

| Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations |                                         |                                            |         |                |                               |       |              |                    |     |    |                                    |               |
|------------------------------------------------------------------------------|-----------------------------------------|--------------------------------------------|---------|----------------|-------------------------------|-------|--------------|--------------------|-----|----|------------------------------------|---------------|
| Mkt.Status                                                                   | Active Ingredient                       | Proprietary Name                           | Appl No | Product Number | Dosage Form                   | Route | Strength     | TE Code            | RLD | RS | Applicant Holder                   | Approval Date |
| OTC                                                                          | LORATADINE                              | CLARITIN                                   | N019658 | 002            | TABLET                        | ORAL  | 10MG         |                    | RLD | RS | BAYER HEALTHCARE LLC               | Nov 27, 2002  |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | A075209 | 001            | TABLET                        | ORAL  | 10MG         |                    |     |    | SANDOZ INC                         | Jan 21, 2003  |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | A076134 | 001            | TABLET                        | ORAL  | 10MG         |                    |     |    | SUN PHARMACEUTICAL INDUSTRIES LTD  | Aug 18, 2003  |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | A076154 | 001            | TABLET                        | ORAL  | 10MG         |                    |     |    | MYLAN PHARMACEUTICALS INC          | Aug 20, 2003  |
| OTC                                                                          | LORATADINE                              | CLARITIN HIVES RELIEF                      | N019658 | 003            | TABLET                        | ORAL  | 10MG         |                    | RLD | RS | BAYER HEALTHCARE LLC               | Nov 19, 2003  |
| DISCN                                                                        | LORATADINE                              | LORATADINE                                 | N021512 | 001            | TABLET                        | ORAL  | 10MG         |                    |     |    | PERRIGO CO                         | Jun 24, 2004  |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | A076301 | 001            | TABLET                        | ORAL  | 10MG         |                    |     |    | L PERRIGO CO                       | Jun 25, 2004  |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | A076471 | 001            | TABLET                        | ORAL  | 10MG         |                    |     |    | APOTEX INC ETOBICOKE SITE          | Feb 14, 2006  |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | A075790 | 001            | TABLET                        | ORAL  | 10MG         |                    |     |    | MYLAN PHARMACEUTICALS INC          | Nov 7, 2008   |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | A078447 | 001            | TABLET                        | ORAL  | 10MG         |                    |     |    | MYLAN PHARMACEUTICALS INC          | Aug 12, 2011  |
| OTC                                                                          | LORATADINE; PSEUDOEPHEDRINE SULFATE     | CLARITIN-D                                 | N019670 | 002            | TABLET, EXTENDED RELEASE      | ORAL  | 5MG; 120MG   |                    | RLD | RS | BAYER HEALTHCARE LLC               | Nov 27, 2002  |
| OTC                                                                          | LORATADINE; PSEUDOEPHEDRINE SULFATE     | CLARITIN-D 24 HOUR                         | N020470 | 002            | TABLET, EXTENDED RELEASE      | ORAL  | 10MG; 240MG  |                    | RLD | RS | BAYER HEALTHCARE LLC               | Nov 27, 2002  |
| OTC                                                                          | LORATADINE; PSEUDOEPHEDRINE SULFATE     | LORATADINE AND PSEUDOEPHEI                 | A076050 | 001            | TABLET, EXTENDED RELEASE      | ORAL  | 5MG; 120MG   |                    |     |    | PERRIGO PHARMA INTERNATIONAL DAC   | Jan 30, 2003  |
| OTC                                                                          | LORATADINE; PSEUDOEPHEDRINE SULFATE     | LORATADINE AND PSEUDOEPHEI                 | A075706 | 001            | TABLET, EXTENDED RELEASE      | ORAL  | 10MG; 240MG  |                    |     |    | ACTAVIS LABORATORIES FL INC        | Feb 21, 2003  |
| DISCN                                                                        | LORATADINE; PSEUDOEPHEDRINE SULFATE     | LORATADINE AND PSEUDOEPHEI                 | A076208 | 001            | TABLET, EXTENDED RELEASE      | ORAL  | 5MG; 120MG   |                    |     |    | ACTAVIS LABORATORIES FL INC        | Jan 28, 2004  |
| OTC                                                                          | LORATADINE; PSEUDOEPHEDRINE SULFATE     | LORATADINE AND PSEUDOEPHEI                 | A075989 | 001            | TABLET, EXTENDED RELEASE      | ORAL  | 10MG; 240MG  |                    |     |    | PERRIGO PHARMA INTERNATIONAL DAC   | Mar 4, 2004   |
| OTC                                                                          | LORATADINE; PSEUDOEPHEDRINE SULFATE     | LORATADINE AND PSEUDOEPHEI                 | A076557 | 001            | TABLET, EXTENDED RELEASE      | ORAL  | 10MG; 240MG  |                    |     |    | SUN PHARMACEUTICAL INDUSTRIES LTD  | Sep 22, 2004  |
| OTC                                                                          | LORATADINE                              | CLARITIN REDITABS                          | N020704 | 002            | TABLET, ORALLY DISINTEGRATING | ORAL  | 10MG         |                    | RLD | RS | BAYER HEALTHCARE LLC               | Nov 27, 2002  |
| OTC                                                                          | LORATADINE                              | ALAVERT                                    | N021375 | 001            | TABLET, ORALLY DISINTEGRATING | ORAL  | 10MG         |                    |     |    | PFIZER INC                         | Dec 19, 2002  |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | A075822 | 001            | TABLET, ORALLY DISINTEGRATING | ORAL  | 10MG         |                    |     |    | PFIZER INC                         | Feb 10, 2003  |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | A076011 | 001            | TABLET, ORALLY DISINTEGRATING | ORAL  | 10MG         |                    |     |    | PERRIGO PHARMA INTERNATIONAL DAC   | Sep 29, 2003  |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | A075990 | 001            | TABLET, ORALLY DISINTEGRATING | ORAL  | 10MG         |                    |     |    | ACTAVIS LABORATORIES FL INC        | Nov 3, 2003   |
| OTC                                                                          | LORATADINE                              | CLARITIN HIVES RELIEF REDITAB              | N020704 | 003            | TABLET, ORALLY DISINTEGRATING | ORAL  | 10MG         |                    | RLD | RS | BAYER HEALTHCARE LLC               | Nov 19, 2003  |
| OTC                                                                          | LORATADINE                              | CLARITIN REDITABS                          | N021993 | 001            | TABLET, ORALLY DISINTEGRATING | ORAL  | 5MG          |                    | RLD | RS | BAYER HEALTHCARE LLC               | Dec 12, 2006  |
| OTC                                                                          | LORATADINE                              | LORATADINE REDIDOSE                        | A077153 | 001            | TABLET, ORALLY DISINTEGRATING | ORAL  | 10MG         |                    |     |    | SUN PHARMACEUTICAL INDUSTRIES LTD  | Apr 11, 2007  |
| OTC                                                                          | LORATADINE                              | CHILDREN'S CLARITIN                        | N021891 | 001            | TABLET, CHEWABLE              | ORAL  | 5MG          |                    | RLD | RS | BAYER HEALTHCARE LLC               | Aug 23, 2006  |
| OTC                                                                          | LORATADINE                              | CLARITIN                                   | N020641 | 002            | SYRUP                         | ORAL  | 1MG/ML       |                    | RLD | RS | BAYER HEALTHCARE LLC               | Nov 27, 2002  |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | A075505 | 001            | SYRUP                         | ORAL  | 1MG/ML       |                    |     |    | TEVA PHARMACEUTICALS USA INC       | Nov 7, 2003   |
| DISCN                                                                        | LORATADINE                              | CLARITIN HIVES RELIEF                      | N020641 | 003            | SYRUP                         | ORAL  | 1MG/ML       | **Federal Register | RLD |    | BAYER HEALTHCARE LLC               | Nov 19, 2003  |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | A075728 | 001            | SYRUP                         | ORAL  | 1MG/ML       |                    |     |    | L PERRIGO CO                       | Aug 20, 2004  |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | A076805 | 001            | SYRUP                         | ORAL  | 1MG/ML       |                    |     |    | TARO PHARMACEUTICAL INDUSTRIES LTD | Aug 20, 2004  |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | A075815 | 001            | SYRUP                         | ORAL  | 1MG/ML       |                    |     |    | WOCKHARDT BIO AG                   | Aug 20, 2004  |
| DISCN                                                                        | LORATADINE                              | LORATADINE                                 | A076529 | 001            | SYRUP                         | ORAL  | 1MG/ML       |                    |     |    | RANBAXY LABORATORIES LTD           | Aug 20, 2004  |
| DISCN                                                                        | LORATADINE                              | LORATADINE                                 | A075565 | 001            | SYRUP                         | ORAL  | 1MG/ML       |                    |     |    | APOTEX INC                         | Oct 5, 2004   |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | A077421 | 001            | SYRUP                         | ORAL  | 1MG/ML       |                    |     |    | SILARX PHARMACEUTICALS INC         | Jun 29, 2006  |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | A201865 | 001            | SYRUP                         | ORAL  | 1MG/ML       |                    |     |    | TARO PHARMACEUTICAL INDUSTRIES LTD | Jul 31, 2015  |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | N021734 | 001            | SUSPENSION                    | ORAL  | 1MG/ML       |                    | RLD | RS | TARO PHARMACEUTICALS USA INC       | Oct 4, 2005   |
| OTC                                                                          | LORATADINE                              | CLARITIN                                   | N021952 | 001            | CAPSULE                       | ORAL  | 10MG         |                    | RLD | RS | BAYER HEALTHCARE LLC               | Jun 16, 2008  |
| OTC                                                                          | LORATADINE                              | LORATADINE                                 | A206214 | 001            | CAPSULE                       | ORAL  | 10MG         |                    |     |    | MARKSANS PHARMA LTD                | Sep 23, 2016  |
| RX                                                                           | DES Loratadine                          | CLARINEX                                   | N021165 | 001            | TABLET                        | ORAL  | 5MG          | AB                 | RLD | RS | MERCK SHARP AND DOHME CORP         | Dec 21, 2001  |
| RX                                                                           | DES Loratadine                          | DES Loratadine                             | A078357 | 001            | TABLET                        | ORAL  | 5MG          | AB                 |     |    | ORCHID HEALTHCARE                  | Feb 19, 2010  |
| RX                                                                           | DES Loratadine                          | DES Loratadine                             | A078352 | 001            | TABLET                        | ORAL  | 5MG          | AB                 |     |    | LUPIN PHARMACEUTICALS INC          | Oct 25, 2010  |
| RX                                                                           | DES Loratadine                          | DES Loratadine                             | A078359 | 001            | TABLET                        | ORAL  | 5MG          | AB                 |     |    | SUN PHARMACEUTICAL INDUSTRIES LTD  | Nov 16, 2010  |
| RX                                                                           | DES Loratadine                          | DES Loratadine                             | A078364 | 001            | TABLET                        | ORAL  | 5MG          | AB                 |     |    | SANDOZ INC                         | Dec 3, 2010   |
| RX                                                                           | DES Loratadine                          | DES Loratadine                             | A078365 | 001            | TABLET                        | ORAL  | 5MG          | AB                 |     |    | DR REDDYS LABORATORIES LTD         | Mar 8, 2011   |
| RX                                                                           | DES Loratadine                          | DES Loratadine                             | A078361 | 001            | TABLET                        | ORAL  | 5MG          | AB                 |     |    | PERRIGO R AND D CO                 | Dec 22, 2011  |
| RX                                                                           | DES Loratadine                          | DES Loratadine                             | A078351 | 001            | TABLET                        | ORAL  | 5MG          | AB                 |     |    | MYLAN PHARMACEUTICALS INC          | Feb 10, 2012  |
| RX                                                                           | DES Loratadine                          | DES Loratadine                             | A078355 | 001            | TABLET                        | ORAL  | 5MG          | AB                 |     |    | BELCHER PHARMACEUTICALS LLC        | Apr 19, 2012  |
| RX                                                                           | DES Loratadine; Pseudoephedrine Sulfate | CLARINEX D 24 Hour                         | N021605 | 001            | TABLET, EXTENDED RELEASE      | ORAL  | 5MG; 240MG   | AB                 | RLD | RS | MERCK SHARP AND DOHME CORP         | Mar 3, 2005   |
| RX                                                                           | DES Loratadine; Pseudoephedrine Sulfate | CLARINEX-D 12 Hour                         | N021313 | 001            | TABLET, EXTENDED RELEASE      | ORAL  | 2.5MG; 120MG |                    | RLD | RS | MERCK SHARP AND DOHME CORP         | Feb 1, 2006   |
| RX                                                                           | DES Loratadine; Pseudoephedrine Sulfate | DES Loratadine AND Pseudoephedrine Sulfate | A078366 | 001            | TABLET, EXTENDED RELEASE      | ORAL  | 5MG; 240MG   | AB                 |     |    | DR REDDYS LABORATORIES LTD         | Apr 26, 2011  |
| RX                                                                           | DES Loratadine                          | CLARINEX                                   | N021300 | 001            | SOLUTION                      | ORAL  | 0.5MG/ML     | AA                 | RLD | RS | MERCK SHARP AND DOHME CORP         | Sep 1, 2004   |
| RX                                                                           | DES Loratadine                          | DES Loratadine                             | A202592 | 001            | SOLUTION                      | ORAL  | 0.5MG/ML     | AA                 |     |    | TARO PHARMACEUTICAL INDUSTRIES LTD | Jun 30, 2015  |
| RX                                                                           | DES Loratadine                          | DES Loratadine                             | A202936 | 001            | SOLUTION                      | ORAL  | 0.5MG/ML     | AA                 |     |    | TARO PHARMACEUTICAL INDUSTRIES LTD | May 26, 2016  |
| RX                                                                           | DES Loratadine                          | CLARINEX                                   | N021312 | 001            | TABLET, ORALLY DISINTEGRATING | ORAL  | 5MG          | AB                 | RLD | RS | MERCK SHARP AND DOHME CORP         | Jun 26, 2002  |
| RX                                                                           | DES Loratadine                          | CLARINEX                                   | N021312 | 002            | TABLET, ORALLY DISINTEGRATING | ORAL  | 2.5MG        | AB                 | RLD |    | MERCK SHARP AND DOHME CORP         | Jul 14, 2005  |
| RX                                                                           | DES Loratadine                          | DES Loratadine                             | A078367 | 001            | TABLET, ORALLY DISINTEGRATING | ORAL  | 2.5MG        | AB                 |     |    | DOCTOR REDDYS LABORATORIES LTD     | Jul 12, 2010  |
| RX                                                                           | DES Loratadine                          | DES Loratadine                             | A078367 | 002            | TABLET, ORALLY DISINTEGRATING | ORAL  | 5MG          | AB                 |     |    | DOCTOR REDDYS LABORATORIES LTD     | Jul 12, 2010  |

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