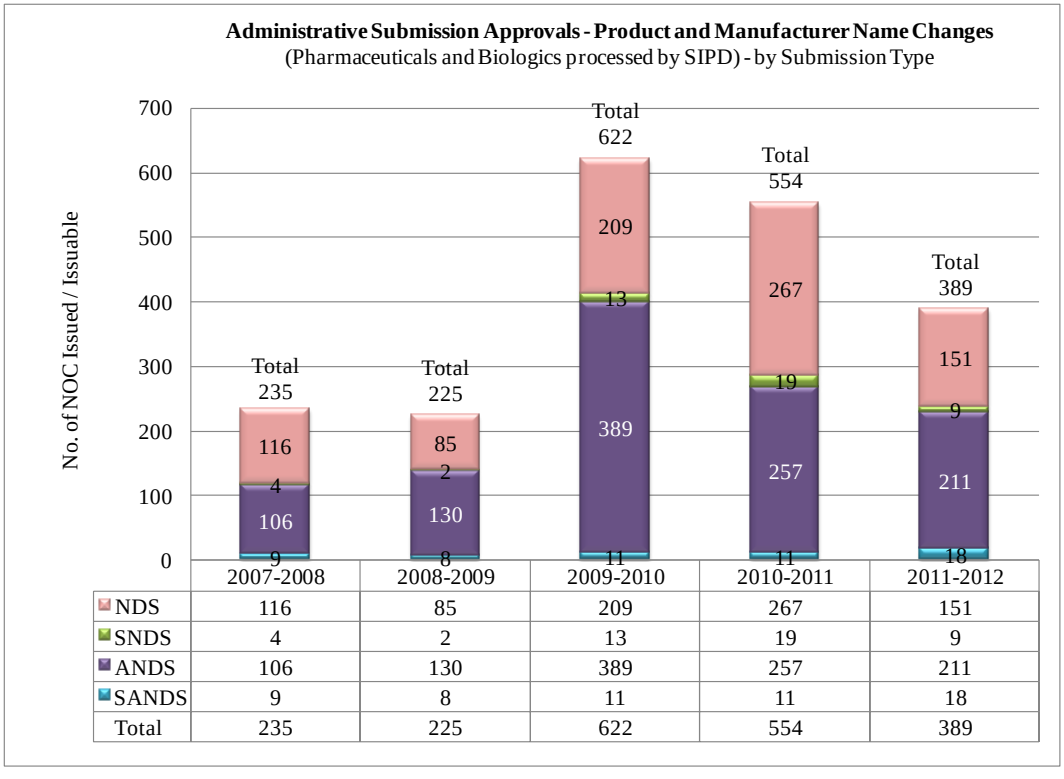
(Product & Manufacturer Name Changes)

Administrative Submissions Received by Submission Type (SIPD)



	2007/2008	2008/2009	2009/2010	2010/2011	2011/2012
DINA	137	138	120	117	103
DINB	1	1		5	5
DIND	10	26	19	42	23
PDC					9
NDS	124	84	226	267	144
SNDS	4	4	13	20	7
ANDS	137	110	426	246	194
SANDS	14	3	11	10	19
NC	29	18	45	92	188
Total	456	384	860	799	692

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



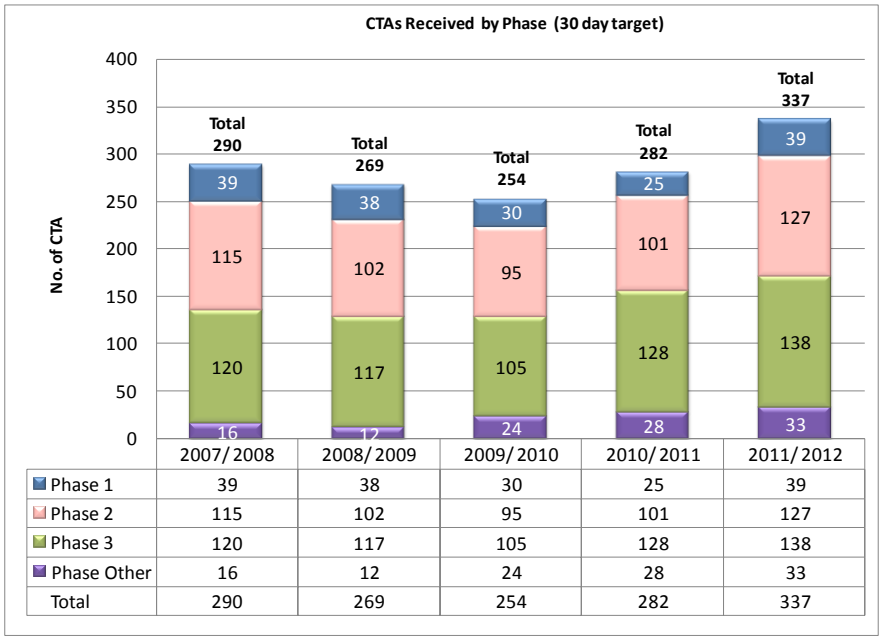
	2007-2008	2008-2009	2009-2010	2010-2011	2011-2012
NDS	116	85	209	267	151
SNDS	4	2	13	19	9
ANDS	106	130	389	257	211
SANDS	9	8	11	11	18
Total	235	225	622	554	389

Clinical Trial Applications and Amendments

(CTA & CTA-A)

CLINICAL TRIAL APPLICATIONS

Number Received - Clinical Trial Application (CTA)

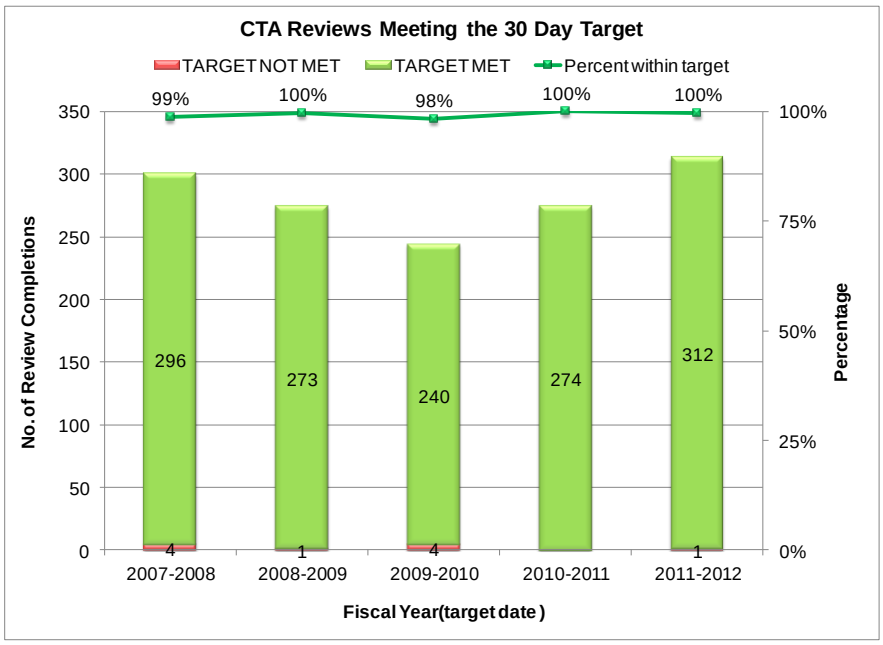


	2007/2008	2008/2009	2009/2010	2010/2011	2011/2012
Phase 1	39	38	30	25	39
Phase 2	115	102	95	101	127
Phase 3	120	117	105	128	138
Phase Other	16	12	24	28	33
Total	290	269	254	282	337

Decision Documents - Clinical Trial Application (CTA)

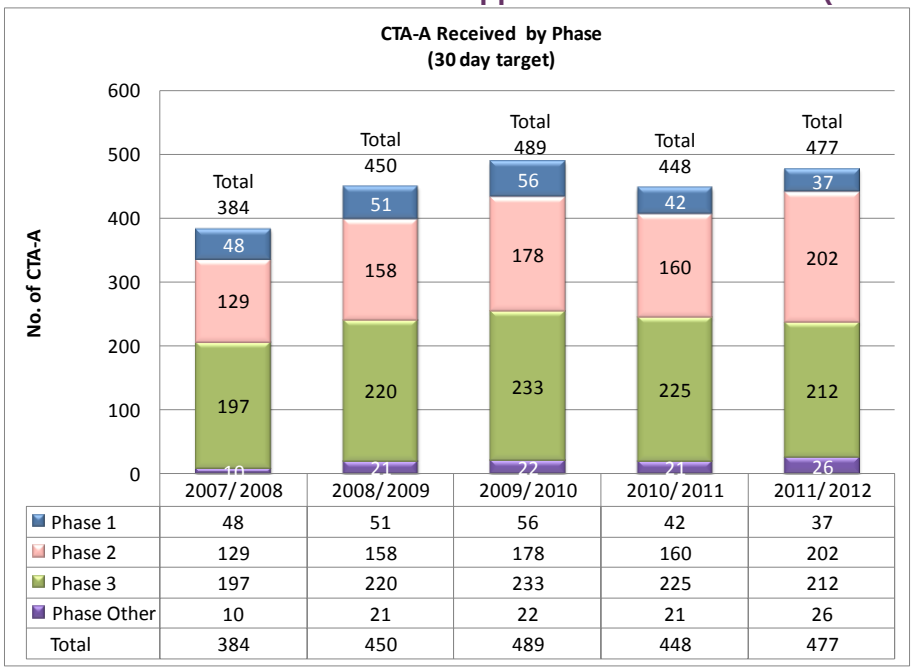
CTA (30 day target)					
DOCUMENT TYPE	**2007-2008**	**2008-2009**	**2009-2010**	**2010-2011**	**2011-2012**
NO OBJECTION LETTER	257	245	233	272	299
CANCELLED BY COMPANY	13	16	17	8	22
NOT SATISFACTORY NOTICE	3	1		3	2
REFUSAL LETTER		1	1		
REJECTION LETTER	1	3		1	1

Performance - Clinical Trials Applications (CTA) Reviews Meeting the 30 Day Target



CLINICAL TRIAL APPLICATION-AMENDMENTS

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

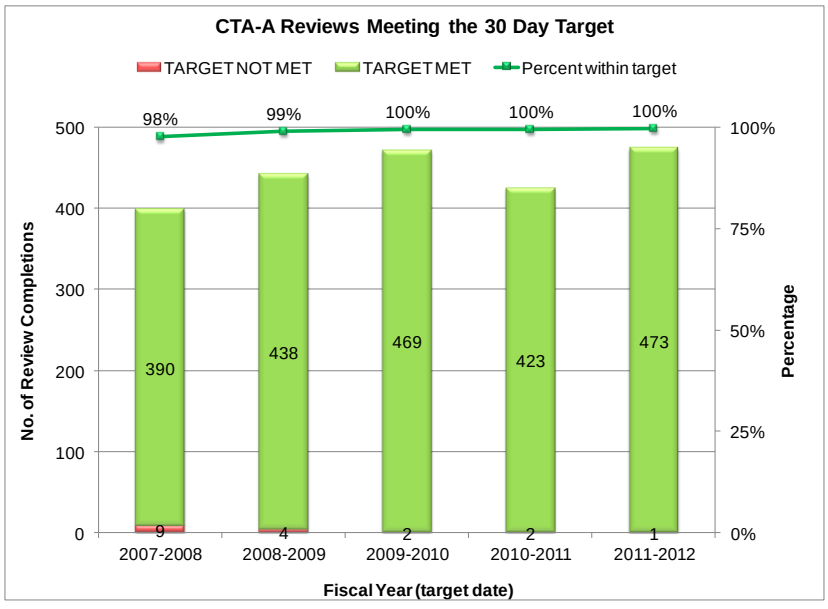


	2007/2008	2008/2009	2009/2010	2010/2011	2011/2012
Phase 1	48	51	56	42	37
Phase 2	129	158	178	160	202
Phase 3	197	220	233	225	212
Phase Other	10	21	22	21	26
Total	384	450	489	448	477

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

CTA-A (30 day target)					
DOCUMENT TYPE	**2007-2008**	**2008-2009**	**2009-2010**	**2010-2011**	**2011-2012**
NO OBJECTION LETTER	376	430	474	433	475
CANCELLED BY COMPANY	5	8	12	6	5
NOT SATISFACTORY NOTICE	2			2	3
REJECTION LETTER	1		1	6	

Performance - Clinical Trial Application Amendments (CTA-A) Reviews Meeting the 30 Day Target



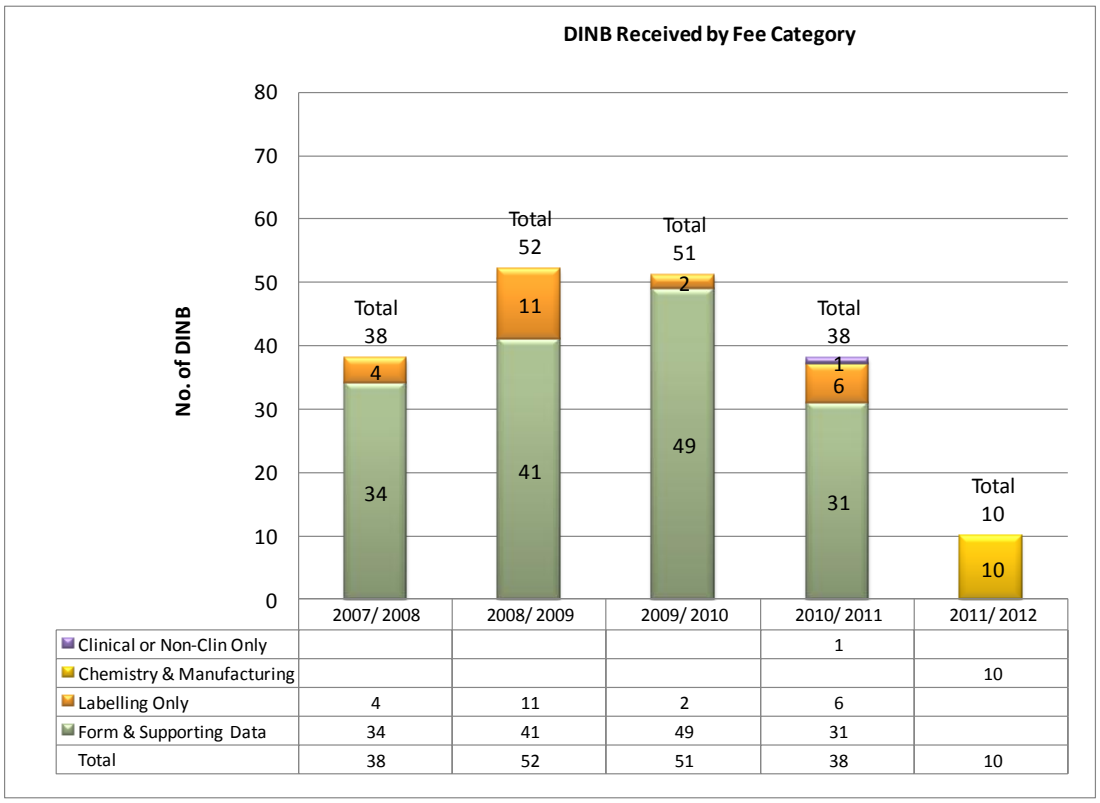
Application for a Drug Identification Number

DINB

Biological Products

DINB: Application for a Drug Identification Number – BIOLOGICAL Products

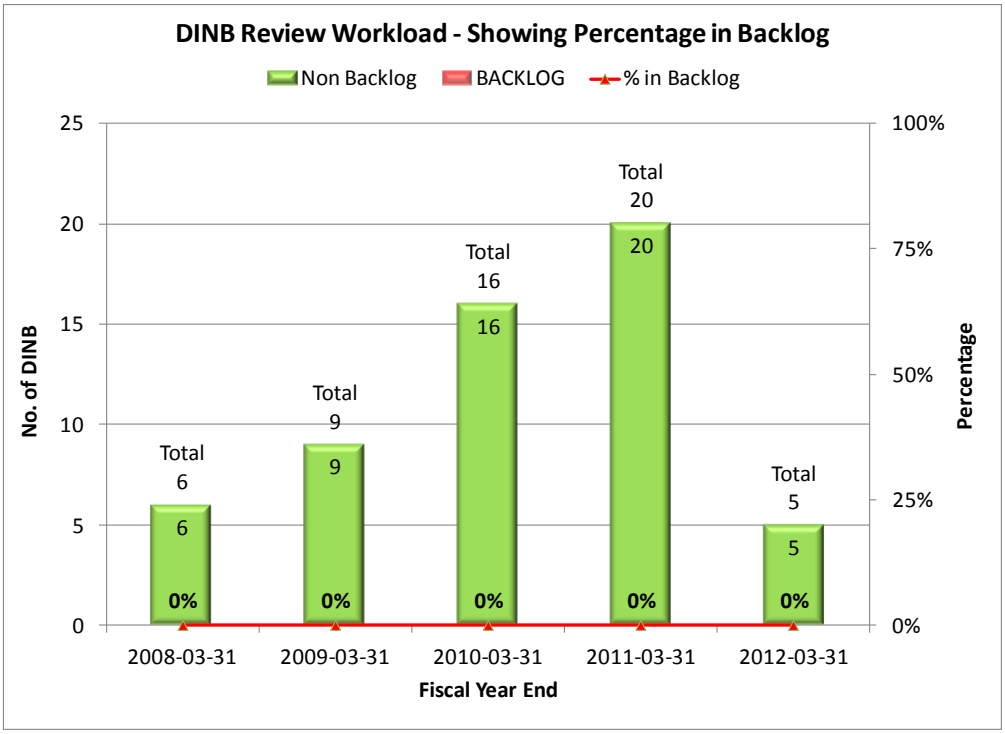
Number Received - DINB



	2007/ 2008	2008/ 2009	2009/ 2010	2010/ 2011	2011/ 2012
Clinical or Non-Clin Only				1	
Chemistry & Manufacturing					10
Labelling Only	4	11	2	6	
Form & Supporting Data	34	41	49	31	
Total	38	52	51	38	10

REVIEW WORKLOAD

Review Workload / Backlog – Showing Percentage in Backlog - DINB

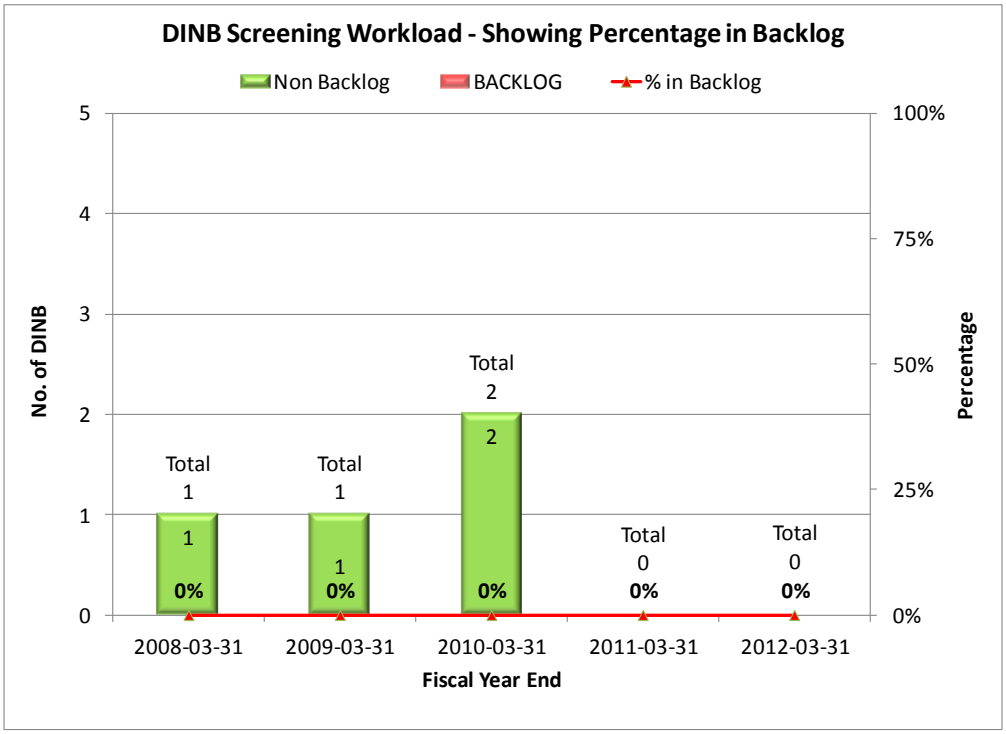


Review Workload by Class - DINB

BGTD DINB All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2008-03-31	2009-03-31	2010-03-31	2011-03-31	2012-03-31
FORM	0	0	0	**5**	0
Backlog	0	0	0	0	0
Form and Supporting Data	**6**	**9**	**16**	**15**	**1**
Backlog	0	0	0	0	0
Chemistry & Manufacturing	0	0	0	0	**4**
Backlog	0	0	0	0	0
Total	**6**	**9**	**16**	**20**	**5**
Non Backlog	**6**	**9**	**16**	**20**	**5**
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 (excluding dministrative) and Fiscal Year End					
	2008-03-31	2009-03-31	2010-03-31	2011-03-31	2012-03-31
FORM	0	0	0	0	0
Backlog	0	0	0	0	0
Form & Supporting Data	**1**	0	**1**	0	0
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	0	**1**	**1**	0	0
Backlog	0	0	0	0	0
Chemistry & Manufacturing	0	0	0	0	0
Backlog	0	0	0	0	0
Total	**1**	**1**	**2**	0	0
Non Backlog	**1**	**1**	**2**	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DECISION DOCUMENTS

Decision Documents – DINB by class

DINB - FORM					
DOCUMENT TYPE	**2007-2008**	**2008-2009**	**2009-2010**	**2010-2011**	**2011-2012**
NO OBJECTION LETTER	3	12		1	5
SCREENING DEFICIENCY NOTICE				4	
NEW DRUG LETTER SCREEN	1				
NOTICE OF DEFICIENCY		2			

DINB - FORM AND SUPPORTING DATA					
DOCUMENT TYPE	**2007-2008**	**2008-2009**	**2009-2010**	**2010-2011**	**2011-2012**
NO OBJECTION LETTER	35	30	34	33	9
NOTIFICATION FORM DIN SUB					3
NOT SATISFACTORY NOTICE			4		
NOTICE OF DEFICIENCY		1		1	1
NOD WITHDRAWAL LETTER		1			1
REJECTION LETTER (SCREENING)			1		
REFUSAL LETTER		1			
SCREENING DEFICIENCY NOTICE	1			5	

DINB - CLIN ONLY					
DOCUMENT TYPE	**2007-2008**	**2008-2009**	**2009-2010**	**2010-2011**	**2011-2012**
NO OBJECTION LETTER					1

DINB - C&M ONLY					
DOCUMENT TYPE	**2007-2008**	**2008-2009**	**2009-2010**	**2010-2011**	**2011-2012**
NO OBJECTION LETTER					2
NOTICE OF DEFICIENCY					1
SCREENING DEFICIENCY NOTICE					6
CANCELLED BY COMPANY					2

DINB - ADMINISTRATIVE					
DOCUMENT TYPE	**2007-2008**	**2008-2009**	**2009-2010**	**2010-2011**	**2011-2012**
NOTIFICATION FORM	1		2		6

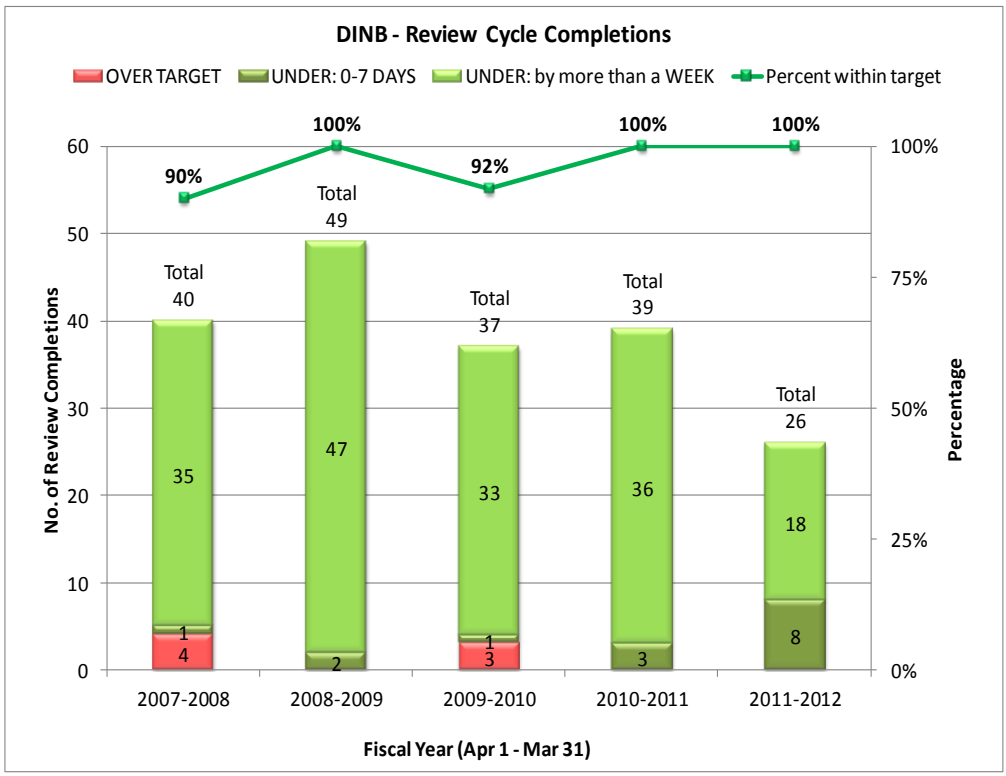
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – DINB

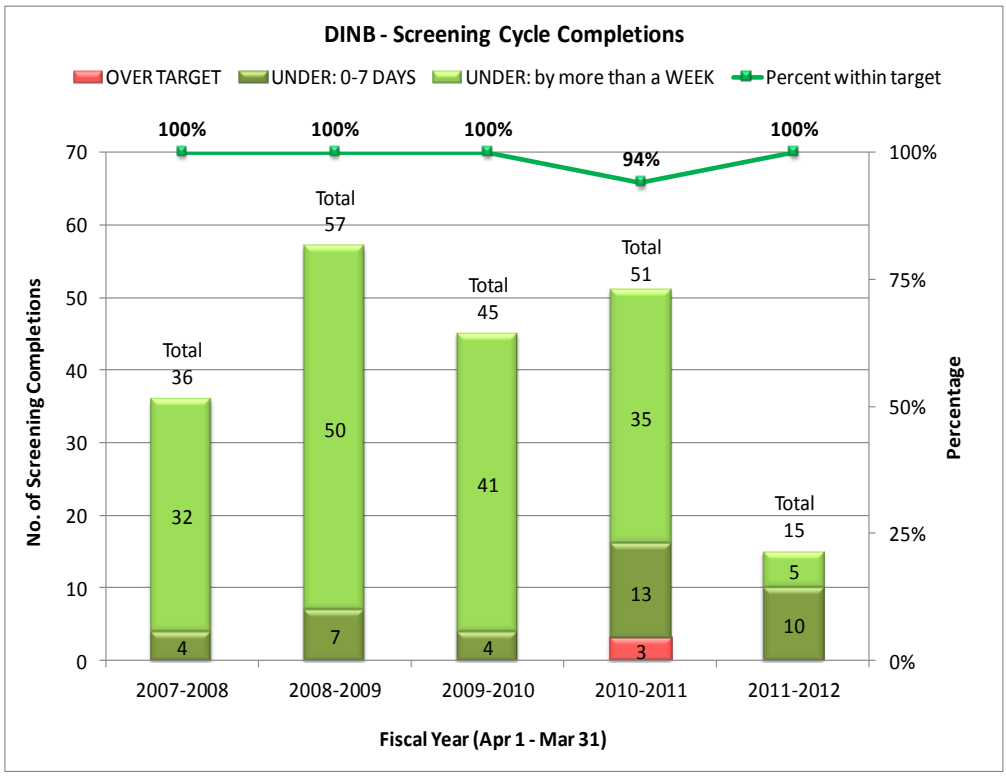
DINB					
	Year of Reconsideration Request				
	07-08	**08-09**	**09-10**	**10-11**	**11-12**
Total	**0**	**0**	**0**	**0**	**0**

PERFORMANCE

Review Cycle Completions - DINB

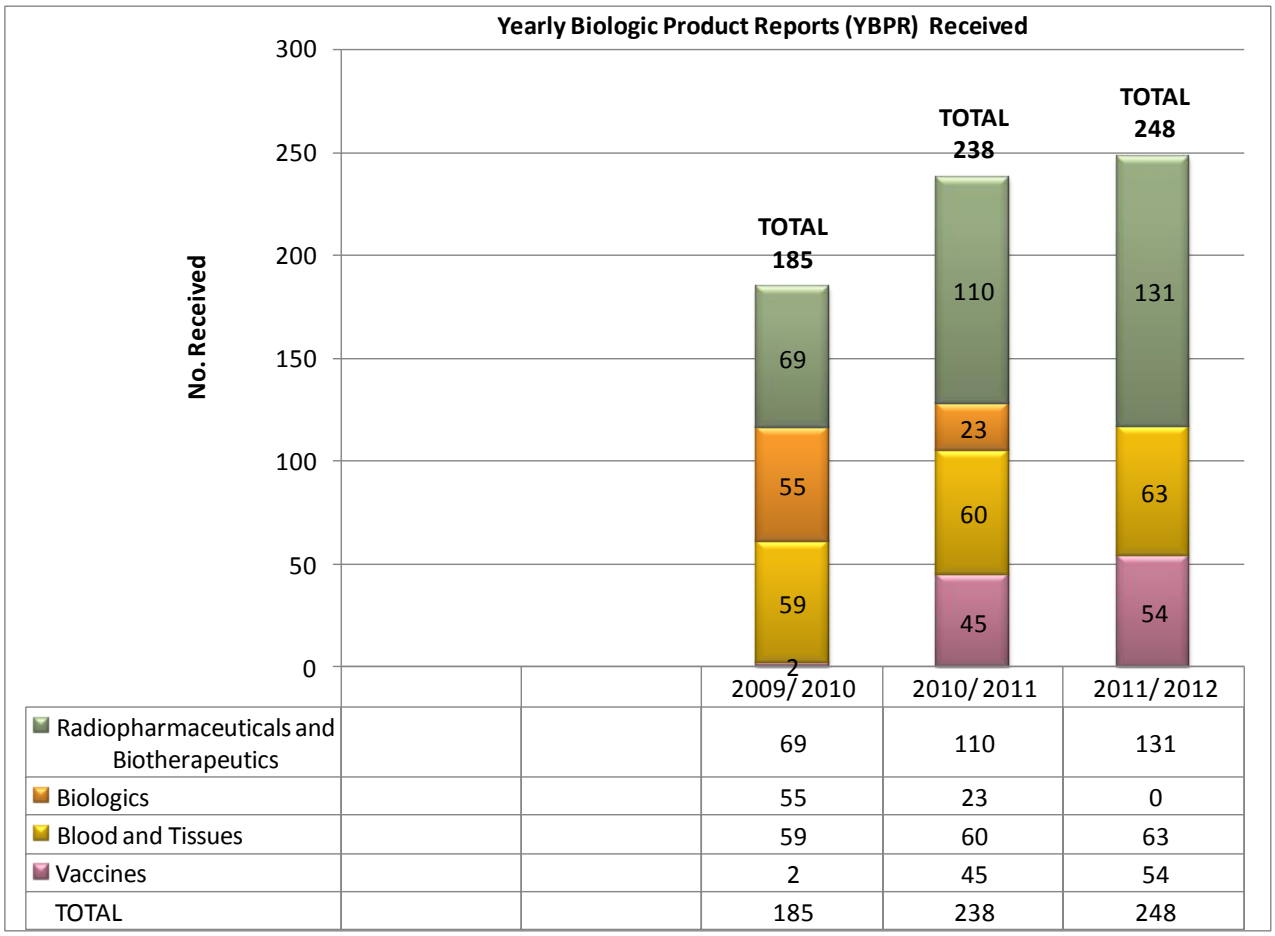


Screening Cycle Completions - DINB



Yearly Biologic Product Reports[11] (YBPR)

Yearly Biologic Product Reports (YBPR) Received



			2009/2010	2010/2011	2011/2012
Radiopharmaceuticals and Biotherapeutics			69	110	131
Biologics			55	23	0
Blood and Tissues			59	60	63
Vaccines			2	45	54
TOTAL			185	238	248

[11] 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.