Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

If you are using a web page screen reader and are unable to access this document, please contact the Sentinel Operations Center for assistance at info@sentinelsystem.org.

Overview for Request: cder_mpl1r_wp044

Request ID: cder_mpl1r_wp044_nsdp_v02

Report Description: In this report we examined use of oral metoclopramide by individuals in the Sentinel Distributed Database (SDD). We described episode length and metoclopramide use stratified by age and coverage type.

Sentinel Routine Querying Module: Modular Program 8

Data Source: We distributed this request to 16 Sentinel Data Partners on December 8, 2016. The study period included data from January 1, 2012 to December 31, 2015.

Study Design: We identified individuals with prevalent use of oral metoclopramide and characterized use by examining all episodes occurring after the index exposure. We operationalized episode length as 0-84 days, 85-365 days, and ≥365 days and reported the number of individuals in each category by type of insurance coverage. Results are reported across the following age groups: <13, <7, 7-<13, 13-<18, and 18+ years of age.

Exposure of Interest: We defined the exposure of interest, metoclopramide, using National Drug Codes (NDCs). Please refer to Appendix A for a list of generic and brand names of medical products used to define exposures in this request.

Cohort Eligibility Criteria: We required members to be enrolled in health plans with either medical or drug coverage to be included in the cohort. No gaps in coverage were allowed.

Follow-up Time: We created exposure episodes based on the number of days of product supplied per dispensing in the outpatient pharmacy dispensing data. We bridged together episodes less than 45 days apart and added 0 days to the end of each episode. We allowed the maximum number of days supplied to be 180 days.

Please see Appendix B for the specifications of parameters used in the analyses for this request.

Limitations: Algorithms used to define exposures are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind.

Notes: Please contact the Sentinel Operations Center (info@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

Glossary of Terms in Modular Program 8*

Enrollment Gap - Sets the number of days that will be bridged between two consecutive enrollment periods to create a

Age Stratifications - Age group categories for reporting. Specifying this parameter will (1) restrict to certain age groups and (2) specify how age groups will be stratified in the result tables. For example, to have results stratified by 20 year increments for members 40-99 years of age, AGESTRAT=40-59 60-79 80-99 would be entered.

Days of Supply Groups - Days of supply categories for reporting. This parameter will specify how claim days of supply will be stratified in result tables examining distribution of days supplied. For example, to have results stratified by 15 days increments for claims with 15-60 days of supply, DISPDAYSSUPSTRAT=15-29 30-44 45-60 would be entered.

Total Days of Supply Thresholds - Total days of supply threshold(s) for reporting. This parameter will specify how members' total days of supply (for all observed dispensings) will be stratified in the result tables examining distribution of members by number of total days supplied. For example, to have results stratified by 60 total days of supply, TOTALDAYSSUPTHRESH=060 120 180 240 300 would be entered.

Exposure - NDC and/or procedure and/or diagnosis code values for the exposure(s) of interest.

New Molecular Entity (NME) Indicator - Specifies whether exposures should be treated as a NME; that is, the MP algorithm will not look prior to the query period start date (either approval or launch date) when applying the washout (WASHPER) condition. This parameter has no impact on how ENRDAYS is processed, i.e., when ENRDAYS is specified the program will always look for enrollment prior to the query period start date if necessary.

Approval Date - Approval date of new molecular entity of interest.

Study End Date - Query period end date.

Washout Period - Length of washout period in days. The washout period is a period of time before an incident exposure index date during which a member cannot have any evidence of exposure(s) of interest.

Enrollment Days - Optional parameter to ensure a minimum number of days of continuous enrollment prior to the start of the first treatment episode.

Minimum Days Supplied - Minimum days of supply for a dispensing to be valid.

Maximum Days Supplied - Maximum days of supply for a claim to be valid.

Episode Gap Type - Specifies the type of algorithm to use for the calculation of episode gaps. Valid values are: (1) F: Fixed episode gap. The value specified in EPISODEGAP will be used to determine if two consecutive claims are in the same episode; and (2) P: Percentage episode gap. The value specified in EPISODEGAP will represent a percentage of the previous dispensing's days of supply to determine if two consecutive claims are in the same episode.

Episode Gap - For a given claim, if EPISODEGAPTYPE is Fixed (F), a gap of more than EPISODEGAP days between the claim date and the date of the last day of supply of the previous claim triggers a new treatment episode. If EPISODEGAPTYPE is Percentage (P), a gap of more than EPISODEGAP percent of the previous claim days of supply days between the claim date and the date of the last day of supply of the previous claim triggers a new treatment episode.

Exposure Extension Period - Extends the length of the treatment episode by a specified number of days. A treatment episode can be extended EXPEXTPER days after the last day of supply of the treatment episode's last claim.

Minimum Episode Duration - Used to reject members with first treatment episode of fewer than a certain number of days.

Stockpiling Type - Specifies the type of stockpiling algorithm to use. Valid values are: (1) S: Standard algorithm. Slides overlapping dispensings to create a continuous sequence of non-overlapping dispensings; and (2) R: Revised algorithm. If a second dispensing occurs at least XX% (i.e., XX% or more) of the time through the previous dispensing, the length of the second dispensing is added to the end of the first dispensing; if the second dispensing occurs less than XX% of the time through the first dispensing then the second dispensing time is begun at the time it is dispensed and the first one is truncated.

Stockpiling Percent -Used in conjunction with Stockpiling Type to specify the percentage to be applied when Stockpiling Type = R

*all terms may not be used in this report

Table 1. Number of Individuals Less Than Thirteen Years of Age Dispensed Metoclopramide in the Sentinel Distributed Database (SDD) from January 1, 2012 to December 31, 2015, by Episode Number, Episode Length, and Coverage Type

Episode Length (Days)[1]	Both Medical and Drug Coverage	Drug Coverage Only	At Least Drug Coverage
Episode 1			
0-84	6,814	68	6,882
85-365	860	10	870
366+	139	2	141
Episode 2			
0-84	647	9	657
85-365	121	3	124
366+	40	0	40
Episode 3			
0-84	211	3	214
85-365	39	1	40
366+	11	0	11
Episode 4			
0-84	77	1	78
85-365	20	0	20
366+	2	0	2
Episode 5			
0-84	46	1	47
85-365	7	0	7
366+	0	0	0
Episode 6			
0-84	22	1	23
85-365	6	0	6
366+	1	0	1
Episode 7			
0-84	13	1	14
85-365	5	0	5
366+	0	0	0
Episode 8			
0-84	7	0	7
85-365	1	0	1
366+	0	0	0
Episode 9			
0-84	4	0	4
85-365	0	0	0
366+	0	0	0
Episode 10			
0-84	0	0	0
85-365	3	0	3
366+	0	0	0

Table 1. Number of Individuals Less Than Thirteen Years of Age Dispensed Metoclopramide in the Sentinel Distributed Database (SDD) from January 1, 2012 to December 31, 2015, by Episode Number, Episode Length, and Coverage Type

Episode Length (Days)[1]	Both Medical and Drug Coverage	Drug Coverage Only	At Least Drug Coverage
Episode 11			
0-84	3	0	3
85-365	0	0	0
366+	0	0	0
Episode 12			
0-84	2	0	2
85-365	0	0	0
366+	0	0	0
Episode 13			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 14			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 15			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 16			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 17			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 18			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
All Episodes			
0-84	7,846	84	7,931
85-365	1,062	14	1,076
366+	193	2	195

Table 2. Number of Individuals Less Than Seven Years of Age Dispensed Metoclopramide in the Sentinel Distributed Database (SDD) from January 1, 2012 to December 31, 2015, by Episode Number, Episode Length, and Coverage Type

Episode Length (Days)[1]	Both Medical and Drug Coverage	Drug Coverage Only	At Least Drug Coverage
Episode 1			
0-84	4,094	39	4,133
85-365	668	6	674
366+	93	1	94
Episode 2			
0-84	299	2	302
85-365	77	3	80
366+	18	0	18
Episode 3			
0-84	76	0	76
85-365	17	0	17
366+	6	0	6
Episode 4			
0-84	25	0	25
85-365	8	0	8
366+	1	0	1
Episode 5			
0-84	15	0	15
85-365	0	0	0
366+	0	0	0
Episode 6			
0-84	6	0	6
85-365	3	0	3
366+	0	0	0
Episode 7			
0-84	5	0	5
85-365	1	0	1
366+	0	0	0
Episode 8			
0-84	2	0	2
85-365	0	0	0
366+	0	0	0
Episode 9			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 10			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0

Table 2. Number of Individuals Less Than Seven Years of Age Dispensed Metoclopramide in the Sentinel Distributed Database (SDD) from January 1, 2012 to December 31, 2015, by Episode Number, Episode Length, and Coverage Type

Episode Length (Days)[1]	Both Medical and Drug Coverage	Drug Coverage Only	At Least Drug Coverage
Episode 11			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 12			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 13			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 14			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 15			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 16			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 17			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 18			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
All Episodes			
0-84	4,522	41	4,564
85-365	774	9	783
366+	118	1	119

Table 3. Number of Individuals Seven to Less Than Thirteen Years of Age Dispensed Metoclopramide in the Sentinel Distributed Database (SDD) from January 1, 2012 to December 31, 2015, by Episode Number, Episode Length, and Coverage Type

Episode Length (Days)[1]	Both Medical and Drug Coverage	Drug Coverage Only	At Least Drug Coverage
Episode 1			
0-84	2,720	29	2,749
85-365	192	4	196
366+	46	1	47
Episode 2			
0-84	348	7	355
85-365	44	0	44
366+	22	0	22
Episode 3			
0-84	135	3	138
85-365	22	1	23
366+	5	0	5
Episode 4			
0-84	52	1	53
85-365	12	0	12
366+	1	0	1
Episode 5			
0-84	31	1	32
85-365	7	0	7
366+	0	0	0
Episode 6			
0-84	16	1	17
85-365	3	0	3
366+	1	0	1
Episode 7			
0-84	8	1	9
85-365	4	0	4
366+	0	0	0
Episode 8			
0-84	5	0	5
85-365	1	0	1
366+	0	0	0
Episode 9			
0-84	4	0	4
85-365	0	0	0
366+	0	0	0
Episode 10			
0-84	0	0	0
85-365	3	0	3
366+	0	0	0

Table 3. Number of Individuals Seven to Less Than Thirteen Years of Age Dispensed Metoclopramide in the Sentinel Distributed Database (SDD) from January 1, 2012 to December 31, 2015, by Episode Number, Episode Length, and Coverage Type

Episode Length (Days)[1]	Both Medical and Drug Coverage	Drug Coverage Only	At Least Drug Coverage
Episode 11			
0-84	3	0	3
85-365	0	0	0
366+	0	0	0
Episode 12			
0-84	2	0	2
85-365	0	0	0
366+	0	0	0
Episode 13			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 14			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 15			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 16			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 17			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 18			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
All Episodes			
0-84	3,324	43	3,367
85-365	288	5	293
366+	75	1	76

Table 4. Number of Individuals Thirteen to Less Than Eighteen Years of Age Dispensed Metoclopramide in the Sentinel Distributed Database (SDD) from January 1, 2012 to December 31, 2015, by Episode Number, Episode Length, and Coverage Type

Episode Length (Days)[1]	Both Medical and Drug Coverage	Drug Coverage Only	At Least Drug Coverage
Episode 1			
0-84	8,857	78	8,935
85-365	382	7	389
366+	79	2	81
Episode 2			
0-84	1,008	7	1,018
85-365	102	2	105
366+	15	1	16
Episode 3			
0-84	264	1	266
85-365	39	1	41
366+	6	0	6
Episode 4			
0-84	96	0	97
85-365	18	0	18
366+	1	0	1
Episode 5			
0-84	47	0	47
85-365	6	0	7
366+	0	0	0
Episode 6			
0-84	20	0	20
85-365	4	0	4
366+	1	0	1
Episode 7			
0-84	6	0	6
85-365	3	0	3
366+	0	0	0
Episode 8			
0-84	6	0	6
85-365	0	0	0
366+	0	0	0
Episode 9			
0-84	3	0	3
85-365	1	0	1
366+	0	0	0
Episode 10			
0-84	1	0	1
85-365	1	0	1
366+	0	0	0

Table 4. Number of Individuals Thirteen to Less Than Eighteen Years of Age Dispensed Metoclopramide in the Sentinel Distributed Database (SDD) from January 1, 2012 to December 31, 2015, by Episode Number, Episode Length, and Coverage Type

Episode Length (Days)[1]	Both Medical and Drug Coverage	Drug Coverage Only	At Least Drug Coverage
Episode 11			
0-84	0	0	0
85-365	1	0	1
366+	0	0	0
Episode 12			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 13			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 14			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 15			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 16			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 17			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
Episode 18			
0-84	0	0	0
85-365	0	0	0
366+	0	0	0
All Episodes			
0-84	10,308	86	10,399
85-365	557	10	570
366+	102	3	105

Table 5. Number of Individuals Eighteen Years of Age or Older Dispensed Metoclopramide in the Sentinel Distributed Database (SDD) from January 1, 2012 to December 31, 2015, by Episode Number, Episode Length, and Coverage Type

Episode Length (Days)[1]	Both Medical and Drug Coverage	Drug Coverage Only	At Least Drug Coverage
Episode 1			
0-84	461,236	123,532	584,768
85-365	47,559	25,762	73,321
366+	12,305	9,168	21,473
Episode 2			
0-84	56,942	21,585	79,203
85-365	16,113	9,042	25,526
366+	3,128	2,158	5,421
Episode 3			
0-84	19,066	8,220	27,636
85-365	7,156	4,012	11,417
366+	1,097	709	1,858
Episode 4			
0-84	9,034	3,995	13,237
85-365	3,706	1,939	5,780
366+	437	279	739
Episode 5			
0-84	5,027	2,205	7,372
85-365	1,948	982	3,005
366+	164	108	283
Episode 6			
0-84	2,931	1,243	4,243
85-365	1,067	504	1,617
366+	66	54	121
Episode 7			
0-84	1,805	744	2,593
85-365	537	252	810
366+	31	21	53
Episode 8			
0-84	1,148	452	1,628
85-365	249	117	380
366+	18	5	23
Episode 9			
0-84	759	258	1,036
85-365	125	61	192
366+	6	3	9
Episode 10			
0-84	447	161	613
85-365	54	34	91
366+	0	0	0

Table 5. Number of Individuals Eighteen Years of Age or Older Dispensed Metoclopramide in the Sentinel Distributed Database (SDD) from January 1, 2012 to December 31, 2015, by Episode Number, Episode Length, and Coverage Type

Episode Length (Days)[1]	Both Medical and Drug Coverage	Drug Coverage Only	At Least Drug Coverage
Episode 11			
0-84	259	94	355
85-365	32	21	53
366+	2	0	2
Episode 12			
0-84	151	52	203
85-365	17	4	21
366+	0	0	0
Episode 13			
0-84	75	20	95
85-365	5	1	6
366+	0	0	0
Episode 14			
0-84	39	9	48
85-365	3	0	3
366+	0	0	0
Episode 15			
0-84	18	3	21
85-365	0	0	0
366+	0	0	0
Episode 16			
0-84	8	2	10
85-365	0	0	0
366+	0	0	0
Episode 17			
0-84	1	0	1
85-365	0	0	0
366+	0	0	0
Episode 18			
0-84	1	0	1
85-365	0	0	0
366+	0	0	0
All Episodes			
0-84	558,947	162,575	723,063
85-365	78,571	42,731	122,222
366+	17,254	12,505	29,982

Appendix A. List of Generic and Brand Names of Medical Products Used to Define the Exposure of Interest in this Request

Generic Name	Brand Name
Grouping/Class (E.g. Antidiabetics)	
metoclopramide HCl	Metoclopramide HCl
metoclopramide HCl	Metozolv ODT
metoclopramide HCl	Reglan

Appendix B. Specifications Defining Parameters for this Request

In this report we examined utilization of oral metoclopramide by individuals in the Sentinel Distributed Database (SDD) using Modular Program 8. Episodes of metoclopramide use were described by episode length and stratified by age and coverage type.

Query Period: January 1, 2012 - December 31, 2015

Age Groups: 0-12, 0-6, 7-12, 13-17, 18+ years

Coverage Requirement: Any

Enrollment Gap: 0 days

Days of Supply Groups: 0-1, 2-30, 31-60, 61-90, 91+ days

Total Days of Supply Thresholds: 30, 90, 180, 270, 360, 450, 540, 630, 720 days

	Exposure	Age Group	NME Indicator	Washout Period (days)	Enrollment Days	Minimum Days Supplied	Maximum Days Supplied	Episode Gap Type	Episode Gap (days)	Exposure Extension Period (days)	Minimum Episode Duration (days)	Stockpiling Type	Stockpiling Percent
1	Oral metoclopramide	0-12 years	No	0	0	0	180	Fixed Days	45	0	0	Standard	N/A
2	Oral metoclopramide	0-6 years	No	0	0	0	180	Fixed Days	45	0	0	Standard	N/A
3	Oral metoclopramide	7-12 years	No	0	0	0	180	Fixed Days	45	0	0	Standard	N/A
4	Oral metoclopramide	13-17 years	No	0	0	0	180	Fixed Days	45	0	0	Standard	N/A
5	Oral metoclopramide	18+ years	No	0	0	0	180	Fixed Days	45	0	0	Standard	N/A

National Drug Codes (NDC) codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."