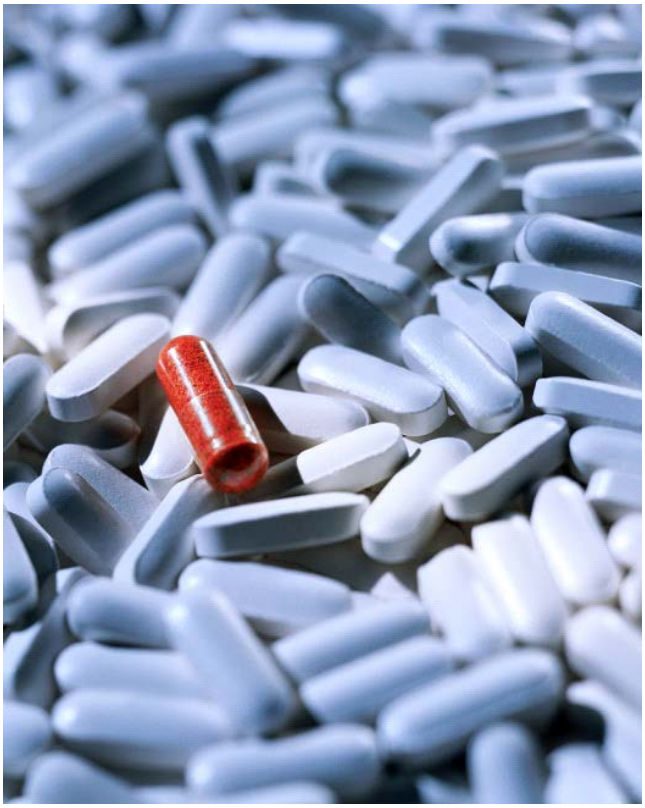
Natural and Non-Prescription Health Products Directorate

Drug Submission Performance Annual Report Fiscal Year 2015 – 2016

Apr 1 2015 – Mar 31 2016



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OVERVIEW

The NNHPD Annual Drug Submission Performance Report reflects Non-Prescription and Disinfectant Drug submission review activity over two consecutive fiscal years (April 1 to March 31) from 2014-15 to 2015-16.

Statistics are provided by Submission Type and show the number received, the number in workload and the number of decisions.

General Information

There are several steps involved in the drug submission review[1] 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.

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.

For new drugs, **approvals** are Notice of Compliances (NOC) Issued or Issuable which are reported in the Decisions' section. An NOC issuable is when a submission's NOC is placed "on hold" awaiting authorization to market, due to changes from Prescription to Non-Prescription or due to Patented Medicines (NOC) Regulations.

[1] For further clarification refer to the Guidance for Industry: Management of Drug Submissions.

A **review cycle completion**[2] is counted upon the conclusion of a 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). Health Canada has set a goal of 90% of review cycle completions to be rendered within performance standards.

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

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[2] 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. This is not to be confused with the 'UF Review 1 (iteration 1)' performance standards that are employed to measure performance to meet the *User Fees Act* reporting Requirements in the 'Health Canada Departmental Performance Report (DPR).

ACRONYMS

Submission Types

ANDS	-	Abbreviated New Drug Submission
CTA	-	Clinical Trial Application
CTA-A	-	Clinical Trial Application-Amendment
DINA	-	Application for a Drug Identification Number
DIND	-	Application for a Drug Identification Number – Disinfectant Product
DINF	-	Application for a Drug Identification Number - Category IV Product – (Labelling Standard)
NDS	-	New Drug Submission
NC	-	Notifiable Change – 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
SANDS	-	Supplemental Abbreviated New Drug Submission
SNDS	-	Supplemental New Drug Submission
SNDS-C	-	Supplemental New Drug Submission – CONFIRMATORY

Documents

NOC	-	Notice of Compliance
NOC-c	-	Notice of Compliance with 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	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**

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Part 1: NON PRESCRIPTION DRUGS
Or Over the Counter (OTC) Drugs

Non-Prescription Drugs: Submission Types Received (Division 1 Related)

Division 1 Related		
SUBMISSION TYPE - USER FEE CATEGORY	**2014/2015**	**2015/2016**
DINA: DIN APPLICATION		
DINA - ADMINISTRATIVE SUBMISSION	100	113
DINA - CHEMISTRY AND MANUFACTURING	4	8
DINA - CLINICAL OR NON CLINICAL-DATA	3	0
DINA - LABELLING ONLY	54	84
DINA - LABELLING STANDARD	33	15
DINA - PUBLISHED DATA ONLY	2	3
DINA Total	***196***	***223***
DINF: DIN APPLICATION - CATEGORY FOUR		
DINF - ADMINISTRATIVE SUBMISSION	0	2
DINF - LABELLING STANDARD	195	224
DINF Total	**195**	**226**
PDC: POST-AUTHORIZATION DIVISION 1 CHANGE		
PDC - REGULAR	254	262

Non-Prescription Drugs: Submission Types Received (Division 8 Related)

Division 8 Related		
SUBMISSION TYPE - USER FEE CATEGORY	**2014/2015**	**2015/2016**
NDS: NEW DRUG SUBMISSION		
NDS - CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	4	1
NDS - LABELLING ONLY	7	1
NDS - PRESCRIPTION TO NON-PRESCRIPTION SWITCH	1	0
NDS - PUBLISHED DATA ONLY	0	1
NDS Total	***12***	***3***
SNDS: SUPPLEMENTAL NEW DRUG SUBMISSION		
SNDS - CHEMISTRY AND MANUFACTURING	1	3
SNDS - LABELLING ONLY	7	6
SNDS - ADMINISTRATIVE SUBMISSION	0	1
SNDS - CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	0	1
SNDS - PUBLISHED DATA ONLY	0	1
SNDS Total	***8***	***12***
NC: NOTIFIABLE CHANGE - NEW DRUG		
NC - SAFETY 90	15	16

Non-Prescription Drugs: Submission Workload/ Backlog (Division 1 Related)

DIVISION 1 Related		Workload on March 31, 2015			Workload on March 31, 2016		
Cycle Type	SUBMISSION TYPE - USER FEE CATEGORY	Non-Backlog	In Backlog	*Total*	Non-Backlog	In Backlog	*Total*
	DIN APPLICATION (DINA)						
Admin Screening	DINA - ADMINISTRATIVE SUBMISSION	4	0	**4**	14	0	**14**
REVIEW	DINA - CHEMISTRY AND MANUFACTURING	1	0	**1**	4	0	**4**
	DINA - CLINICAL OR NON-CLINICAL DATA	2	0	**2**	1	0	**1**
	DINA - LABELLING ONLY	24	0	**24**	30	0	**30**
	DINA - PUBLISHED DATA ONLY	2	0	**2**	1	0	**1**
	DINA in Review Total	*29*	*0*	***29***	*36*	*0*	**36**
SCREENING	DINA - LABELLING ONLY	6	0	**6**	14	0	**14**
	DINA - LABELLING STANDARD	2	0	**2**	2	0	**2**
	DINA in Screening Total	*8*	*0*	***8***	*16*	*0*	**16**
	DIN APPLICATION - CATEGORY FOUR (DINF)						
SCREENING	DINF - LABELLING STANDARD	5	1	**6**	24	0	**24**
	POST-AUTHORIZATION DIVISION 1 CHANGE (PDC)						
SCREENING	PDC - REGULAR	7	0	**7**	17	6	**23**

Non-Prescription Drugs: Submission Workload/ Backlog (Division 8 Related)

DIVISION 8 Related		Workload on March 31, 2015			Workload on March 31, 2016		
Cycle Type	SUBMISSION TYPE - USER FEE CATEGORY	Non-Backlog	In Backlog	*Total*	Non-Backlog	In Backlog	*Total*
	NEW DRUG SUBMISSION (NDS)						
REVIEW	NDS - CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	4	0	**4**	1	0	**1**
	NDS - LABELLING ONLY	2	0	**2**	1	0	**1**
	NDS in Review Total	*6*	*0*	***6***	*2*	*0*	***2***
	SUPPLEMENTAL NEW DRUG SUBMISSION (SNDS)						
REVIEW	SNDS - LABELLING ONLY	2	0	**2**	1	0	**1**
	SNDS - PUBLISHED DATA ONLY	0	0	**0**	1	0	**1**
	SNDS - CHEMISTRY AND MANUFACTURING	1	0	**1**	2	0	**2**
	SNDS - CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	0	0	**0**	1	0	**1**
	SNDS in Review Total	*3*	*0*	**3**	*5*	*0*	**5**
	NOTIFIABLE CHANGE - NEW DRUG (NC)						
REVIEW	NC - SAFETY 90	2	0	**2**	2	0	**2**
	NEW DRUG SUBMISSION (NDS)						
SCREENING	NDS - PRESCRIPTION TO NON-PRESCRIPTION SWITCH	1	0	***1***	0	0	***0***
	NDS - PUBLISHED DATA ONLY	0	0	***0***	1	0	***1***
	NDS in Review Total	*1*	*0*	***1***	*1*	*0*	***1***
	SUPPLEMENTAL NEW DRUG SUBMISSION (SNDS)						
SCREENING	SNDS - CHEMISTRY AND MANUFACTURING	0	0	***0***	1	0	***1***

Non-Prescription Drugs: Performance (Division 1 Related)

DIVISION 1 Related				Performed 2014/2015			Performed 2015/2016		
Cycle Type	Submission Type - User Fee Category	Status- Iteration	*Perf. Std days*	Within Target	Over Target	Total	Within Target	Over Target	Total
	DINA: DIN APPLICATION								
Admin Screening	DINA - ADMINISTRATIVE SUBMISSION	ADMIN-SCREENING - 1	*45*	93	7	**100**	98	0	**98**
		ADMIN-SCREENING - 2	*45*	2	0	**2**	0	0	**0**
	DINA Administrative Screening Total			*95*	*7*	***102***	*98*	*0*	***98***
	DINF: DIN APPLICATION - CATEGORY FOUR								
Admin Screening	DINF - ADMINISTRATIVE SUBMISSION	ADMIN-SCREENING - 1	*45*	0	0	**0**	1	0	**1**
	DINA: DIN APPLICATION								
REVIEW	DINA - CHEMISTRY AND MANUFACTURING	REVIEW 1 - 1	*210*	6	0	**6**	2	0	**2**
		REVIEW 1 - 2	*210*	1	0	**1**	0	0	**0**
	DINA - COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	REVIEW 1 - 1	*210*	1	0	**1**	0	0	**0**
	DINA - CLINICAL OR NON-CLINICAL DATA	REVIEW 1 - 1	*210*	2	0	**2**	2	0	**2**
	DINA - LABELLING ONLY	REVIEW 1 - 1	*180*	63	0	**63**	63	0	**63**
		REVIEW 2 - 1	*120*	0	8	**8**	1	0	**1**
	DINA - PUBLISHED DATA ONLY	REVIEW 1 - 1	*210*	0	0	**0**	3	0	**3**
	DINA Review Total			*73*	*8*	***81***	*71*	*0*	***71***
SCREENING	DINA - CHEMISTRY AND MANUFACTURING	SCREENING 1 - 1	*45*	4	0	**4**	8	0	**8**
		SCREENING 1 - 2	*45*	1	0	**1**	3	0	**3**
	DINA - CLINICAL OR NON-CLINICAL DATA	SCREENING 1 - 1	*45*	3	0	**3**	0	0	**0**
		SCREENING 1 - 2	*45*	1	0	**1**	0	0	**0**
		SCREENING 1 - 3	*45*	0	0	**0**	1	0	**1**
	DINA - COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	SCREENING 1 - 1	*45*	1	0	**1**	0	0	**0**
	DINA - LABELLING ONLY	SCREENING 1 - 1	*45*	56	0	**56**	77	0	**77**
		SCREENING 1 - 2	*45*	22	0	**22**	15	0	**15**
		SCREENING 2 - 1	*45*	8	0	**8**	1	0	**1**
	DINA - LABELLING STANDARD	SCREENING 1 - 1	*45*	29	0	**29**	13	0	**13**
		SCREENING 1 - 2	*45*	8	0	**8**	3	0	**3**
	DINA - PUBLISHED DATA ONLY	SCREENING 1 - 1	*45*	2	0	**2**	2	0	**2**
		SCREENING 1 -2	*45*	1	0	**1**	0	0	**0**
		SCREENING 2 - 1	*45*	0	0	**0**	1	0	**1**
	DINA Screening Total			*136*	*0*	***136***	*124*	*0*	***124***
	DINF: DIN APPLICATION - CATEGORY FOUR								
SCREENING	DINF - LABELLING STANDARD	SCREENING 1 - 1	*45*	226	4	**230**	200	0	**200**
		SCREENING 1 - 2	*45*	11	0	**11**	0	0	**0**
	DINF Screening Total			*237*	*4*	**241**	*200*	*0*	**200**
	PDC: POST-AUTHORIZATION DIVISION 1 CHANGE								
SCREENING	PDC - REGULAR	SCREENING 1 - 1	*30*	219	37	**256**	205	23	**228**

Non-Prescription Drugs: Performance (Division 8 Related)

DIVISION 8 Related				Performed 2014/2015			Performed 2015/2016		
Cycle Type	Submission Type - User Fee Category	Status- Iteration	*Perf. Std days*	Within Target	Over Target	Total	Within Target	Over Target	Total
	SNDS: SUPPLEMENTAL ABBREVIATED NEW DRUG SUBMISSION								
Admin Screening	SNDS - ADMINISTRATIVE SUBMISSION	ADMIN-SCREENING - 1	*45*	0	0	**0**	1	0	**1**
	ANDS: ABBREVIATED NEW DRUG SUBMISSION								
REVIEW	ANDS - LABELLING ONLY	REVIEW RECONSID - 1	*115*	1	0	**1**	0	0	**0**
	NDS: NEW DRUG SUBMISSION								
REVIEW	NDS - COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	REVIEW 1 - 1	*180*	2	0	**2**	0	0	**0**
	NDS - PRESCRIPTION TO NON-PRESCRIPTION SWITCH	REVIEW 1 - 1	*180*	1	0	**1**	1	0	**1**
	NDS - LABELLING ONLY	REVIEW 1 - 1	*60*	5	0	**5**	2	0	**2**
	NDS - CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY AND MANUFACTURING	REVIEW 1 - 1	*300*	0	0	**0**	3	1	**4**
	NDS Review Total			*8*	*0*	**8**	*6*	*1*	**7**
	SNDS: SUPPLEMENTAL NEW DRUG SUBMISSION								
REVIEW	SNDS - CLINICAL OR NON-CLINICAL DATA	REVIEW 1 - 1	*300*	3	0	**3**	0	0	**0**
	SNDS - COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	REVIEW 1 - 1	*180*	1	0	**1**	0	0	**0**
		REVIEW 1 - 2	*180*	0	1	**1**	0	0	**0**
	SNDS - LABELLING ONLY	REVIEW 1 - 1	*60*	5	0	**5**	7	0	**7**
		REVIEW 2 - 1	*60*	0	0	**0**	1	0	**1**
	SNDS - PUBLISHED DATA ONLY	REVIEW 1 - 1	*300*	1	0	**1**	0	0	**0**
	SNDS - CHEMISTRY AND MANUFACTURING	REVIEW 1 - 1	*180*	0	0	**0**	1	0	**1**
		RIVIEW 2 - 1	*150*	0	0	**0**	1	0	**1**
	SNDS Review Total			*10*	*1*	***11***	*10*	*0*	***10***
	NC: NOTIFIABLE CHANGE - NEW DRUG								
REVIEW	NC - SAFETY 90	REVIEW 1 - 1	*90*	17	0	**17**	14	0	**14**
	NDS: NEW DRUG SUBMISSION								
SCREENING	NDS - COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	SCREENING 1 - 1	*45*	1	0	**1**	0	0	**0**
	NDS - CLINICAL OR NON-CLINICAL DATA	SCREENING 1 - 1	*45*	4	0	**4**	0	0	**0**
		SCREENING 1 - 2	*45*	3	0	**3**	0	0	**0**
	NDS - LABELLING ONLY	SCREENING 1 - 1	*45*	7	0	**7**	1	0	**1**
		SCREENING 1 - 2	*45*	0	1	**1**	0	0	**0**
	NDS - CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY AND MANUFACTURING	SCREENING 1 - 1	*45*	0	0	**0**	1	0	**1**
		SCREENING 1 - 2	*45*	0	0	**0**	1	0	**1**
	NDS - PRESCRIPTION TO NON-PRESCRIPTION SWITCH	SCREENING 1 - 1	*45*	0	0	**0**	1	0	**1**
	NDS Screening Total			*15*	*1*	***16***	*4*	*0*	***4***
	SNDS: SUPPLEMENTAL NEW DRUG SUBMISSION								
SCREENING	SNDS - COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	SCREENING 1 - 2	*45*	1	0	**1**	0	0	**0**
	SNDS - LABELLING ONLY	SCREENING 1 - 1	*7*	7	0	**7**	6	0	**6**
		SCREENING 1 - 2	*7*	0	1	**1**	0	0	**0**
		SCREENING 2 - 1	*7*	0	0	**0**	1	0	**1**
	SNDS - CHEMISTRY AND MANUFACTURING	SCREENING 1 - 1	*45*	1	0	**1**	2	0	**2**
		SCREENING 1 - 2	*45*	0	0	**0**	1	0	**1**
		SCREENING 2 - 1	*45*	0	0	**0**	1	0	**1**
	SNDS - CLINICAL AND NON-CLINICAL AND CHEMISTRY AND MANUFACTURING	SCREENING 1 - 1	*45*	0	0	**0**	1	0	**1**
	SNDS - PUBLISHED DATA ONLY	SCREENING 1 - 1	*45*	0	0	**0**	1	0	**1**
	SNDS Screening Total			*9*	*1*	***10***	*13*	*0*	***13***
	NC: NOTIFIABLE CHANGE - NEW DRUG								
SCREENING	NC - SAFETY 90	SCREENING 1 - 1	*7*	16	0	**16**	16	0	**16**
		SCREENING 1 - 2	*7*	0	0	**0**	1	0	**1**
	NC Screening Total			*16*	*0*	***16***	*17*	*0*	***17***

Non-Prescription Drugs: Decisions (Division 1 Related)

Division 1 Related					
Subm Type Code	Submission Type	User Fee Category	Decision	2014/2015	2015/2016
DINA	DIN APPLICATION	ADMINISTRATIVE SUBMISSION	CANCELLATION LETTER	6	5
			NOTIFICATION FORM DIN SUB	86	85
			REJECTION LETTER (SCR)	11	12
			SCREENING DEFICIENCY NOTICE	6	1
		CHEMISTRY AND MANUFACTURING	NOTICE OF DEFICIENCY	1	0
			NOTIFICATION FORM DIN SUB	5	2
			NO OBJECTION LETTER	1	0
			CANCELLATION LETTER	0	1
			SCREENING DEFICIENCY NOTICE	0	6
		CLINICAL OR NON-CLINICAL DATA	NOTIFICATION FORM DIN SUB	2	0
			SCREENING DEFICIENCY NOTICE	1	0
			NO OBJECTION LETTER	0	1
			NOTICE OF DEFICIENCY	0	1
		COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTIFICATION FORM DIN SUB	1	0
		LABELLING ONLY	CANCELLATION LETTER	5	9
			DIN INCORR SUBTYPE-CLASS	11	3
			NO OBJECTION LETTER	2	6
			NOTICE OF NON-COMPLIANCE	3	9
			NOTIFICATION FORM DIN SUB	63	48
			REJECTION LETTER (SCR)	1	4
			SCREENING DEFICIENCY NOTICE	11	20
			NOTICE OF DEFICIENCY	0	1
			WITHDRAWAL NO RESP TO NOD	0	1
		LABELLING STANDARD	CANCELLATION LETTER	2	1
			NOTIFICATION FORM DIN SUB	25	12
			REJECTION LETTER (SCR)	2	2
			SCREENING DEFICIENCY NOTICE	9	3
		PUBLISHED DATA	SCREENING DEFICIENCY NOTICE	1	1
			CANCELLATION LETTER	0	1
			NOTICE OF NON-COMPLIANCE	0	1
			NOTIFICATION FORM DIN SUB	0	2
DINF	DIN APPLICATION - CATEGORY FOUR	LABELLING STANDARD	CANCELLATION LETTER	6	2
			DIN INCORR SUBTYPE-CLASS	4	0
			NEW DRUG LETTER SCREEN	4	1
			NOTIFICATION FORM DIN SUB	218	199
			REJECTION LETTER (SCR)	3	0
			SCREENING DEFICIENCY NOTICE	11	1
		ADMINISTRATIVE SUBMISSION	CANCELLATION LETTER	0	1
			REJECTION LETTER (SCR)	0	1
PDC	POST-AUTHORIZATION DIVISION 1 CHANGE	REGULAR	CANCELLATION LETTER	8	14
			NO OBJECTION LETTER	241	212
			NOT SATISFACTORY NOTICE	7	12
			NOTIFICATION FORM DIN SUB	1	1

Non-Prescription Drugs: Decisions (Division 8 Related)

Division 8 Related Decisions:
***Approvals are the NOCs Issued or Issuable at the conclusion of review (and not NOCs issued at the end of a switch or patent hold).**

Subm Type Code	Submission Type	User Fee Category	Decision	2014/2015	2015/2016
ANDS	ABBREVIATED NEW DRUG SUBMISSION	LABELLING ONLY	NOTICE OF COMPLIANCE*	1	0
NDS	NEW DRUG SUBMISSION	CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	3	1
			NOC ON HOLD (SWITCH)*	0	2
			NOD WITHDRAWAL LETTER	0	1
			NOTICE OF COMPLIANCE*	0	1
			NOTICE OF DEFICIENCY	0	1
		COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOC ON HOLD (SWITCH)*	2	0
		LABELLING ONLY	NOTICE OF COMPLIANCE*	5	2
			SCREENING DEFICIENCY NOTICE	1	0
		PRESCRIPTION TO NON-PRESCRIPTION SWITCH	NOC ON HOLD (SWITCH)*	1	1
SNDS	SUPPLEMENTAL NEW DRUG SUBMISSION	CLINICAL OR NON-CLINICAL DATA	NOC ON HOLD (SWITCH)*	1	0
			NOTICE OF COMPLIANCE*	2	0
		CHEMISTRY AND MANUFACTURING	NOTICE OF COMPLIANCE*	0	1
			NOTICE OF NON-COMPLIANCE	0	1
			SCREENING DEFICIENCY NOTICE	0	1
		COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	2	0
		ADMINISTRATIVE SUBMISSION	CANCELLATION LETTER	0	1
		LABELLING ONLY	NOC ON HOLD (SWITCH)*	1	1
			NOTICE OF COMPLIANCE*	4	6
			SCREENING DEFICIENCY NOTICE	1	0
			CANCELLATION LETTER	1	0
			NOTICE OF NON-COMPLIANCE	0	1
		PUBLISHED DATA ONLY	CANCELLATION LETTER	1	0
NC	NOTIFIABLE CHANGE - NEW DRUG	SAFETY 90	NO OBJECTION LETTER	18	12
			NOT SATISFACTORY NOTICE	0	1
			SCREENING DEFICIENCY NOTICE	0	3
			NC-HOLD (SWITCH)	1	1

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Part 2: DISINFECTANTS

Disinfectants - Submissions and DIN Applications Received

Division 1 Related		
SUBMISSION TYPE - USER FEE CATEGORY	**2014/2015**	**2015/2016**
DIND: DIN DISINFECTANTS		
DIND - ADMINISTRATIVE SUBMISSION	81	75
DIND - DISINFECTANTS	41	49
DIND - LABELLING STANDARD	17	16
DIND Total	***139***	***140***
PDC: POST-AUTHORIZATION DIVISION 1 CHANGE		
PDC - RRGULAR	90	38
Division 8 Related		
SUBMISSION TYPE - USER FEE CATEGORY	**2014/2015**	**2015/2016**
MPNDS: PRE - NDS MEETING		
MPNDS - CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	1	0
NC: NOTIFIABLE CHANGE - NEW DRUG		
NC - SAFETY 90	4	0
NDS-D: NEW DRUG SUBMISSION-DISINFECTANTS		
DISINFECTANTS	1	1

Disinfectants: Submission Workload/ Backlog

DIVISION 1 Related		Workload on March 31, 2015			Workload on March 31, 2016		
Cycle Type	SUBMISSION TYPE - USER FEE CATEGORY	Non-Backlog	In Backlog	***Total***	Non-Backlog	In Backlog	***Total***
	DIND - DIN DISINFECTANTS						
Admin Screening	DIND - ADMINISTRATIVE SUBMISSION	1	0	**1**	8	0	**8**
REVIEW	DIND - DISINFECTANTS	21	0	**21**	27	0	**27**
SCREENING	DIND - DISINFECTANTS	4	0	**4**	7	0	**7**
	DIND - LABELLING STANDARD	0	0	**0**	2	0	**2**
	DIND in Screening Total	*4*	*0*	**4**	*9*	*0*	**9**
	POST-AUTHORIZATION DIVISION 1 CHANGE (PDC)						
SCREENING	PDC - REGULAR	1	0	**1**	0	0	**0**

DIVISION 8 Related		Workload on March 31, 2015			Workload on March 31, 2016		
Cycle Type	SUBMISSION TYPE - USER FEE CATEGORY	Non-Backlog	In Backlog	***Total***	Non-Backlog	In Backlog	***Total***
	NOTIFIABLE CHANGE - NEW DRUG (NC)						
REVIEW	NC - SAFETY 90	1	0	**1**	0	0	**0**
	NEW DRUG SUBMISSION (NDS)						
REVIEW	NDS - DISINFECTANTS	1	0	**1**	0	0	**0**

Disinfectants: Performance

DIVISION 1 Related				Performed 2014/2015			Performed 2015/2016		
Cycle Type	Submission Type - User Fee Category	Status- Iteration	*Perf. Std days*	Within Target	Over Target	Total	Within Target	Over Target	Total
	DIND: DIN DISINFECTANTS								
Admin Screening	DIND - ADMINISTRATIVE SUBMISSION	ADMIN-SCREENING - 1	*45*	82	8	**90**	64	1	**65**
		ADMIN-SCREENING - 2	*45*	17	0	**17**	9	0	**9**
		ADMIN-SCREENING - 3	*45*	1	0	**1**	0	0	**0**
	DIND Admin-Screening Total			*100*	*8*	**108**	*73*	*1*	**74**
	DIN DISINFECTANTS (DIND)								
REVIEW	DIND - DISINFECTANTS	REVIEW 1 - 1	*210*	41	2	**43**	32	3	**35**
		REVIEW 2 - 1	*150*	3	0	**3**	8	0	**8**
	DIND Review Total			*44*	*2*	**46**	*40*	*3*	**43**
	DIN DISINFECTANTS (DIND)								
SCREENING	DIND - DISINFECTANTS	SCREENING 1 - 1	*45*	41	0	**41**	47	1	**48**
		SCREENING 1 - 2	*45*	2	2	**4**	28	0	**28**
		SCREENING 2 - 1	*45*	6	0	**6**	10	0	**10**
	DIND - LABELLING STANDARD	SCREENING 1 - 1	*45*	17	1	**18**	15	0	**15**
		SCREENING 1 - 2	*45*	8	0	**8**	4	0	**4**
	DIND Screening Total			*74*	*3*	**77**	*104*	*1*	**105**
	PDC: POST-AUTHORIZATION DIVISION 1 CHANGE								
SCREENING	PDC - REGULAR	SCREENING 1 - 1	*30*	72	38	**110**	43	1	**44**

DIVISION 8 Related				Performed 2014/2015			Performed 2015/2016		
Cycle Type	Submission Type - User Fee Category	Status- Iteration	*Perf. Std days*	Within Target	Over Target	Total	Within Target	Over Target	Total
	NDS - NEW DRUG SUBMISSION								
REVIEW	NDS - DISINFECTANTS	REVIEW 1 - 1	*300*	3	0	**3**	1	0	**1**
		REVIEW 2 - 1	*150*	3	0	**3**	0	0	**0**
	NDS Review Total			6	0	**6**	1	0	**1**
	NC: NOTIFIABLE CHANGE - NEW DRUG								
REVIEW	NC - SAFETY 90	REVIEW 1 - 1	*90*	2	0	**2**	1	0	**1**
	NDS: NEW DRUG SUBMISSION								
SCREENING	NDS - DISINFECTANTS	SCREENING 1 - 1	*45*	1	0	**1**	1	0	**1**
		SCREENING 2 -1	*45*	3	0	**3**	0	0	**0**
	NDS Screening Total			4	0	**4**	1	0	**1**
	NOTIFIABLE CHANGE - NEW DRUG (NC)								
SCREENING	NC - SAFETY 90	SCREENING 1 - 1	*7*	3	0	**3**	0	0	**0**

Disinfectants: Decisions

Division 1 Related Decisions					
Subm Type Code	Submission Type	User Fee Category	Decision	2014/2015	2015/2016
DIND	DIN DISINFECTANTS	ADMINISTRATIVE SUBMISSION	CANCELLATION LETTER	2	3
			NO OBJECTION LETTER	1	0
			DIN INCORR SUBTYPE-CLASS	1	0
			NOTIFICATION FORM DIN SUB	90	54
			REJECTION LETTER (SCR)	3	9
			SCREENING DEFICIENCY NOTICE	14	11
		DISINFECTANTS	DIN INCORR SUBTYPE-CLASS	2	0
			NO OBJECTION LETTER	14	10
			CANCELLATION LETTER	2	2
			NEW DRUG LETTER SCREEN	0	3
			NOD WITHDRAWAL LETTER	0	1
			NON WITHDRAWAL LETTER	1	1
			NOTICE OF NON-COMPLIANCE	8	13
			NOTIFICATION FORM DIN SUB	25	20
			SCREENING DEFICIENCY NOTICE	3	30
			REJECTION LETTER (SCR)	1	3
			WITHDRAWAL NO RESP TO NON	0	1
			WITH.UNACCEPT.RESP.NON SC	1	0
		LABELLING STANDARD	NOTIFICATION FORM DIN SUB	18	13
			SCREENING DEFICIENCY NOTICE	8	6
			REJECTION LETTER (SCR)	1	1
PDC	POST-AUTHORIZATION DIVISION 1 CHANGE	REGULAR	CANCELLATION LETTER	2	1
			NO OBJECTION LETTER	83	37
			NOT SATISFACTORY NOTICE	24	3
			REJECTION LETTER (SCR)	1	0
Division 8 Related Decisions: ***Approvals are the NOCs Issued or Issuable at the conclusion of review (and not NOCs issued at the end of a switch or patent hold).**					
Subm Type Code	Submission Type	User Fee Category	Decision	2014/2015	2015/2016
NC	NOTIFIABLE CHANGE - NEW DRUG	SAFETY 90	NO OBJECTION LETTER	2	1
			CANCELLATION LETTER	1	0
NDS-D	NDS DISINFECTANT	DISINFECTANTS	NOTICE OF NON-COMPLIANCE	3	0
			NOTICE OF COMPLIANCE*	3	1
			CANCELLATION LETTER	0	1
			SCREENING DEFICIENCY NOTICE	0	1