Sentinel

SENTINEL METHODS

Methods Development Project: Identify and Evaluate Manufacturer-Level Drug Utilization and Switching Patterns in Sentinel

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The Sentinel System is sponsored by the U.S. Food and Drug Administration (FDA) to proactively monitor the safety of FDA-regulated medical products and complements other existing FDA safety surveillance capabilities. The Sentinel System is one piece of FDA's Sentinel Initiative, a long-term, multi-faceted effort to develop a national electronic system. Sentinel Collaborators include Data and Academic Partners that provide access to healthcare data and ongoing scientific, technical, methodological, and organizational expertise. The Sentinel Coordinating Center is funded by the FDA through the Department of Health and Human Services (HHS) Contract number HHSF223200910006I.

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I. INTRODUCTION

In 2008, the Office of Generic Drugs (OGD) at the Center for Drug Evaluation and Research (CDER) first became interested in issues related to product switching after publications began to surface questioning the effectiveness of generic antiepileptic drugs. In 2010, OGD issued its first of several major extramural contracts to evaluate equivalence of generic formulations. Both pharmacokinetic substitution studies of anti-epileptics and immunosuppressants, and post-market electronic database studies of switching have been launched (see Appendix 1 for those conducted in electronic healthcare databases). Additionally, 30%-40% of the approximately 600 spontaneous quality-related reports received by OGD per month describe issues related to switching from generic to brand or vice-versa. Lastly, OGD issued three prominent drug safety communications between 2011 and 2015 regarding the therapeutic non-bioequivalence of some generic products of bupropion extended release tablets, methylphenidate extended release tablets, and lansoprazole delayed-release orally disintegrating tablets.[1-4]

In 2013, OGD began to collaborate with the Office of Surveillance and Epidemiology (OSE) at CDER, to use the Sentinel System. At this time, four Sentinel Routine Analytic Framework (RAF) tools were run to examine brand/generic switching amongst several products, including: clonazepam, losartan, carbamazepine, divalproex, lamotrigine, levetiracetam, topiramate, zonisamide, felbamate, clopidogrel, pravastatin, metoprolol, and warfarin.[5] The request involving warfarin was unique from the others in that it evaluated switching at the manufacturer level, which the other requests had not attempted. These early efforts resulted in several conclusions regarding the use of Sentinel RAF tools to study brand/generic switching patterns:

(a) The current suite of Sentinel RAF tools were not developed to characterize the duration of each episode at the point when a switch occurred, so were unable to answer questions about how long an individual is on a brand or generic product before switching. Also, the existing RAF tools were not able to determine whether people are new or existing users in the group in which their treatment pattern began (brand or generic),

(b) Assessing generic drugs requires a more complete crosswalk to identify re-labelers and re-packagers of generic drugs and to identify authorized generics in order to trace the product back to a manufacturer, and

(c) Further evaluation of the approach of looking at product switching is needed to determine if product switching could indeed be used for signal detection purposes.

II. STUDY PURPOSE

The purpose of this developmental methods project is to explore the potential for the Sentinel System[6] and its Sentinel Distributed Database (SDD) to support these types of investigations and to assess their potential for detecting new safety issues related to manufacturer-level switching of the same product.[7,8] As such, this project is intended to address the limitations identified in the prior work in Sentinel, and build upon, contextualize, and extend the extramural work done by OGD.

The Sentinel System could potentially:

- Provide population-based evidence to support equivalence for approved drug products,
- Support identification of potentially problematic drug products for product-specific bioequivalence guidance revision,

- Complement FDA findings on post-marketing bioequivalence studies and internal examinations of formulation or pharmacokinetics/pharmacodynamics when generics are identified as higher risk or non-equivalent,
- Identify potential topics or signals for future investigation (e.g., drugs to evaluate for post-marketing population-based safety and effectiveness studies).

To that end, this Workgroup will design, develop, test and evaluate a prototype analytic tool to characterize product utilization and switching patterns. The tool will be able to capture switching patterns at the manufacturer-level, based on product NDC. As required by the Drug Listing Act of 1972, drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs.[9] The NDC code identifies the labeler, product, and trade package size. The first segment, the labeler code, is assigned by the FDA. A labeler is any firm that manufactures (including repackers or relabelers), or distributes (under its own name) the drug. The second segment, the product code, identifies a specific strength, dosage form, and formulation of a drug for a particular firm. The third segment, the package code, identifies package sizes and types.

Two products will be used as analytic tool development use-cases. Based on the literature, we are expecting to see certain patterns of use. A more in-depth rationale for using these products as use-cases is discussed below in sections IV. B. and IV. E. A third analysis may be included on an as-yet unnamed use-case.

1. Toprol XL (metoprolol ER), and
2. Lamictal XR (lamotrigine ER).

If application of this tool to the set of selected product use-cases proves promising, FDA may elect to incorporate this prototype into the suite of RAF tools, in order to respond to concerns about generic products in a rapid query manner. Characterizing and evaluating switching or switchback patterns may also be used as a proxy identifier of potential bioequivalence issues; patient switching or switchback behavior may indicate safety or effectiveness concerns associated with a specific generic product.

III. SPECIFIC AIMS

1. Design, develop, test and evaluate a flexible and reusable prototype analytic tool that could be used to conduct rapid population-based assessments on new generic products in the future; and
2. Use the Sentinel System to characterize utilization and switching patterns associated with the two use-cases.

IV. ANALYTIC DEVELOPMENT

A. DATA SOURCE

This developmental methods project will utilize data in the SDD from four data partner sites: Aetna, HealthCore, Humana, and Optum. The SDD contains quality-checked data across 18 different data partner sites and contains over 220 million unique patient identifiers.

These sites were selected to be included in this project for several reasons:

1. They are the largest four data partner sites, collectively comprising 88% of the total patient data within the SDD,
2. Each of the sites is a national health insurer, whose inclusion could minimize any regional differences that might exist with respect to product availability, uptake, and usage,
3. A recent analysis using Sentinel RAF tools showed that each of these sites had adequate uptake of the products (see part B below) that will be used as use-cases for the development of the analytic tool.

The four included sites' data sources consist of administrative claims-based systems. Each site maps their source data in accordance with the structure of the Sentinel Common Data Model and stores those SCDM-formatted data behind their respective firewalls. The SCDM is a detailed, patient-level model that contains data on each covered member's medically-attended care, across a defined period of health care enrollment that initiated a health insurance claim. A discussion of SCDM structure and data elements can be found here:

https://www.sentinelsystem.org/sentinel/data/distributed-database-common-data-model

Table 1 shows the availability of data at each site.

Table 1: SDD data partner: data availability start and end dates, as of December 2016

Data partner site	Data contribution start date	Data contribution end date
Aetna	01/01/2008	09/30/2015
HealthCore	01/01/2006	04/30/2016
Humana	06/01/2007	01/31/2016
Optum	01/01/2008	09/30/2015

B. PRODUCTS BEING USED AS USE-CASES SUPPORTING PROTOTYPE TOOL DEVELOPMENT

One area in which OGD is interested is the equivalence of generic modified release (MR) products. MR products are at higher risk for equivalence concerns because they are more complex formulations to develop and manufacture. Utilization and switching patterns may also be more complex with modified release products because of the availability of both immediate-release and modified-release formulations with the same active ingredient. Therefore, modified release products were chosen for the two use cases selected for development of this prototype.

Toprol XL (metoprolol ER)

Toprol XL is a beta blocker indicated for the treatment of hypertension, angina pectoris, and heart failure. It was approved by the FDA January 10, 1992 (NDA 019962; AstraZeneca). The first generic metoprolol ER product was approved on July 31, 2006. As of July 31, 2016, generics from 6 manufacturers have been approved (under 11 ANDAs) and Par markets an authorized generic version of Toprol XL under an agreement with AstraZeneca.

Despite the availability of generics, the brand drug, Toprol XL, maintains a relatively high market share (10% in 2015). Between 2008 and 2014, several manufacturers recalled some of their generic metoprolol ER products due to failures in meeting quality standards.[10] In 2014, OGD funded a study in patients to help understand the pharmacokinetic-pharmacodynamic relationship of different metoprolol products. [11]

Lamictal XR (lamotrigine ER)

Lamictal XR is an anticonvulsant agent indicated for treatment of certain types of seizures in patients aged 13 years and older. It was approved by the FDA on May 29, 2009 (NDA 022115; GlaxoSmithKline). The first generic lamotrigine ER product was approved on December 26, 2012. As of July 31, 2016, generics from 7 manufacturers have been approved (under 8 ANDAs).

The equivalence of generic antiepileptic drugs (AEDs) was an area of debate among some healthcare providers. OGD has funded several bioequivalence studies involving lamotrigine.[12,13] Two FDA-funded studies have found equivalence between different lamotrigine immediate-release (IR) formulations in epilepsy patients and the American Epilepsy Society (AES) recently revised its position from "against generic substitution without physician's approval" to "the AES acknowledges that drug formulation substitution with FDA-approved generic products reduces cost without compromising efficacy." [14] A FDA-funded study with lamotrigine ER formulations is ongoing to further address neurologist's questions regarding modified release AED products. While lamotrigine is not a narrow therapeutic index drug, it does have some characteristics that place it at higher risk if there is any potential inequivalence, such as the potential for serious therapeutic failure with sub-therapeutic concentrations.

Table 2: Drug products of interest and associated products with same active ingredient

Drug(s) of interest	# generics	First generic approval date	Authorized generic?
Toprol XL (metoprolol ER)	6	7/31/2006	Yes
Lamictal XR (lamotrigine ER)	7	12/26/2012	No

C. ANALYTIC APPROACH

The tool will be flexibly designed in order to facilitate re-use across multiple studies and will leverage existing RAF tools to the extent reasonable, particularly the features, philosophy and analytic approach of the Sentinel Cohort Identification and Descriptive Analysis (CIDA) tool. Cohort identification-related criteria that will be flexibly designed to allow user-defined/specified inputs are listed in Appendix 2. "Switching" will be flexibly defined and could include any switching pattern between products in user-specified product groups. In essence, since outpatient dispensings in the SDD are defined by NDC, any information gleaned from the NDC that could be used to differentiate product characteristics, would be able to be used to capture and characterize product switching. This includes, but may not be limited to:

a) From a brand product to a generic product
b) From a generic product to a brand product
c) From a generic to another generic of the same product (e.g., between different generic versions from different manufacturers within a given drug/active pharmaceutical ingredient [API]), and
d) Switches away to other dosage forms with the same active ingredient or other products within the same drug class.

The tool will be designed to allow the user to specify which products should be grouped together. For example, any NDCs representative of a brand product manufactured by Manufacturer A could be grouped together as GroupA. Likewise, any NDCs representative of a generic product manufactured by Manufacturer B could be grouped together as GroupB. Tool users would be able to specify the treatment patterns they wish to identify and report on (e.g. GroupA->GroupB->GroupA, GroupB->GroupA->GroupB, GroupA->GroupB->GroupC, and so forth). The tool will also be designed to support the evaluation of multiple switch patterns within one execution of the tool. For example, the tool will be designed to support, within one execution, identification of switching between/amongst the 7 different metoprolol products that are each produced by different manufacturers. This first prototype version of the tool will support evaluate for up to two switches per switch pattern, in order to identify and characterize one-switch treatment patterns (e.g. GroupA->GroupB), as well as two-switch "switch-backs" (e.g., GroupB->GroupA->GroupB) or "switch-aways" (e.g., GroupA->GroupB->GroupC). Appendix 3 provides a more detailed description of how product treatment episodes will be evaluated for switching.

D. ANALYSIS AND REPORTING

The tool will return aggregate data from each site to facilitate reporting; no patient-level data will be generated for sharing or reporting. Data will be reported by each data partner, as well as across all data partners. Though we plan to report out by data partner, the specific data partner site name will always be masked in all final reports and tables.

There will be two sets of outputs, providing aggregate data across the following areas:

[1] Tables and figures showing product uptake and utilization trends over time

[2] Tables and Kaplan-Meier plots showing product switching (e.g., ProductA→ProductB), product switch-backs (e.g., ProductA→ProductB→ProductA) and product switch-aways (e.g., ProductA→ProductB→ProductC), and related durations associated with those switching events. See Appendix 2 for more details, including proposed reporting table shells.

E. EVALUATION

The tool will undergo evaluation to ascertain whether the results generated by the tool show the utilization and switching patterns we expect to see, given the known use-cases we will use for this developmental methods project. For the Toprol XL use case, we expect to see high rates of switching from products from Sandoz and Ethex to other metoprolol ER products, including the brand-name Toprol XL, Par's authorized generic, and Watson's generic version between September 2008 and January 2009. In September 2008, Sandoz recalled all of its metoprolol ER products due to quality concerns. In December 2008, KV Pharmaceuticals, which markets prescription medications through Ethex, voluntarily suspended shipment of all prescription tablet products, including their metoprolol ER generics. We also expect that utilization plots will show disappearing use of the Sandoz and Ethex products by early 2009 and corresponding increases in utilization of the other products.

For the Lamictal XR use case, we would expect to see high rates of switch-back from generic to brand-name products due to negative perceptions of generic antiepileptic drugs. Previous Canadian studies have found that, among patients who switch from brand-name lamotrigine IR to generic versions, between 13% and 28% switch back to the brand-name version though FDA funded studies demonstrated bioequivalence of generic lamotrigine IR to the RLD and other generics.[15] The switchback rate of lamotrigine IR is higher than switchback rates observed for other drugs (e.g., 2-9%).[16] Higher rates of switch-back may be observed for the first generic lamotrigine MR product because many patients on the brand-name version will incur automatic substitution at the time of approval of the first generic and may have negative perceptions of generic AEDs. We expect to observe similar switch-back rates for the different generic products among patients who initiate the brand-name and subsequently switch to a generic product.

V. STRENGTHS AND LIMITATIONS

Relying on electronic healthcare databases from several large national health insurers has many advantages. First, there is capture of medically-attended care across a large, diverse, commercial-claims representative patient population. Additionally, these sources contain detailed information on the outpatient dispensings of over 190 million patient lives, as well as the ability to follow those patients over a defined, known period of health plan enrollment in order to assess the medically-attended care provided across that period.

Outpatient dispensings are captured in the SCDM by National Drug Code (NDC), for which detailed product data exists, including, but not limited to: manufacturer, application number, product approval date, dosage form, strength, generic name, brand name, pharmaceutical class, and active ingredients.

There are also inherent limitations to using administrative claims data for surveillance or research purposes. First, as with any claims-based data source, we cannot follow patients when they terminate health insurance coverage with one company. That is, if a person terminates insurance with one company's health plan and enrolls in another company's health plan, that person would appear as a new patient/enrollee in the SDD. Capture of medically-attended care is limited to what we see within each individual data partner site, not across sites. Second, the SDD captures outpatient dispensings for which a claim was paid. We do not know the range of products stocked by the pharmacies filling prescription medication orders or why a pharmacy might decide to stock one generic over another. We also do not capture information on health plan formulary data for Sentinel Data Partners. We therefore cannot comment or report on product uptake and usage from these perspectives. We also would not observe prescriptions filled but not paid for by an insurer, such as low-cost generics purchased directly by a

consumer, nor would we observe use of over-the-counter products. Third, a claim indicates that a person was dispensed a particular medication, but we cannot determine whether a person took the medication as indicated or at all. Fourth, medications administered by healthcare providers within a provider care-setting may be captured in claims data, and the SCDM, as procedure codes (e.g., HCPCS). This tool will be flexibly designed to provide the ability to identify products by either NDC or procedure code. It should be noted, however, that procedure codes may not contain detailed product data to be able to distinguish between manufacturers and procedure codes do not provide 'days' supply' information, which typically accompanies drug dispensing claims. So although this tool may theoretically be able to be used to support bioequivalence studies for products identified via procedure codes, it should be noted that before making practical use of this tool in this way, additional work may be needed to clearly identify product manufacturers for any product(s) whose current capture in the SCDM does not clearly identify the same (e.g., HCPCS suffixes). This work may consist of, but may not be limited to, investigation of the extent to which product modifiers distinguishing between manufacturers are captured in Sentinel source data systems (e.g., claims), in order to be able to be captured in the SCDM.

Additionally, we will enumerate, but not provide detailed metrics for, patients who follow non-switching treatment pattern changes. That is, if a medical product-use pattern does not qualify as a switch under the definition of how we will define switching (e.g., a product change that occurs within user-specified X days of the first product-group but overlap by no more than user-specified Y days or percent), this tool will report, for cohort attrition purposes, basic counts, product-use duration summary statistics and reason for censoring for those patients (e.g., for a person who starts on a brand product and does not switch to any other product of interest). Detailed data about these non-switching treatment patterns will not be provided by this tool but could be an enhancement for a future tool version.

Lastly, we are not evaluating for health outcomes of interest (HOIs) during specific exposures or HOIs within some window around when a switch or switch-back occurs. However, we anticipate this capability being a future analytic need and will take every opportunity in the initial design and build of this tool to accommodate this future capability.

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VII. APPENDIX 1: FDA/OGD CONTRACTS RELATED TO PRODUCT SWITCHING

Grant	Institution, PI	Duration	Aims Related to Product Switching
Assessing Clinical Equivalence for Generic Drugs Approved by Innovative Methods *(U01FD004856)*	Brigham and Women's Hospital, PI: Aaron Kesselheim	9/15/2013 to 3/31/2015	Aim #3: identify switchback rates of 6 'model' generic drugs and determine whether the switchback rates differ significantly from switchbacks related to use of 'control' drugs. Then, compare switchback outcomes to patient-centered outcomes [outcomes were disease specific (AE-related) hospitalizations]. Database: Optum LifeSciences Research Database
Postmarketing Surveillance of Generic Drug Usage and Substitution Patterns *(U01FD004855)*	University of Maryland Baltimore/IMPAQ International, PI: Ilene Harris	9/15/2013 to 10/31/2015	Aim 2: Estimate brand and generic drug use and switchback rates, and investigate medical service use associated with generic switching Database: CMS Medicare claims, 5% random sample
Assessing the post-marketing safety of authorized generic drug products *(1U01FD005279)*	Brigham & Women's Hospital, PI: Joshua Gagne	9/10/2014-8/31/2016	Aim 1: Compare substitution and switchback rates, adherence, medical utilization, and clinical outcomes between authorized generic and other generic versions of model drug products and between other generic versions and brand versions of these drugs Databases (5): PA and NJ Medicare data + pharmaceutical assistance programs dispensing data; national Medicaid Analytic Extract (MAX); Optum Life Sciences Research database; Aetna + CVS CareMark; Medicare enrollment, A, B + CVS CareMark data
Post-market Authorized Generic Evaluation (PAGE) *(1U01FD005272)*	Auburn University, PI: Richard Hansen	9/10/2014-8/31/2016	Aim 1: To determine and compare switchback rates, medical service utilization, and clinical outcomes between authorized generics and generics using healthcare claim data with electronic medical records. Database: Marshfield Clinic Electronic Health Record (EHR) + Security Health Plan (SHP)

VIII. APPENDIX 2: FUNCTIONAL SPECIFICATION FOR ANALYTIC TOOL DESIGN

The tool will be flexibly designed to prioritize re-use; that is, the design will accommodate the ability to answer a set of questions that could be applied to many products, as opposed to only a specific product or products. In keeping with the philosophy and approach of the CIDA tool, any study-specific, cohort-identification criteria will be flexibly supplied to the programming code via user-specified macro parameters and/or input files, rather than hard-coded into the programming code itself. The study-specific, cohort-identification that will be designed flexibly to allow user-defined/specified inputs include:

- Enrollment coverage requirements
- Allowable enrollment gaps
- Minimum enrollment duration requirement prior to product use
- Inclusion/exclusion criteria: defined using any combination of NDCs, procedure and/or diagnosis codes, and laboratory result values found in the SCDM. Procedure and diagnosis codes can be restricted to those observed in specific care settings (e.g., inpatient, outpatient) and diagnosis codes can be restricted by position (e.g., principal discharge diagnosis, secondary diagnosis)
- Products to include (defined by NDCs or other coding systems, such as HCPCS)
- Start approval date (user-defined and specific to each product group)
- Data-driven computation of start marketing date. The tool will be designed to compute a value for start marketing date, within each data partner site, based on the minimum first dispensing date observed across products within a group. Data-driven computation of start marketing date is needed because start marketing date may not be reliably known from commercial medical product look-up resources or reliably known to FDA from manufacturers.
- Minimum days of supply for dispensing claim inclusion
- Maximum days of supply for dispensing claim inclusion
- Product groupings (products can be grouped in any way the user wishes; products in the same groups will be processed and reported as a group)
- Stockpiling algorithm. See Appendix 3.
- Age group inclusion and stratification
- Allowable gap to identify switch/switch-back/switch-away treatment patterns from non-switch-related treatment patterns. We propose that gaps be expressed as a number of days. See Appendix 4.
- Allowable overlap to identify switch/switch-back/switch-away treatment patterns from non-switch-related treatment patterns. We propose that overlaps be expressed as a number of days OR as a percent. See Appendix 4.
- Index date definition. Index date will be user-defined, as one of the following. Note that this tool will allow user-specified redefinition of an index date. For example, for a first switch of brand-to-generic, the index date would likely often be generic approval date (calendar time). For a second switch of generic-to-brand switchback, the index date may be an individual's date of brand-to-generic switch (patient-specific):
    - Absolute calendar date (e.g., start approval date or computed start marketing date): may be useful for brand-to-generic switching
    - Patient-specific date (e.g., patient's date of brand initiation or a patients brand-to-generic switch date for following up for switch-backs/switch-aways): may be useful for patient who initiate the brand when the generic is on the market
- Minimum post-index enrollment, to ensure sufficient follow-up

1. High-level programming steps

a) Import and process input files
b) Extract relevant records from relevant tables
    1. For non-NDC product usage (e.g., HCPCS codes indicating injection administration), allow a user-specified supply to be attached to that injection procedure. Note: Even though product usage defined with codes other than NDCs (e.g., HCPCS codes) typically cannot be used to identify product manufacturer, we recommend, for maximum analytic flexibility, designing this tool to allow for product usage to be defined using non-NDC coding systems.
c) Identify invalid claims, i.e., those with days of supply outside the allowable range(s)
d) Stockpile dispensings (See Appendix 3 for description of stockpiling algorithm options)
e) Adjust enrollment based on death date (if requested). Please note that there can be a 1-2 year lag in death data.
f) Restrict to records overlapping valid enrollment span
g) Define index date(s)
h) Define index incidence
i) Apply user-specified inclusion/exclusion criteria
j) Create treatment episodes
k) Remove episodes if: index date does not overlap the query period, pre-exposure enrollment criteria not met, post-exposure enrollment criteria not met
l) Provide the optional capability to save all data across all SCDM tables for the patients selected into any cohort. This provides the capability to conduct further analyses using all available data from the original patient cohort
m) Evaluate treatment episodes for switching patterns, in accordance with user-specified patterns. See Appendix 4.

2. Input files: a minimum set of input files needed to support flexible cohort-identification and switch-pattern recognition criteria

- Cohort file: used to define cohort enrollment requirements, including insurance coverage requirements (e.g., medical, drug, or both), minimum and/or maximum pre/post-index number of days of continuous enrollment required), washout days (prevalent or incident use, etc.)
- Cohort codes file: primary file for specifying medical product codes used to define product exposure and exposure incidence criteria, start approval date, etc.
- Stockpiling file: defines how valid dispensings are selected and used by the stockpiling algorithm to create exposure episodes. See Appendix 3 for more details.
- TreatmentPathways: defines the product switching patterns to be identified and characterized (e.g., define cohorts of product users in the "cohort file". Specify for the tool to evaluate switch-patterns in this TreatmentPathways file in the following manner: SwitchPattern1=ProductA->ProductB; SwitchPattern2= ProductA->ProductB->ProductA; SwitchPattern3= ProductA->ProductB->ProductC). This file will allow the user-specified redefinition of an index date. For example, for a first switch of brand-to-generic, the index date may be specified by the user as the generic approval date (calendar time). For a "second switch" of generic-to-brand switchback, the index date may be an individual's date of brand-to-generic switch (patient-specific).

3. Reporting

- Signature file: contains metadata associated with the request, including request identifiers, program identifiers, database version, and run time metrics
- Waterfall/attrition table for each study cohort: includes the number of patients excluded and remaining at each cohort creation criterion application during the CIDA tool execution.
- Set of aggregate-level output datasets (specific number and structure to-be-decided) to support the creation of reporting tables outlined in table shells (below)

Below are reporting table shells and figure descriptions that the tool will output.

a. Utilization metrics

Products will be identified by NDC and categorized by two-level system: ProductGroup1 and ProductGroup2. ProductGroup1 is intended to be a higher-level grouping of multiple products designated into different ProductGroup2 categories. For example, we may have 7 different ProductGroup2 categories that each represent a different metoprolol product (e.g., one for each of the 6 generic manufacturers and 1 for the brand manufacturer), and we may have one ProductGroup1 category that groups together all of these metoprolol products from ProductGroup2. We will use the more granular ProductGroup2 category to create treatment episodes that will be used for utilization reporting purposes and for product switching evaluation purposes. We will attach a ProductGroup1 category label to those episodes for higher-level utilization reporting purposes only. It is envisioned that ProductGroup1 will likely be used to group products having the same active ingredient, while ProdcutGroup2 will likely be used to identify products of specific manufacturers.

Table 3a: Utilization over time: Number of new users, by ProductGroup1 and ProductGroup2, demographic characteristic, month-year and overall. *One table for each site and one for all sites aggregated*.

Table 3b: Utilization over time: Number of overall users (new + prevalent), by ProductGroup1 and ProductGroup2, demographic characteristic, month-year and overall. *One table for each site and one for all sites aggregated*.

Table 3c: Utilization over time: Number of dispensings (all dispensings), by ProductGroup1 and ProductGroup2, demographic characteristic, month-year and overall. *One table for each site and one for all sites aggregated*.

Figures to support Tables 3a-3c: line graphs

Table 3: Represents the basic structure of reporting Tables 3a-3c

Demographics	Jan 2015	Feb 2015	Mar 2015	…	Dec 2015
ProductGroup1					
Total					
Male					
Female					
AgeGroup1					
AgeGroup2					
AgeGroup3					
AgeGroup4					
ProductGroup2					
Total					
Male					
Female					
AgeGroup1					
AgeGroup2					
AgeGroup3					
AgeGroup4					

Figures to support Tables 4-6: histograms or bar graphs

Table 4: Number of days supplied per valid dispensing, by ProductGroup1 and ProductGroup2, overall and by site

	Min	Max	Mean	25th percentile	Median	75th percentile	Total days supplied	Total dispensings
ProductGroup1 Site1 Site2 Site3 Site4								
ProductGroup2 Site1 Site2 Site3 Site4								

Table 5: Summary statistics for product uptake: Time (in days) from [user-specified approval date or computed start marketing date] to first observed dispensing, by ProductGroup1 and ProductGroup2, overall and by site

	Min	Max	Mean	25th percentile	Median	75th percentile	Total time, in days	Total dispensings
ProductGroup1								
Site1								
Site2								
Site3								
Site4								
ProductGroup2								
Site1								
Site2								
Site3								
Site4								

Table 6: Product treatment episode duration summary statistics (in days), by ProductGroup1 and ProductGroup2, stratified by reason for episode end. ***One table for each site and one for all sites aggregated.***

	Episode end reason					
	All	**End query period**	**End enrollment**	**End available data**	**Product discontinuation**	**Death**
ProductGroup1 **Minimum** **Maximum** **Mean** **25th percentile** **Median** **75th percentile** **Total time, in days** **Number of episodes** **Number of patients**						
ProductGroup2 **Minimum** **Maximum** **Mean** **25th percentile** **Median** **75th percentile** **Total time, in days** **Number of episodes** **Number of patients**						

b. Switching metrics: Kaplan-Meier plots and descriptive summary statistics

Figure 1: Basic patterns of product use and switching events

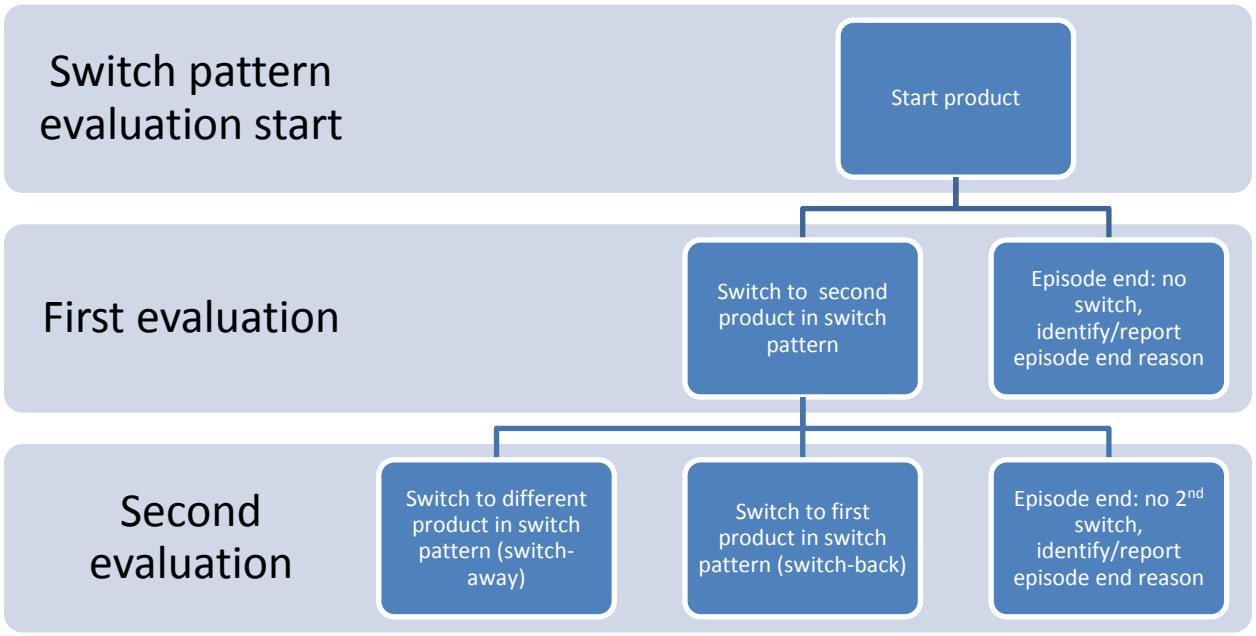

Figure 1 shows the basic patterns of product use and switching events that the tool will identify and provide metrics for.

Below are descriptions of the switching-related metrics the tool will create. Proposed table shells are provided for clarity.

A. Kaplan-Meier curve for time to first switch (of initiators of a start product of interest)

The K-M curve for time to first switch (or episode end) will include all patients exposed to a start product of interest as of a user-specified index date. This index date could be a computed product start marketing date, a product approval date, or some other user-specified date representing a suitable start anchor point. Patients in this closed cohort will be followed from the index date until time of first switch to a generic product or until the end of the episode.

B. Kaplan-Meier curve for time to second switch (of patients with at least one-switch pattern)

The K-M curve for time to second switch will index patients at the time of their first switch and follow them, with time since first switch serving as the index date, until a second switch or until the end of the episode.

Table 7: Summary statistics for time to first switch in days (of initiators of a start product of interest), by SwitchPattern and stratified by switched or episode end (and by reason for episode end). ***One table for each site and one for all sites aggregated.***

	All	Switched	Episode end (reason for end)				
			End query period	End enrollment	End available data	Product discontinuation	Death
SwitchPatternA **Minimum** **Maximum** **Mean** **25th percentile** **Median** **75th percentile** **Total time, in days** **Number of episodes** **Number of patients**							
SwitchPatternB **Minimum** **Maximum** **Mean** **25th percentile** **Median** **75th percentile** **Total time, in days** **Number of episodes** **Number of patients**							

Table 8: Summary statistics for time to second switch in days (of patients with at least one switch), by SwitchPattern and stratified by switched or episode end (and by reason for episode end). ***One table for each site and one for all sites aggregated.***

	All	Switched	Episode end (reason for end)				
			End query period	End enrollment	End available data	Product discontinuation	Death
SwitchPatternA							
Minimum							
Maximum							
Mean							
25th percentile							
Median							
75th percentile							
Total time, in days							
Number of episodes							
Number of patients							
SwitchPatternB							
Minimum							
Maximum							
Mean							
25th percentile							
Median							
75th percentile							
Total time, in days							
Number of episodes							
Number of patients							

Table 9: Switch pattern episode duration summary statistics, by switch pattern and site

	Number of patients	Minimum	Maximum	Mean	25th percentile	Median	75th percentile	Total time, in days
SwitchPatternA								
Site 1								
Site 2								
Site 3								
Site 4								
SwitchPatternB								
Site 1								
Site 2								
Site 3								
Site 4								

Table 10: Frequency distribution of patients who switch, by number of months to first-switch. One table for each switch pattern (at least one switch pattern). ***One table for each site and one for all sites aggregated.***

Months	Number and percent (of patients with at least one switch pattern)
1	
2	
…	
x	

Table 11: Frequency distribution of patients who switch, by number of months to second-switch. One table for each switch pattern (two-switch patterns only). ***One table for each site and one for all sites aggregated.***

Months	Number and percent (of patients with two-switch pattern)
1	
2	
…	
x	

Table 12: Number of months for X percent of patient to switch (at least one-switch pattern). X percent TBD (e.g., 10%, 25%, 50%, 75%, etc.). ***One table for each site and one for all sites aggregated.***

Percentile	Number of months from initial product index to first switch
10	
25	
50	
75	
100	

Table 13: Number of months for X percent of patient to switch-back or switch-away (two-switch pattern only). X percent TBD (e.g., 10%, 25%, 50%, 75%, etc.).

Percentile	Number of months from first switch product index to second switch
10	
25	
50	
75	
100	

Table 14: Time to first switch, in days, from user-specified index date

	Min	Max	Mean	25th percentile	Median	75th percentile	Total time, in days	Number of episodes with at least one-switch pattern	Number of patients with at least one-switch pattern
SwitchPatternA									
Site1									
Site2									
Site3									
Site4									
SwitchPatternB									
Site1									
Site2									
Site3									
Site4									

Table 15: Time to second-switch (for two-switch patterns: switch-backs or switch-aways), in days weeks or months from user-specified index date. Note that whether the two-switch pattern is a switch-back or a switch-away will be inherent in the SwitchPattern#.

	Min	Max	Mean	25th percentile	Median	75th percentile	Total time, in days	Number of episodes with at least two-switch pattern	Number of patients with at least two-switch pattern
SwitchPatternA									
Site1									
Site2									
Site3									
Site4									
SwitchPatternB									
Site1									
Site2									
Site3									
Site4									

IX. APPENDIX 3: STOCKPILING ALGORITHM

Because patients may refill their drug prescriptions before the end of days' supply of the prior prescription, a stockpiling algorithm is used to account for claims with overlapping days of supply of the same query GROUP. Since this early-refill pattern may artificially reduce the length of the treatment episode, the dispensing date of the subsequent overlapping dispensing is adjusted. For example, all codes contained in exposure GROUP "Exposure1" will be input together in the stockpiling algorithm to adjust claim service dates. Claims in exposure GROUP "Exposure2" will be adjusted separately from "Exposure1" claims. Once service dates have been adjusted, treatment episodes can be created at the GROUP level using all claims with adjusted dates.

Figure 2: Standard Stockpiling Algorithm

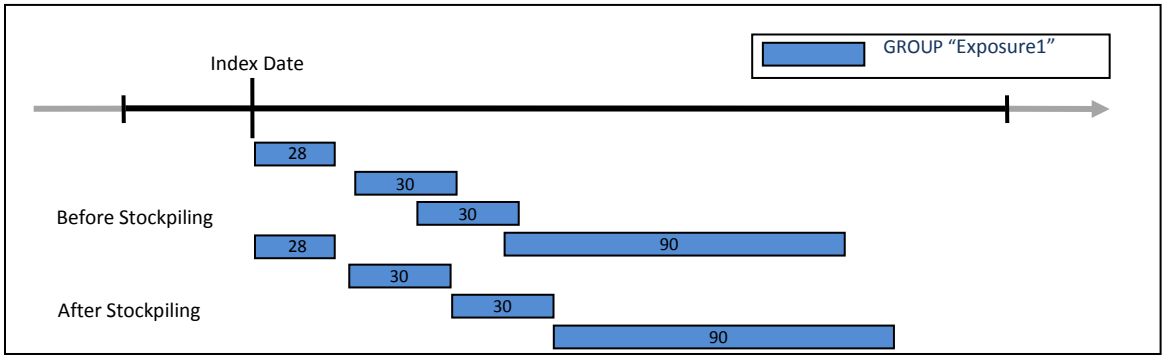

Figure 2 illustrates the standard stockpiling algorithm and how the service dates of various claims of the same GROUP are adjusted. Note that this stockpiling process occurs before the identification of continuous treatment episodes.

Figure 3: Alternative Stockpiling Algorithm

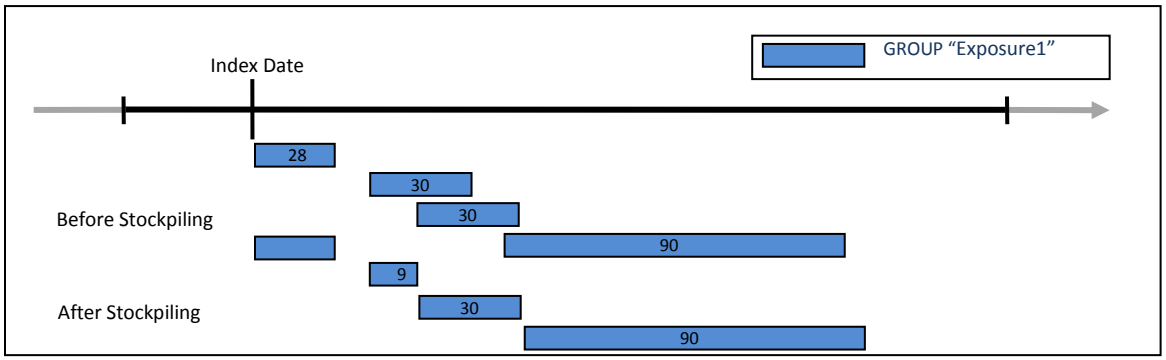

Figure 3 illustrates the alternative stockpiling algorithm with a 50% percent value. In **Figure 3**, the second claim is truncated because the third one occurs less than 50% of the time through the second dispensing.

X. APPENDIX 4: MINING SWITCH-PATTERNS

Because there may be a gap or overlap in observed episodes that are being assessed for switch-pattern behavior, this tool will have the ability to accept user-specified gap or overlap tolerance thresholds to determine whether an observed pattern will qualify as a switch or not. Note that stockpiling overlap handling is not same as gap/overlap tolerance limit handling for switches, and the user-specified stockpiling value is separate from the episode switch-pattern gap and overlap tolerance thresholds. Note, also, that we propose an allowable gap to be expressed as a number of days, and we propose an allowable overlap to be expressed either as a number of days or as a percent (of the first product group episode duration). Examples of how these tolerance thresholds will be applied are below.

Figure 4: Observed versus allowable gap assessment for determination of switch-pattern qualification

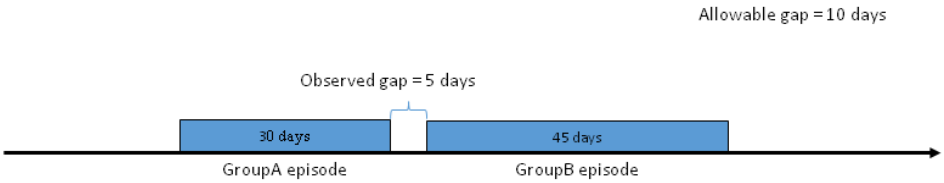

Figure 4 shows an example of an observed gap in treatment episodes being assessed for switch pattern behavior. To assess for meeting the criteria as a product switch from GroupA to GroupB, the SwitchPattern will be assigned a user-specified value for an allowable gap and an allowable overlap in dispensing. In this example, the allowable gap for the evaluation of switching patterns between GroupA and GroupB was specified as 10 days. The observed gap was 5 days. This observed dispensing pattern would therefore qualify as a switch, since the observed gap of 5 days is below the user-specified threshold allowable gap of 10 days.

Figure 5: Observed versus allowable overlap (expressed in days) assessment for determination of switch-pattern qualification

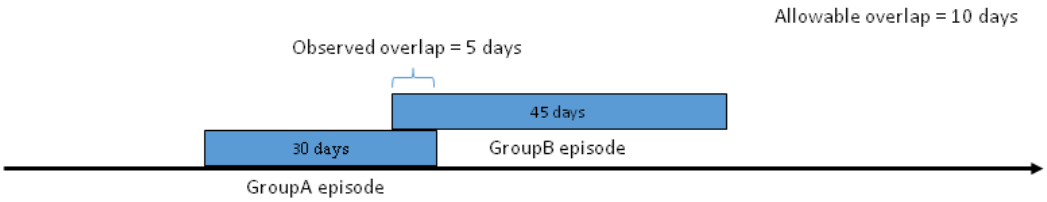

Figure 5 shows an example of an observed overlap in treatment episodes being assessed for switch pattern behavior. In this example, the allowable overlap for the evaluation of switching patterns between GroupA and GroupB was specified as 10 days. The observed overlap was 5 days. This observed dispensing pattern would therefore qualify as a switch, since the observed overlap of 5 days is below the user-specified threshold allowable overlap of 10 days.

Figure 6: Observed versus allowable overlap (expressed as a percent) assessment for determination of switch-pattern qualification

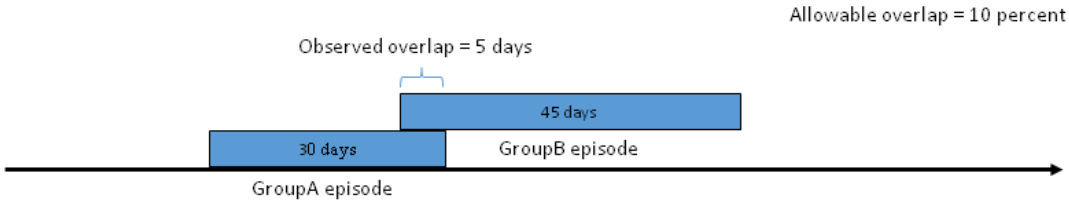

Figure 6 shows an example of an observed overlap in treatment episodes being assessed for switch pattern behavior. In this example, the allowable overlap for the evaluation of switching patterns between GroupA and GroupB was specified as 10 percent (of the first episode duration). The observed overlap was 5 days (of a 30 day episode). This observed dispensing pattern would therefore not qualify as a switch, since the observed overlap of 5 days (which is about 17 percent of the first episode) is above the user-specified threshold allowable overlap of 10 percent.

XI. APPENDIX 5: META-DATA FOR PRODUCTS USED AS PROTOTYPE TOOL DEVELOPMENT USE-CASES

Table containing product NDCs, names, ingredients, strength, unit, form, approval dates, NDA/ANDA, manufacturer names, etc.

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
52125-111	TOPROLXL	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	REMEDYREPACK INC.	8-Mar-13	-
52125-111	TOPROLXL	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	REMEDYREPACK INC.	4-Oct-13	-
52125-725	TOPROLXL	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	REMEDYREPACK INC.	4-Oct-13	-
52125-726	TOPROLXL	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	REMEDYREPACK INC.	4-Oct-13	-
0186-1092	TOPROL	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	AstraZeneca LP	1-Feb-92	-
0186-1090	TOPROL	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	AstraZeneca LP	1-Feb-92	-
0186-1094	TOPROL	METOPROLOL SUCCINATE	200	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	AstraZeneca LP	1-Feb-92	-
0186-1088	TOPROL	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	AstraZeneca LP	26-Mar-01	-
63629-3566	TOPROL	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	Bryant Ranch Prepack	1-Feb-92	-

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
63629-3475	TOPROL	METOPROLOL SUCCINATE	200	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	Bryant Ranch Prepack	1-Feb-92	-
63629-3636	TOPROL	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	Bryant Ranch Prepack	1-Feb-92	-
63629-2844	TOPROL	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	Bryant Ranch Prepack	26-Mar-01	-
55154-9608	TOPROL	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	Cardinal Health	10-May-10	-
55154-9609	TOPROL	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	Cardinal Health	10-May-10	-
55154-5026	TOPROL	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	Cardinal Health	10-May-10	-
49999-483	TOPROL	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	Lake Erie Medical DBA Quality Care Products LLC	1-Feb-92	-
51138-463	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	Med-Health Pharma, LLC	1-Jun-11	21-Jun-12
51138-464	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	Med-Health Pharma, LLC	1-Jun-11	21-Jun-12
51138-462	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	Med-Health Pharma, LLC	1-Jun-11	21-Jun-12
51138-465	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	200	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	Med-Health Pharma, LLC	1-Jun-11	21-Jun-12

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
43063-211	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	PD-Rx Pharmaceuticals, Inc.	21-Jul-11	-
43063-210	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	PD-Rx Pharmaceuticals, Inc.	21-Jul-11	-
54868-5068	TOPROL	METOPROLOL SUCCINATE	200	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	Physicians Total Care, Inc.	26-May-04	30-Jun-12
54868-4223	TOPROL	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	Physicians Total Care, Inc.	12-Oct-04	30-Jun-10
54868-4661	TOPROL	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	Physicians Total Care, Inc.	22-Mar-05	30-Jun-10
54868-3587	TOPROL	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA	NDA019962	Physicians Total Care, Inc.	9-Jul-03	30-Jun-10
49884-825	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA AUTHORIZED GENERIC	NDA019962	Par Pharmaceutical Inc.	21-Nov-06	-
49884-404	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA AUTHORIZED GENERIC	NDA019962	Par Pharmaceutical Inc.	21-Nov-06	31-Aug-19
49884-827	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA AUTHORIZED GENERIC	NDA019962	Par Pharmaceutical Inc.	26-Jul-07	-
49884-407	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	200	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA AUTHORIZED GENERIC	NDA019962	Par Pharmaceutical Inc.	26-Jul-07	30-Nov-16
49884-406	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA AUTHORIZED GENERIC	NDA019962	Par Pharmaceutical Inc.	26-Jul-07	30-Sep-19

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
49884-828	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	200	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA AUTHORIZED GENERIC	NDA019962	Par Pharmaceutical Inc.	26-Jul-07	-
49884-405	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA AUTHORIZED GENERIC	NDA019962	Par Pharmaceutical Inc.	2-Aug-07	31-Oct-19
49884-826	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA AUTHORIZED GENERIC	NDA019962	Par Pharmaceutical Inc.	2-Aug-07	-
54569-5961	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA AUTHORIZED GENERIC	NDA019962	A-S Medication Solutions	26-Jul-07	-
54569-5954	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA AUTHORIZED GENERIC	NDA019962	A-S Medication Solutions	2-Aug-07	-
58118-0405	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA AUTHORIZED GENERIC	NDA019962	Clinical Solutions Wholesale	2-Aug-07	-
52125-051	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA AUTHORIZED GENERIC	NDA019962	REMEDYREPACK INC.	8-Mar-13	-
52125-064	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA AUTHORIZED GENERIC	NDA019962	REMEDYREPACK INC.	8-Mar-13	-
54868-5729	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA076969	Physicians Total Care, Inc.	6-Feb-08	-
54868-5731	Metoprolol Succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA076969	Physicians Total Care, Inc.	5-Jan-10	-

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
54868-5732	Metoprolol Succinate	METOPROLOL SUCCINATE	200	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA076969	Physicians Total Care, Inc.	31-Jul-07	-
54868-5730	Metoprolol Succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA076969	Physicians Total Care, Inc.	3-Aug-07	-
0781-1223	Metoprolol Tartrate	METOPROLOL TARTRATE	50	mg/1	TABLET, FILM COATED	ORAL	ANDA	ANDA073288	Sandoz Inc.	25-Mar-94	-
0781-1228	Metoprolol Tartrate	METOPROLOL TARTRATE	100	mg/1	TABLET, FILM COATED	ORAL	ANDA	ANDA073289	Sandoz Inc.	25-Mar-94	-
0781-3071	Metoprolol Tartrate	METOPROLOL TARTRATE	5	mg/5 mL	INJECTION, SOLUTION	INTRAVENOUS	ANDA	ANDA077360	Sandoz Inc.	2-Oct-07	-
0781-5630	Metoprolol Tartrate and Hydrochlorothiazide	METOPROLOL TARTRATE; HYDROCHLOROTHIAZIDE	50; 25	mg/1; mg/1	TABLET	ORAL	NDA AUTHORIZED GENERIC	NDA018303	Sandoz Inc.	1-Dec-84	31-May-12
0781-5631	Metoprolol Tartrate and Hydrochlorothiazide	METOPROLOL TARTRATE; HYDROCHLOROTHIAZIDE	100; 25	mg/1; mg/1	TABLET	ORAL	NDA AUTHORIZED GENERIC	NDA018303	Sandoz Inc.	1-Dec-84	30-Apr-14
55154-1348	Metoprolol Tartrate	METOPROLOL TARTRATE	100	mg/1	TABLET, FILM COATED	ORAL	ANDA	ANDA076969	Cardinal Health	10-Jun-09	-
55154-1336	Metoprolol Tartrate	METOPROLOL TARTRATE	50	mg/1	TABLET, FILM COATED	ORAL	ANDA	ANDA076969	Cardinal Health	10-Jun-09	-
0185-0284	Metoprolol Succinate	METOPROLOL SUCCINATE	200	mg/1	TABLET, COATED	ORAL	ANDA	ANDA076969	Eon Labs, Inc.	20-Mar-08	31-Mar-12
0185-0283	Metoprolol Succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, COATED	ORAL	ANDA	ANDA076969	Eon Labs, Inc.	20-Mar-08	31-Mar-12
0185-0281	Metoprolol Succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, COATED	ORAL	ANDA	ANDA076969	Eon Labs, Inc.	31-Jul-06	31-Mar-12

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
0185-0282	Metoprolol Succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, COATED	ORAL	ANDA	ANDA076969	Eon Labs, Inc.	18-May-07	31-Mar-12
0904-6034	Metoprolol Tartrate	METOPROLOL TARTRATE	100	mg/1	TABLET, FILM COATED	ORAL	ANDA	ANDA076969	Major Pharmaceuticals	10-Jun-09	-
0904-6033	Metoprolol Tartrate	METOPROLOL TARTRATE	50	mg/1	TABLET, FILM COATED	ORAL	ANDA	ANDA076969	Major Pharmaceuticals	10-Jun-09	-
58177-358	metoprolol succinate	METOPROLOL SUCCINATE	190	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA076640	Ethex Corporation	1-Nov-09	
58177-368	metoprolol succinate	METOPROLOL SUCCINATE	90	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA076640	Ethex Corporation	1-Nov-09	
58177-293	metoprolol succinate	METOPROLOL SUCCINATE	23.75	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA077176	Ethex Corporation	1-Nov-09	
58177-369	metoprolol succinate	METOPROLOL SUCCINATE	47.5	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA077176	Ethex Corporation	1-Nov-09	
62037-833	Metoprolol Succinate	METOPROLOL SUCCINATE	200	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA077298	Actavis Pharma, Inc.	15-Apr-10	-
62037-832	Metoprolol Succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA077298	Actavis Pharma, Inc.	15-Apr-10	-
62037-831	Metoprolol Succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA076862	Actavis Pharma, Inc.	4-Aug-09	-

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
62037-830	Metoprolol Succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA077118	Actavis Pharma, Inc.	4-Aug-09	-
0591-0462	Metoprolol Tartrate	METOPROLOL TARTRATE	50	mg/1	TABLET, FILM COATED	ORAL	ANDA	ANDA074217	Actavis Pharma, Inc.	27-May-94	-
0591-0463	Metoprolol Tartrate	METOPROLOL TARTRATE	100	mg/1	TABLET, FILM COATED	ORAL	ANDA	ANDA074217	Actavis Pharma, Inc.	27-May-94	-
43353-795	Metoprolol Succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA077298	Aphena Pharma Solutions - Tennessee, LLC	15-Apr-10	-
43353-583	Metoprolol Succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA076862	Aphena Pharma Solutions - Tennessee, LLC	4-Aug-09	-
54569-5870	Metoprolol Succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA077118	A-S Medication Solutions	4-Aug-09	-
69189-0830	Metoprolol Succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA077118	Avera McKennan Hospital	9-Mar-15	-
63629-4387	Metoprolol Succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA077298	Bryant Ranch Prepack	15-Apr-10	-
68258-6019	Metoprolol Succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA076862	Dispensing Solutions, Inc.	4-Aug-09	-
60429-139	Metoprolol Succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA077118	Golden State Medical Supply, Inc.	22-Mar-13	-

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
60429-140	Metoprolol Succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA076862	Golden State Medical Supply, Inc.	22-Mar-13	-
60429-141	Metoprolol Succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA077298	Golden State Medical Supply, Inc.	15-Apr-10	-
60429-142	Metoprolol Succinate	METOPROLOL SUCCINATE	200	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA077298	Golden State Medical Supply, Inc.	15-Apr-10	-
35356-934	Metoprolol Succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA077118	Lake Erie Medical DBA Quality Care Products LLC	4-Aug-09	-
63739-454	Metoprolol Succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA077298	McKesson Packaging Services Business Unit of McKesson Corporation	2-Feb-11	-
51138-173	Metoprolol Succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA076862	Med Health Pharma, LLC	18-Jan-11	26-Mar-12
51138-174	Metoprolol Succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA077298	Med Health Pharma, LLC	18-Jan-11	26-Mar-12
51138-175	Metoprolol Succinate	METOPROLOL SUCCINATE	200	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA077298	Med Health Pharma, LLC	18-Jan-11	26-Mar-12
51138-172	Metoprolol Succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA077118	Med Health Pharma, LLC	18-Jan-11	26-Mar-12
51138-204	Metoprolol succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET	ORAL	ANDA	ANDA076862	Med-Health Pharma, LLC	30-Jan-11	26-Mar-12

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
51138-206	Metoprolol succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET	ORAL	ANDA	ANDA076862	Med-Health Pharma, LLC	30-Jan-11	26-Mar-12
51138-207	Metoprolol succinate	METOPROLOL SUCCINATE	200	mg/1	TABLET	ORAL	ANDA	ANDA076862	Med-Health Pharma, LLC	30-Jan-11	26-Mar-12
51138-205	Metoprolol succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET	ORAL	ANDA	ANDA076862	Med-Health Pharma, LLC	30-Jan-11	26-Mar-12
51655-581	Metoprolol succinate	METOPROLOL SUCCINATE	25	mg/30 1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA077118	Northwind Pharmaceuticals	6-May-14	-
51655-580	Metoprolol Succinate	METOPROLOL SUCCINATE	50	mg/30 1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA076862	Northwind Pharmaceuticals	7-May-14	-
43063-663	Metoprolol Succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA076862	PD-Rx Pharmaceuticals, Inc.	4-Aug-09	-
63187-547	Metoprolol Succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA077298	Proficient Rx LP	15-Apr-10	-
63187-545	Metoprolol Succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA077118	Proficient Rx LP	4-Aug-09	-
63187-546	Metoprolol Succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA076862	Proficient Rx LP	4-Aug-09	-
21695-972	Metoprolol Succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA077298	Rebel Distributors Corp	15-Apr-10	-

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
21695-950	Metoprolol Succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA076862	Rebel Distributors Corp	3-Aug-09	-
55648-737	Meto+D3+G2: G44+G2:G41+ G2+G2:G42	METOPROLOL SUCCINATE	200	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Wockhardt Limited	22-Jul-10	-
55648-735	Metoprolol Succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Wockhardt Limited	22-Jul-10	-
55648-736	Metoprolol Succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Wockhardt Limited	22-Jul-10	-
55648-734	Metoprolol Succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Wockhardt Limited	22-Jul-10	-
64679-737	Metoprolol Succinate	METOPROLOL SUCCINATE	200	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Wockhardt USA LLC.	22-Jul-10	-
64679-736	Metoprolol Succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Wockhardt USA LLC.	22-Jul-10	-
64679-734	Metoprolol Succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Wockhardt USA LLC.	22-Jul-10	-
64679-735	Metoprolol Succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED,	ORAL	ANDA	ANDA090615	Wockhardt USA LLC.	22-Jul-10	-

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
					EXTENDED RELEASE						
68084-302	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	200	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	American Health Packaging	13-Aug-10	31-Jul-14
68084-303	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	American Health Packaging	13-Aug-10	31-May-15
68084-304	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	American Health Packaging	13-Aug-10	30-Apr-15
68084-301	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	American Health Packaging	13-Aug-10	31-Mar-15
68001-104	Metoprolol Succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	BluePoint Laboratories	12-Aug-13	9-Jan-14
68001-102	Metoprolol Succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	BluePoint Laboratories	12-Aug-13	9-Jan-14
68001-103	Metoprolol Succinate	METOPROLOL SUCCINATE	200	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	BluePoint Laboratories	12-Aug-13	9-Jan-14

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
68001-101	Metoprolol Succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	BluePoint Laboratories	12-Aug-13	9-Jan-14
63629-4096	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Bryant Ranch Prepack	22-Jul-10	-
63629-4241	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Bryant Ranch Prepack	22-Jul-10	-
55154-3393	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Cardinal Health	5-Oct-10	-
55154-2098	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Cardinal Health	13-Aug-10	-
55154-4778	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Cardinal Health	13-Aug-10	-
55154-2099	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Cardinal Health	13-Aug-10	-
58118-0736	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Clinical Solutions Wholesale	22-Jul-10	-

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
58118-0734	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Clinical Solutions Wholesale	22-Jul-10	-
54458-302	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	International Labs, Inc.	22-Sep-11	-
54458-301	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	International Labs, Inc.	22-Sep-11	-
54458-300	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	International Labs, Inc.	22-Sep-11	-
35356-898	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Lake Erie Medical DBA Quality Care Products LLC	22-Jul-10	-
35356-888	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Lake Erie Medical DBA Quality Care Products LLC	22-Jul-10	-
0904-6171	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Major Pharmaceuticals	5-Oct-10	-
0904-6169	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Major Pharmaceuticals	5-Oct-10	-
0904-6170	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED,	ORAL	ANDA	ANDA090615	Major Pharmaceuticals	5-Oct-10	-

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
					EXTENDED RELEASE						
0615-6597	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	NCS HealthCare of KY, Inc. dba Vangard Labs	22-Jul-10	-
0615-6598	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	NCS HealthCare of KY, Inc. dba Vangard Labs	22-Jul-10	-
0615-6589	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	NCS HealthCare of KY, Inc. dba Vangard Labs	22-Jul-10	-
0615-7530	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	200	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	NCS HealthCare of KY, Inc. dba Vangard Labs	22-Jul-10	-
52125-230	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	REMEDYREPACK INC.	8-Mar-13	11-Mar-14
52125-252	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	REMEDYREPACK INC.	17-Jun-13	18-Jun-13
60760-976	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	St Mary's Medical Park Pharmacy	8-Aug-13	-
60760-978	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	St Mary's Medical Park Pharmacy	8-Aug-13	-

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
50436-7053	Metoprolol Succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Unit Dose Services	22-Jul-10	-
50436-7056	Metoprolol Succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090615	Unit Dose Services	22-Jul-10	-
51079-169	Metoprolol Succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA202033	Mylan Institutional Inc.	27-Jan-12	
51079-171	Metoprolol Succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA202033	Mylan Institutional Inc.	27-Jan-12	
51079-170	Metoprolol Succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA202033	Mylan Institutional Inc.	27-Jan-12	
65015-177	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	APPROVED DRUG PRODUCT MANUFACTURED EXCLUSIVELY FOR PRIVATE LABEL DISTRIBUTOR	ANDA202033	MYLAN LABORATORIES LIMITED	28-Dec-11	

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
65015-175	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	APPROVED DRUG PRODUCT MANUFACTURED EXCLUSIVELY FOR PRIVATE LABEL DISTRIBUTOR	ANDA202033	MYLAN LABORATORIES LIMITED	28-Dec-11	
65015-178	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	200	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	APPROVED DRUG PRODUCT MANUFACTURED EXCLUSIVELY FOR PRIVATE LABEL DISTRIBUTOR	ANDA202033	MYLAN LABORATORIES LIMITED	28-Dec-11	
65015-176	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	APPROVED DRUG PRODUCT MANUFACTURED EXCLUSIVELY FOR PRIVATE LABEL DISTRIBUTOR	ANDA202033	MYLAN LABORATORIES LIMITED	28-Dec-11	
0378-4595	Metoprolol Succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA202033	Mylan Pharmaceuticals Inc.	21-Dec-11	

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
0378-4597	Metoprolol Succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA202033	Mylan Pharmaceuticals Inc.	21-Dec-11	
0378-4598	Metoprolol Succinate	METOPROLOL SUCCINATE	200	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA202033	Mylan Pharmaceuticals Inc.	21-Dec-11	
0378-4596	Metoprolol Succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA202033	Mylan Pharmaceuticals Inc.	21-Dec-11	
0378-0032	Metoprolol Tartrate	METOPROLOL TARTRATE	50	mg/1	TABLET, FILM COATED	ORAL	ANDA	ANDA076704	Mylan Pharmaceuticals Inc.	23-Dec-93	
0378-0047	Metoprolol Tartrate	METOPROLOL TARTRATE	100	mg/1	TABLET, FILM COATED	ORAL	ANDA	ANDA076704	Mylan Pharmaceuticals Inc.	23-Dec-93	
0378-4594	Metoprolol Tartrate	METOPROLOL TARTRATE	75	mg/1	TABLET, FILM COATED	ORAL	ANDA	ANDA076704	Mylan Pharmaceuticals Inc.	29-Mar-16	
0378-4593	Metoprolol Tartrate	METOPROLOL TARTRATE	37.5	mg/1	TABLET, FILM COATED	ORAL	ANDA	ANDA076704	Mylan Pharmaceuticals Inc.	29-Mar-16	
0378-0018	Metoprolol Tartrate	METOPROLOL TARTRATE	25	mg/1	TABLET, FILM COATED	ORAL	ANDA	ANDA076704	Mylan Pharmaceuticals Inc.	23-Feb-04	
0378-0434	Metoprolol Tartrate and Hydrochlorothiazide	METOPROLOL TARTRATE; HYDROCHLOROTHIAZIDE	100; 25	mg/1; mg/1	TABLET	ORAL	ANDA	ANDA076792	Mylan Pharmaceuticals Inc.	23-Aug-04	
0378-0445	Metoprolol Tartrate and	METOPROLOL TARTRATE;	100; 50	mg/1; mg/1	TABLET	ORAL	ANDA	ANDA076792	Mylan Pharmaceuticals Inc.	23-Aug-04	

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
	Hydrochlorothiazide	HYDROCHLOROTHIAZIDE									
0378-0424	Metoprolol Tartrate and Hydrochlorothiazide	METOPROLOL TARTRATE; HYDROCHLOROTHIAZIDE	50; 25	mg/1; mg/1	TABLET	ORAL	ANDA	ANDA076792	Mylan Pharmaceuticals Inc.	23-Aug-04	
51079-802	Metoprolol Tartrate	METOPROLOL TARTRATE	100	mg/1	TABLET, FILM COATED	ORAL	ANDA	ANDA076704	Mylan Institutional Inc.	3-May-94	
51079-801	Metoprolol Tartrate	METOPROLOL TARTRATE	50	mg/1	TABLET, FILM COATED	ORAL	ANDA	ANDA076704	Mylan Institutional Inc.	3-May-94	
51079-255	Metoprolol Tartrate	METOPROLOL TARTRATE	25	mg/1	TABLET, FILM COATED	ORAL	ANDA	ANDA076704	Mylan Institutional Inc.	20-Sep-04	
55154-4388	Metoprolol Succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA202033	Cardinal Health	27-Jan-12	
55154-4385	Metoprolol Succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA202033	Cardinal Health	27-Jan-12	
55111-466	Metoprolol succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	Dr. Reddy's Laboratories Limited	10-Sep-12	
55111-467	Metoprolol succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	Dr. Reddy's Laboratories Limited	10-Sep-12	
55111-469	Metoprolol succinate	METOPROLOL SUCCINATE	200	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA078889	Dr. Reddy's Laboratories Limited	10-Sep-12	

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
55111-468	Metoprolol succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA078889	Dr. Reddy's Laboratories Limited	10-Sep-12	
33261-898	Metoprolol succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	Aidarex Pharmaceuticals LLC	10-Sep-12	
68084-673	Metoprolol succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA078889	American Health Packaging	12-May-14	
68084-659	Metoprolol succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	American Health Packaging	6-Mar-14	
68084-666	Metoprolol succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	American Health Packaging	6-Mar-14	
68001-120	Metoprolol succinate	METOPROLOL SUCCINATE	200	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA078889	BluePoint Laboratories	25-Nov-13	
68001-119	Metoprolol succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA078889	BluePoint Laboratories	25-Nov-13	
68001-121	Metoprolol succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	BluePoint Laboratories	1-Jan-14	
68001-122	Metoprolol succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	BluePoint Laboratories	1-Jan-14	
55154-7134	Metoprolol succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA078889	Cardinal Health	12-May-14	
55154-6886	Metoprolol succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	Cardinal Health	10-Sep-12	

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
55154-4987	Metoprolol succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	Cardinal Health	6-Mar-14	
55154-4993	Metoprolol succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	Cardinal Health	6-Mar-14	
68151-1840	Metoprolol succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	Carilion Materials Management	1-Jan-14	
61919-900	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	DirectRX	1-Jan-15	
68645-477	Metoprolol succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	Legacy Pharmaceutical Packaging	10-Sep-12	
68645-478	Metoprolol succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	Legacy Pharmaceutical Packaging	10-Sep-12	
68645-479	Metoprolol succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA078889	Legacy Pharmaceutical Packaging	10-Sep-12	
0904-6323	Metoprolol succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	Major Pharmaceuticals	10-Sep-12	
0904-6322	Metoprolol succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	Major Pharmaceuticals	10-Sep-12	
0904-6324	Metoprolol succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA078889	Major Pharmaceuticals	10-Sep-12	
76237-403	Metoprolol succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	McKesson Contract Packaging	10-Sep-12	

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
45865-798	Metoprolol succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	Medsource Pharmaceuticals	10-Sep-12	
0615-7825	Metoprolol succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA078889	NCS HealthCare of KY, Inc. dba Vangard Labs	10-Sep-12	
0615-7824	Metoprolol succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	NCS HealthCare of KY, Inc. dba Vangard Labs	10-Sep-12	
0615-7823	Metoprolol succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	NCS HealthCare of KY, Inc. dba Vangard Labs	10-Sep-12	
43063-624	Metoprolol succinate	METOPROLOL SUCCINATE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	PD-Rx Pharmaceuticals, Inc.	10-Sep-12	
61786-339	Metoprolol succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	REMEDYREPACK INC.	8-Jan-16	
61786-549	Metoprolol succinate	METOPROLOL SUCCINATE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA078889	REMEDYREPACK INC.	12-Jan-16	
60760-977	METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	St Mary's Medical Park Pharmacy	8-Aug-13	
50436-7054	Metoprolol succinate	METOPROLOL SUCCINATE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA090617	Unit Dose Services	10-Sep-12	
0173-0781	LAMICTAL	LAMOTRIGINE	250	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA	NDA022115	GlaxoSmithKline LLC	15-Aug-11	-
0173-0754	LAMICTAL	LAMOTRIGINE	25	mg/1	TABLET, FILM COATED,	ORAL	NDA	NDA022115	GlaxoSmithKline LLC	6-Jul-09	-

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
					EXTENDED RELEASE						
0173-0756	LAMICTAL	LAMOTRIGINE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA	NDA022115	GlaxoSmithKline LLC	6-Jul-09	-
0173-0757	LAMICTAL	LAMOTRIGINE	200	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA	NDA022115	GlaxoSmithKline LLC	6-Jul-09	-
0173-0755	LAMICTAL	LAMOTRIGINE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA	NDA022115	GlaxoSmithKline LLC	6-Jul-09	-
0173-0761	LAMICTAL	LAMOTRIGINE	300	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA	NDA022115	GlaxoSmithKline LLC	31-Mar-11	-
0173-0643	LAMICTAL	LAMOTRIGINE	150	mg/1	TABLET	ORAL	NDA	NDA020241	GlaxoSmithKline LLC	17-Jan-95	-
0173-0644	LAMICTAL	LAMOTRIGINE	200	mg/1	TABLET	ORAL	NDA	NDA020241	GlaxoSmithKline LLC	18-Jan-95	-
0173-0642	LAMICTAL	LAMOTRIGINE	100	mg/1	TABLET	ORAL	NDA	NDA020241	GlaxoSmithKline LLC	17-Jan-95	-
0173-0774	LAMICTAL	LAMOTRIGINE	50	mg/1	TABLET, ORALLY DISINTEGRATING	ORAL	NDA	NDA022251	GlaxoSmithKline LLC	5-Jun-09	-
0173-0776	LAMICTAL	LAMOTRIGINE	100	mg/1	TABLET, ORALLY DISINTEGRATING	ORAL	NDA	NDA022251	GlaxoSmithKline LLC	5-Jun-09	-
0173-0777	LAMICTAL	LAMOTRIGINE	200	mg/1	TABLET, ORALLY	ORAL	NDA	NDA022251	GlaxoSmithKline LLC	5-Jun-09	-

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
					DISINTEGRATING						
0173-0772	LAMICTAL	LAMOTRIGINE	25	mg/1	TABLET, ORALLY DISINTEGRATING	ORAL	NDA	NDA022251	GlaxoSmithKline LLC	5-Jun-09	-
0173-0527	LAMICTAL	LAMOTRIGINE	25	mg/1	TABLET, CHEWABLE	ORAL	NDA	NDA020764	GlaxoSmithKline LLC	3-Sep-98	-
0173-0526	LAMICTAL	LAMOTRIGINE	5	mg/1	TABLET, CHEWABLE	ORAL	NDA	NDA020764	GlaxoSmithKline LLC	4-Sep-98	-
0173-0633	LAMICTAL	LAMOTRIGINE	25	mg/1	TABLET	ORAL	NDA	NDA020241	GlaxoSmithKline LLC	15-Aug-96	-
0173-0699	LAMICTAL	LAMOTRIGINE	2	mg/1	TABLET, CHEWABLE	ORAL	NDA	NDA020764	GlaxoSmithKline LLC	12-Oct-00	-
49884-604	Lamotrigine Extended Release	LAMOTRIGINE	250	mg/1	TABLET	ORAL	ANDA	ANDA201791	Par Pharmaceutical Inc.	18-Jan-13	
49884-563	Lamotrigine Extended Release	LAMOTRIGINE	100	mg/1	TABLET	ORAL	ANDA	ANDA201791	Par Pharmaceutical Inc.	18-Jan-13	
49884-561	Lamotrigine Extended Release	LAMOTRIGINE	25	mg/1	TABLET	ORAL	ANDA	ANDA201791	Par Pharmaceutical Inc.	18-Jan-13	
49884-562	Lamotrigine Extended Release	LAMOTRIGINE	50	mg/1	TABLET	ORAL	ANDA	ANDA201791	Par Pharmaceutical Inc.	18-Jan-13	
49884-564	Lamotrigine Extended Release	LAMOTRIGINE	200	mg/1	TABLET	ORAL	ANDA	ANDA201791	Par Pharmaceutical Inc.	18-Jan-13	
49884-605	Lamotrigine Extended Release	LAMOTRIGINE	300	mg/1	TABLET	ORAL	ANDA	ANDA201791	Par Pharmaceutical Inc.	18-Jan-13	

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
49884-486	Lamotrigine	LAMOTRIGINE	100	mg/1	TABLET, ORALLY DISINTEGRATING	ORAL	ANDA	ANDA204158	Par Pharmaceutical Inc.	16-Dec-15	
49884-487	Lamotrigine	LAMOTRIGINE	200	mg/1	TABLET, ORALLY DISINTEGRATING	ORAL	ANDA	ANDA204158	Par Pharmaceutical Inc.	16-Dec-15	
49884-484	Lamotrigine	LAMOTRIGINE	25	mg/1	TABLET, ORALLY DISINTEGRATING	ORAL	ANDA	ANDA204158	Par Pharmaceutical Inc.	16-Dec-15	
49884-485	Lamotrigine	LAMOTRIGINE	50	mg/1	TABLET, ORALLY DISINTEGRATING	ORAL	ANDA	ANDA204158	Par Pharmaceutical Inc.	16-Dec-15	
49884-880	Lamotrigine	-	-	-	KIT	-	ANDA	ANDA204158	Par Pharmaceutical Inc.	27-Nov-15	
49884-881	Lamotrigine	-	-	-	KIT	-	ANDA	ANDA204158	Par Pharmaceutical Inc.	27-Nov-15	
49884-882	Lamotrigine	-	-	-	KIT	-	ANDA	ANDA204158	Par Pharmaceutical Inc.	27-Nov-15	
55648-275	Lamotrigine	LAMOTRIGINE	300	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA202498	Wockhardt Limited	29-Nov-12	-
55648-271	Lamotrigine	LAMOTRIGINE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA202498	Wockhardt Limited	29-Nov-12	-
55648-274	Lamotrigine	LAMOTRIGINE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA202498	Wockhardt Limited	29-Nov-12	-

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
55648-272	Lamotrigine	LAMOTRIGINE	200	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA202498	Wockhardt Limited	29-Nov-12	-
55648-273	Lamotrigine	LAMOTRIGINE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA202498	Wockhardt Limited	29-Nov-12	-
64679-275	Lamotrigine	LAMOTRIGINE	300	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA202498	Wockhardt USA LLC.	29-Nov-12	-
64679-273	Lamotrigine	LAMOTRIGINE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA202498	Wockhardt USA LLC.	29-Nov-12	-
64679-274	Lamotrigine	LAMOTRIGINE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA202498	Wockhardt USA LLC.	29-Nov-12	-
64679-271	Lamotrigine	LAMOTRIGINE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA202498	Wockhardt USA LLC.	29-Nov-12	-
64679-272	Lamotrigine	LAMOTRIGINE	200	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA202498	Wockhardt USA LLC.	29-Nov-12	-
64220-419	Lamotrigine Extended Release	LAMOTRIGINE	100	mg/1	TABLET	ORAL	APPROVED DRUG PRODUCT MANUFACTURED EXCLUSIVELY FOR PRIVATE LABEL DISTRIBUTOR	ANDA201791	Zhejiang Huahai Pharmaceutical Co., Ltd.	18-Jan-13	-
64220-428	Lamotrigine Extended Release	LAMOTRIGINE	250	mg/1	TABLET	ORAL	APPROVED DRUG PRODUCT MANUFACTU	ANDA201791	Zhejiang Huahai Pharmaceutical Co., Ltd.	18-Jan-13	-

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
							RED EXCLUSIVELY FOR PRIVATE LABEL DISTRIBUTOR				
64220-427	Lamotrigine Extended Release	LAMOTRIGINE	200	mg/1	TABLET	ORAL	APPROVED DRUG PRODUCT MANUFACTURED EXCLUSIVELY FOR PRIVATE LABEL DISTRIBUTOR	ANDA201791	Zhejiang Huahai Pharmaceutical Co., Ltd.	18-Jan-13	-
64220-417	Lamotrigine Extended Release	LAMOTRIGINE	25	mg/1	TABLET	ORAL	APPROVED DRUG PRODUCT MANUFACTURED EXCLUSIVELY FOR PRIVATE LABEL DISTRIBUTOR	ANDA201791	Zhejiang Huahai Pharmaceutical Co., Ltd.	18-Jan-13	-
64220-429	Lamotrigine Extended Release	LAMOTRIGINE	300	mg/1	TABLET	ORAL	APPROVED DRUG PRODUCT MANUFACTURED EXCLUSIVELY FOR PRIVATE LABEL DISTRIBUTOR	ANDA201791	Zhejiang Huahai Pharmaceutical Co., Ltd.	18-Jan-13	-

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
64220-418	Lamotrigine Extended Release	LAMOTRIGINE	50	mg/1	TABLET	ORAL	APPROVED DRUG PRODUCT MANUFACTURED EXCLUSIVELY FOR PRIVATE LABEL DISTRIBUTOR	ANDA201791	Zhejiang Huahai Pharmaceutical Co., Ltd.	18-Jan-13	-
49884-604	Lamotrigine Extended Release	LAMOTRIGINE	250	mg/1	TABLET	ORAL	ANDA	ANDA201791	Par Pharmaceutical Inc.	18-Jan-13	-
49884-563	Lamotrigine Extended Release	LAMOTRIGINE	100	mg/1	TABLET	ORAL	ANDA	ANDA201791	Par Pharmaceutical Inc.	18-Jan-13	-
49884-561	Lamotrigine Extended Release	LAMOTRIGINE	25	mg/1	TABLET	ORAL	ANDA	ANDA201791	Par Pharmaceutical Inc.	18-Jan-13	-
49884-562	Lamotrigine Extended Release	LAMOTRIGINE	50	mg/1	TABLET	ORAL	ANDA	ANDA201791	Par Pharmaceutical Inc.	18-Jan-13	-
49884-564	Lamotrigine Extended Release	LAMOTRIGINE	200	mg/1	TABLET	ORAL	ANDA	ANDA201791	Par Pharmaceutical Inc.	18-Jan-13	-
49884-605	Lamotrigine Extended Release	LAMOTRIGINE	300	mg/1	TABLET	ORAL	ANDA	ANDA201791	Par Pharmaceutical Inc.	18-Jan-13	-
52536-252	Lamotrigine	LAMOTRIGINE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA202887	Wilshire Pharmaceuticals, Inc.	17-Mar-14	-
52536-250	Lamotrigine	LAMOTRIGINE	25	mg/1	TABLET, FILM COATED,	ORAL	ANDA	ANDA202887	Wilshire Pharmaceuticals, Inc.	17-Mar-14	-

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
					EXTENDED RELEASE						
52536-251	Lamotrigine	LAMOTRIGINE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA202887	Wilshire Pharmaceuticals, Inc.	17-Mar-14	-
52536-253	Lamotrigine	LAMOTRIGINE	200	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA202887	Wilshire Pharmaceuticals, Inc.	17-Mar-14	-
55111-720	Lamotrigine	LAMOTRIGINE	200	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA202383	Dr.Reddy's Laboratories Limited	20-Jun-13	-
55111-428	Lamotrigine	LAMOTRIGINE	300	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA202383	Dr.Reddy's Laboratories Limited	20-Jun-13	-
55111-719	Lamotrigine	LAMOTRIGINE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA202383	Dr.Reddy's Laboratories Limited	20-Jun-13	-
55111-717	Lamotrigine	LAMOTRIGINE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA202383	Dr.Reddy's Laboratories Limited	20-Jun-13	-
55111-718	Lamotrigine	LAMOTRIGINE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA202383	Dr.Reddy's Laboratories Limited	20-Jun-13	-
55111-220	Lamotrigine	LAMOTRIGINE	25	mg/1	TABLET	ORAL	ANDA	ANDA076708	Dr.Reddy's Laboratories Limited	29-Jan-09	-
55111-222	Lamotrigine	LAMOTRIGINE	150	mg/1	TABLET	ORAL	ANDA	ANDA076708	Dr.Reddy's Laboratories Limited	29-Jan-09	-
55111-223	Lamotrigine	LAMOTRIGINE	200	mg/1	TABLET	ORAL	ANDA	ANDA076708	Dr.Reddy's Laboratories Limited	29-Jan-09	-

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
55111-221	Lamotrigine	LAMOTRIGINE	100	mg/1	TABLET	ORAL	ANDA	ANDA076708	Dr.Reddy's Laboratories Limited	29-Jan-09	-
55111-225	Lamotrigine	LAMOTRIGINE	5	mg/1	TABLET, CHEWABLE	ORAL	ANDA	ANDA076701	Dr. Reddy's Laboratories Limited	29-Jan-09	-
55111-226	Lamotrigine	LAMOTRIGINE	25	mg/1	TABLET, CHEWABLE	ORAL	ANDA	ANDA076701	Dr. Reddy's Laboratories Limited	29-Jan-09	-
0228-1422	Lamotrigine	LAMOTRIGINE	100	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA200672	Actavis Pharma, Inc.	1-Apr-16	-
0228-1580	Lamotrigine	LAMOTRIGINE	300	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA200672	Actavis Pharma, Inc.	1-Apr-16	-
0228-1410	Lamotrigine	LAMOTRIGINE	25	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA200672	Actavis Pharma, Inc.	1-Apr-16	-
0228-1435	Lamotrigine	LAMOTRIGINE	50	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA200672	Actavis Pharma, Inc.	1-Apr-16	-
0228-1453	Lamotrigine	LAMOTRIGINE	200	mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	ANDA	ANDA200672	Actavis Pharma, Inc.	1-Apr-16	-
13668-341	Lamotrigine	LAMOTRIGINE	100	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA203370	Torrent Pharmaceuticals Limited	23-Dec-13	-

PRODUCT NDC	PROPRIETARY NAME	ACTIVE INGREDIENTS	STRENGTH	UNIT	DOSAGE FORM	ADMIN ROUTE	MARKETING CATEGORY	APPLICATION NUMBER	LABELER NAME	START MARKETING DATE	END MARKETING DATE
13668-342	Lamotrigine	LAMOTRIGINE	200	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA203370	Torrent Pharmaceuticals Limited	23-Dec-13	-
13668-340	Lamotrigine	LAMOTRIGINE	50	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA203370	Torrent Pharmaceuticals Limited	23-Dec-13	-
13668-339	Lamotrigine	LAMOTRIGINE	25	mg/1	TABLET, EXTENDED RELEASE	ORAL	ANDA	ANDA203370	Torrent Pharmaceuticals Limited	23-Dec-13	-
13668-049	LAMOTRIGINE	LAMOTRIGINE	200	mg/1	TABLET	ORAL	ANDA	ANDA078947	Torrent Pharmaceuticals Limited	27-Jan-09	-
13668-045	LAMOTRIGINE	LAMOTRIGINE	25	mg/1	TABLET	ORAL	ANDA	ANDA078947	Torrent Pharmaceuticals Limited	27-Jan-09	-
13668-048	LAMOTRIGINE	LAMOTRIGINE	150	mg/1	TABLET	ORAL	ANDA	ANDA078947	Torrent Pharmaceuticals Limited	27-Jan-09	-
13668-047	LAMOTRIGINE	LAMOTRIGINE	100	mg/1	TABLET	ORAL	ANDA	ANDA078947	Torrent Pharmaceuticals Limited	27-Jan-09	-
13668-266	LAMOTRIGINE	-	-	-	KIT	-	ANDA	ANDA078947	Torrent Pharmaceuticals Limited	14-Sep-09	-