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).

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Appendix C. Specifications Defining Parameters used in this Request

In this request we used the Cohort Identification and Descriptive Analysis (CIDA) module, version 3.0.2 to investigate numbers of pediatric patients diagnosed and/or hospitalized with respiratory syncytial virus (RSV) and RSV-Related Events and Preventative Services in the Sentinel Distributed Database (SDD).

Enrollment Gap: 45 days
Query Period: January 1, 2008 - September 30, 2015
Age Groups: 0-2, 0-5, 3-5, 6-11, 6-17, 12-23, and 18-23 months
Coverage Requirement: Drug and Medical
Pre-Exposure Enrollment Requirement: 0 days

	Event/Index Date					Incidence Criteria		
Scenario	**Incident Event**	**Care Setting**	**Principal Discharge Diagnosis**	**Combo**	**Cohort Definition**	**Washout (days)***	**Incident with respect to:**	**Incidence Care Setting**
1	RSV diagnosis	IP, ED, or AV	Any	N/A	All valid events	30	RSV diagnosis	Any
2	RSV diagnosis, *or* 2 RSV diagnoses	IP or ED AV	Any N/A	N/A Diagnoses must occur within 14 days of each other, index date is date of the first diagnosis	All valid events	30	RSV diagnosis	Any
3	PCR lab test for RSV, or antigen lab test for RSV	Any	N/A	N/A	All valid events	30	PCR lab test for RSV, or antigen lab test for RSV	Any
4	PCR lab test for RSV	Any	N/A	N/A	All valid events	30	PCR lab test for RSV	Any
5	Antigen lab test for RSV	Any	N/A	N/A	All valid events	30	Antigen lab test for RSV	Any
6	Synagis dispensing or procedure	Any	N/A	N/A	All valid events	30	Synagis dispensing or procedure	Any
7	Bronchiolitis diagnosis	Any	Any	N/A	All valid events	30	Bronchiolitis diagnosis	Any

*The washout will be done in the combination tool to avoid requiring pre-index enrollment.

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes, National Drug Codes (NDCs), Current Procedural Terminology, Fourth Edition (CPT-4) codes, and Healthcare Common Procedure Coding System (HCPCS) codes are provided by Optum360. NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."