Disclaimer

The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-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 Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

Data obtained through Mini-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 the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-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 B. Specifications Defining Parameters for this Request

Modular Program #3 (version 5.0) was used to investigate switching between generic clonzaepam and brand klonopin in the Mini-Sentinel Distributed Database (MSDD). The first scenario outlined below examines generic users with a pre-existing condition of brand use in the prior 183 days who switch back to brand use within their generic treatment episode. The second scenario examines brand users with a pre-existing condition of generic use in the prior 183 days who switch back to generic use within their brand treatment episode.

Enrollment Gap: 45 days
Query Period: January 1, 2004 to December 31, 2012
Age Groupings: 0-<22, 22-<45, 45-<65, 65+ years

	Drug/Exposure								Pre-Existing Condition			Event/Outcome				
Scenario	**Incident exposure**	**Incident with respect to:**	**Episode Gap**	**Exposure extension period**	**Minimum episode duration**	**Minimum days supplied**	**Washout (days)**	**Incidence Type***	**Pre-Existing Condition**	**Lookback Start**	**Lookback End**	**Event/ Outcome**	**Incident with respect to:**	**Washout (days)**	**Washout Type****	**Blackout Period**
1	Generic Clonazepam	Generic Clonazepam	10	30	0	0	183	Single (SING)	Brand Klonopin	-183	-1	Brand Klonopin	Brand Klonopin	0	Multiple (MULT)	0
2	Brand Klonopin	Brand Klonopin	10	30	0	0	183	SING	Generic Clonazepam	-183	-1	Generic Clonazepam	Generic Clonazepam	0	MULT	0

National Drug Codes (NDCs) checked against First Data Bank's "National Drug Data File (NDDF®) Plus"

International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) diagnosis and procedure codes checked against "Ingenix 2012 ICD-9-CM Data File" provided by OptumInsight

Healthcare Common Procedure Coding System (HCPCS) codes checked against "Optum 2012 HCPCS Level II Data File" provided by OptumInsight

Current Procedural Terminology, Fourth Revision (CPT-4) codes checked against "Optum 2012 Current Procedure Codes & Relative Values Data File" provided by OptumInsight

*Single incidence type for the exposure will only consider the first incident episode for each user during the query period that satisfies the Washout Period criteria (183 days). There can be at most one episode per user.

**Multiple washout type for the event will only consider the first event for each episode that satisfies the Washout Period criteria of 183 days. There can be at most one event per episode and consequently, one event per user.