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.

Appendix F. Specifications Defining Parameters Used in this Request

	Drug/Exposure					Outcome			
Scenario	**Exposure**	**Incident with Respect to:**	**Washout (Days)**	**Cohort Definition**	**Intention-to-Treat (Days)**	**Outcome**	**Purpose of Outcome**	**Washout (Days)**	**Care Setting**
13	HCTZ, CTZ, BFMTZ, ACE inhibitor, beta blocker, or CaChannel	HCTZ, CTZ, BFMTZ, ACE inhibitor, beta blocker, or CaChannel	183	Include first valid exposure only	7,000 (look for outcome until end of enrollment)	squamous cell carcinoma event (combo of squamous cell carcinoma diagnosis code as index *AND* treatment procedure code *OR* chemotherapeutic agent code within 30 days)	To capture squamous cell carcinoma event; *sensitivity analysis*	0	Any

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Current Procedural Terminology, Fourth Edition (CPT-4) codes are provided by Optum360.

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