

## Quarter 4 - October 2019 Corrected Records

| Q4 2019<br>Change Log |                                                                 | 101<br>Corrections      |                           |                               |
|-----------------------|-----------------------------------------------------------------|-------------------------|---------------------------|-------------------------------|
| Corrected Records     |                                                                 |                         |                           |                               |
| Quarter               | Inactive Ingredient                                             | Route of Administration | Dosage Form               | Maximum Potency per Unit Dose |
| Q4 2019               | ALCOHOL                                                         | ORAL                    | SYRUP                     | 81.3 mg/ml                    |
| Q3 2019               | ALCOHOL                                                         | ORAL                    | SYRUP                     | 950 mg                        |
| Q4 2019               | BLACK INK                                                       | ORAL                    | CAPSULE                   | 0.50 mg                       |
| Q3 2019               | BLACK INK                                                       | ORAL                    | CAPSULE                   | 77.00 mg                      |
| Q4 2019               | BENZYL BENZOATE                                                 | ORAL                    | CAPSULE                   | NA                            |
| Q3 2019               | BENZYL BENZOATE                                                 | ORAL                    | CAPSULE                   | 0.6084 ml                     |
| Q4 2019               | BUTYL ALCOHOL                                                   | ORAL                    | CAPSULE, EXTENDED RELEASE | 0.005 mg                      |
| Q3 2019               | BUTYL ALCOHOL                                                   | ORAL                    | CAPSULE, EXTENDED RELEASE | 0.1664 mg/mg                  |
| Q4 2019               | CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) | OPHTHALMIC              | GEL                       | 4.00 %w/w                     |
| Q3 2019               | CARBOMER 940                                                    | OPHTHALMIC              | GEL                       | 4.00 %w/w                     |
| Q4 2019               | CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) | TOPICAL                 | CREAM                     | 1.20 %w/w                     |
| Q3 2019               | CARBOMER 940                                                    | TOPICAL                 | CREAM                     | 1.20 %w/w                     |
| Q4 2019               | CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) | TOPICAL                 | CREAM, AUGMENTED          | 1.00 %w/w                     |
| Q3 2019               | CARBOMER 940                                                    | TOPICAL                 | CREAM, AUGMENTED          | 1.00 %w/w                     |
| Q4 2019               | CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) | TOPICAL                 | EMULSION                  | 0.60 %w/w                     |
| Q3 2019               | CARBOMER 940                                                    | TOPICAL                 | EMULSION                  | 0.60 %w/w                     |
| Q4 2019               | CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) | TOPICAL                 | GEL                       | 3.50 %w/w                     |
| Q3 2019               | CARBOMER 940                                                    | TOPICAL                 | GEL                       | 3.50 %w/w                     |
| Q4 2019               | CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) | TOPICAL                 | LOTION                    | 0.50 %w/w                     |
| Q3 2019               | CARBOMER 940                                                    | TOPICAL                 | LOTION                    | 0.50 %w/w                     |
| Q4 2019               | CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) | TOPICAL                 | OINTMENT, AUGMENTED       | 2.25 %w/w                     |
| Q3 2019               | CARBOMER 940                                                    | TOPICAL                 | OINTMENT, AUGMENTED       | 2.25 %w/w                     |
| Q4 2019               | CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) | TRANSDERMAL             | GEL                       | 1.50 %w/w                     |
| Q3 2019               | CARBOMER 940                                                    | TRANSDERMAL             | GEL                       | 1.50 %w/w                     |
| Q4 2019               | CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) | TRANSDERMAL             | GEL, METERED              | 1.00 %w/w                     |
| Q3 2019               | CARBOMER 940                                                    | TRANSDERMAL             | GEL, METERED              | 1.00 %w/w                     |
| Q4 2019               | CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)   | TOPICAL                 | LOTION                    | 0.30 %w/w                     |
| Q3 2019               | CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)   | TOPICAL                 | LOTION                    | 0.60 %w/w                     |
| Q4 2019               | CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) | ORAL                    | TABLET                    | 4.00 mg                       |
| Q3 2019               | CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) | ORAL                    | TABLET                    | 56.14 mg                      |
| Q4 2019               | CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)   | TOPICAL                 | CREAM                     | 0.2 %w/w                      |
| Q3 2019               | CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)   | TOPICAL                 | CREAM                     | 0.2 %w/v                      |
| Q4 2019               | CARBOXYMETHYLCELLULOSE SODIUM                                   | ORAL                    | GRANULE                   | NA                            |
| Q3 2019               | CARBOXYMETHYLCELLULOSE SODIUM                                   | ORAL                    | GRANULE                   | 5.14 mg/ml                    |
| Q4 2019               | COCOYL CAPRYLOCAPRATE                                           | TOPICAL                 | GEL                       | 2.50 %w/w                     |
| Q3 2019               | COCO-CAPRYLATE/CAPRATE                                          | TOPICAL                 | GEL                       | 2.50 %w/w                     |
| Q4 2019               | CARNAUBA WAX                                                    | ORAL                    | TABLET, SUGAR COATED      | NA                            |
| Q3 2019               | CARNAUBA WAX                                                    | ORAL                    | TABLET, SUGAR COATED      | 0.09 mg                       |
| Q4 2019               | EDETATE DISODIUM                                                | ORAL                    | ELIXIR                    | 0.26 mg/ml                    |
| Q3 2019               | EDETATE DISODIUM                                                | ORAL                    | ELIXIR                    | 0.26 mg                       |
| Q4 2019               | ETHYLCELLULOSE                                                  | ORAL                    | TABLET, EXTENDED RELEASE  | 308.80 mg                     |
| Q3 2019               | ETHYLCELLULOSE                                                  | ORAL                    | TABLET, EXTENDED RELEASE  | 375.00 mg                     |
| Q4 2019               | FLAVOR CHERRY 842                                               | ORAL                    | SOLUTION                  | 4.94 mg/ml                    |
| Q3 2019               | FLAVOR CHERRY 842                                               | ORAL                    | SOLUTION                  | 4.94 mg                       |
| Q4 2019               | FLAVOR GRAPE 6175                                               | ORAL                    | SUSPENSION                | 2 mg/ml                       |
| Q3 2019               | FLAVOR GRAPE 6175                                               | ORAL                    | SUSPENSION                | 2 mg                          |
| Q4 2019               | FLAVOR BANANA 11090                                             | ORAL                    | SOLUTION                  | 10 mg/ml                      |
| Q3 2019               | FLAVOR BANANA 11090                                             | ORAL                    | SOLUTION                  | 10 mg                         |
| Q4 2019               | FLAVOR GRAPE 501417C                                            | ORAL                    | SOLUTION                  | 1 mg/ml                       |
| Q3 2019               | FLAVOR GRAPE 501417C                                            | ORAL                    | SOLUTION                  | 1 mg                          |
| Q4 2019               | GELATIN CAPSULE, HARD                                           | ORAL                    | CAPSULE                   | 107.00 mg                     |
| Q3 2019               | GELATIN CAPSULE, HARD                                           | ORAL                    | CAPSULE                   | 118.00 mg                     |
| Q4 2019               | GELATIN CAPSULE, HARD                                           | ORAL                    | CAPSULE, EXTENDED RELEASE | 120.00 mg                     |
| Q3 2019               | GELATIN CAPSULE, HARD                                           | ORAL                    | CAPSULE, EXTENDED RELEASE | 125.00 mg                     |
| Q4 2019               | HIGH DENSITY POLYETHYLENE                                       | RECTAL                  | SUPPOSITORY               | NA                            |
| Q3 2019               | HIGH DENSITY POLYETHYLENE                                       | RECTAL                  | SUPPOSITORY               | 375 mg                        |
| Q4 2019               | HYDROXYETHYL CELLULOSE, UNSPECIFIED                             | AURICULAR (OTIC)        | SOLUTION                  | 0.25 %w/w                     |
| Q3 2019               | HYDROXYETHYL CELLULOSE                                          | AURICULAR (OTIC)        | SOLUTION                  | 0.25 %w/w                     |

|         |                                                      |                  |                                       |                    |
|---------|------------------------------------------------------|------------------|---------------------------------------|--------------------|
| Q4 2019 | HYDROXYETHYL CELLULOSE, UNSPECIFIED                  | AURICULAR (OTIC) | SUSPENSION                            | 0.20 %w/w          |
| Q3 2019 | HYDROXYETHYL CELLULOSE                               | AURICULAR (OTIC) | SUSPENSION                            | 0.20 %w/w          |
| Q4 2019 | HYDROXYETHYL CELLULOSE, UNSPECIFIED                  | BUCCAL           | FILM                                  | 24.16 mg           |
| Q3 2019 | HYDROXYETHYL CELLULOSE                               | BUCCAL           | FILM                                  | 54.92 mg           |
| Q4 2019 | HYDROXYETHYL CELLULOSE, UNSPECIFIED                  | OPHTHALMIC       | SOLUTION                              | 0.50 %w/v          |
| Q3 2019 | HYDROXYETHYL CELLULOSE                               | OPHTHALMIC       | SOLUTION                              | 1.60 %w/v          |
| Q4 2019 | HYDROXYETHYL CELLULOSE, UNSPECIFIED                  | OPHTHALMIC       | SOLUTION/ DROPS                       | 0.50 %w/v          |
| Q3 2019 | HYDROXYETHYL CELLULOSE                               | OPHTHALMIC       | SOLUTION/ DROPS                       | 0.50 %w/v          |
| Q4 2019 | HYDROXYETHYL CELLULOSE, UNSPECIFIED                  | OPHTHALMIC       | SUSPENSION                            | 0.05 %w/w          |
| Q3 2019 | HYDROXYETHYL CELLULOSE                               | OPHTHALMIC       | SUSPENSION                            | 0.25 %w/w          |
| Q4 2019 | HYDROXYETHYL CELLULOSE, UNSPECIFIED                  | OPHTHALMIC       | SUSPENSION/ DROPS                     | 0.35 %w/w          |
| Q3 2019 | HYDROXYETHYL CELLULOSE                               | OPHTHALMIC       | SUSPENSION/ DROPS                     | 0.35 %w/w          |
| Q4 2019 | HYDROXYETHYL CELLULOSE, UNSPECIFIED                  | ORAL             | SOLUTION                              | 25.00 mg/ 5.00 ml  |
| Q3 2019 | HYDROXYETHYL CELLULOSE                               | ORAL             | SOLUTION                              | 7.50 mg            |
| Q4 2019 | HYDROXYETHYL CELLULOSE, UNSPECIFIED                  | ORAL             | SUSPENSION                            | 1.25 mg/ 1.00 ml   |
| Q3 2019 | HYDROXYETHYL CELLULOSE                               | ORAL             | SUSPENSION                            | 150.00 mg/ 5.00 ml |
| Q4 2019 | HYDROXYETHYL CELLULOSE, UNSPECIFIED                  | ORAL             | SYRUP                                 | 100.00 mg/ 5.00 ml |
| Q3 2019 | HYDROXYETHYL CELLULOSE                               | ORAL             | SYRUP                                 | 100.00 mg/ 5.00 ml |
| Q4 2019 | HYDROXYETHYL CELLULOSE, UNSPECIFIED                  | ORAL             | TABLET                                | 12.00 mg           |
| Q3 2019 | HYDROXYETHYL CELLULOSE                               | ORAL             | TABLET                                | 22.96 mg           |
| Q4 2019 | HYDROXYETHYL CELLULOSE, UNSPECIFIED                  | ORAL             | TABLET, CHEWABLE                      | 11.80 mg           |
| Q3 2019 | HYDROXYETHYL CELLULOSE                               | ORAL             | TABLET, CHEWABLE                      | 11.80 mg           |
| Q4 2019 | HYDROXYETHYL CELLULOSE, UNSPECIFIED                  | ORAL             | TABLET, COATED                        | NA                 |
| Q3 2019 | HYDROXYETHYL CELLULOSE                               | ORAL             | TABLET, COATED                        | NA                 |
| Q4 2019 | HYDROXYETHYL CELLULOSE, UNSPECIFIED                  | ORAL             | TABLET, EXTENDED RELEASE              | 175.00 mg          |
| Q3 2019 | HYDROXYETHYL CELLULOSE                               | ORAL             | TABLET, EXTENDED RELEASE              | 400.00 mg          |
| Q4 2019 | HYDROXYETHYL CELLULOSE, UNSPECIFIED                  | ORAL             | TABLET, FILM COATED, EXTENDED RELEASE | 99.75 mg           |
| Q3 2019 | HYDROXYETHYL CELLULOSE                               | ORAL             | TABLET, FILM COATED, EXTENDED RELEASE | 140.00 mg          |
| Q4 2019 | HYDROCHLORIC ACID                                    | TOPICAL          | CREAM                                 | 0.033 %w/w         |
| Q3 2019 | HYDROCHLORIC ACID                                    | TOPICAL          | CREAM                                 | 0.034 ml/mg        |
| Q4 2019 | LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED | ORAL             | CAPSULE                               | 20.00 mg           |
| Q3 2019 | LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED | ORAL             | CAPSULE                               | 35.63 mg           |
| Q4 2019 | LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED | ORAL             | TABLET                                | 80.00 mg           |
| Q3 2019 | LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED | ORAL             | TABLET                                | 100.00 mg          |
| Q4 2019 | LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED | ORAL             | TABLET, CHEWABLE                      | 25.00 mg           |
| Q3 2019 | LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED | ORAL             | TABLET, CHEWABLE                      | 35.00 mg           |
| Q4 2019 | LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED | ORAL             | TABLET, DELAYED RELEASE               | 19.50 mg           |
| Q3 2019 | LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED | ORAL             | TABLET, DELAYED RELEASE               | 26.30 mg           |
| Q4 2019 | LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED | ORAL             | TABLET, FILM COATED                   | 50.00 mg           |
| Q3 2019 | LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED | ORAL             | TABLET, FILM COATED                   | 52.50 mg           |
| Q4 2019 | LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED | ORAL             | TABLET, ORALLY DISINTEGRATING         | 33.60 mg           |
| Q3 2019 | LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED | ORAL             | TABLET, ORALLY DISINTEGRATING         | 42.00 mg           |
| Q4 2019 | MANNITOL                                             | INTRAVENOUS      | INJECTION, SOLUTION                   | 4.95 %w/v          |
| Q3 2019 | MANNITOL                                             | INTRAVENOUS      | INJECTION, SOLUTION                   | 61.30 mg/ml        |
| Q4 2019 | MINERAL OIL                                          | RECTAL           | SUPPOSITORY                           | NA                 |
| Q3 2019 | MINERAL OIL                                          | RECTAL           | SUPPOSITORY                           | 8 ml               |
| Q4 2019 | OPADRY AMB OY-B-28920 WHITE                          | ORAL             | TABLET                                | 2.50 mg            |
| Q3 2019 | OPADRY AMB OY-B-28920 WHITE                          | ORAL             | TABLET                                | 36.00 mg           |
| Q4 2019 | OPADRY YS-1-7040 WHITE                               | ORAL             | TABLET                                | 20.50 mg           |
| Q3 2019 | OPADRY YS-1-7040 WHITE                               | ORAL             | TABLET                                | 35.76 mg           |
| Q4 2019 | OPADRY YS-1-7706G WHITE                              | ORAL             | TABLET                                | 8.25 mg            |
| Q3 2019 | OPADRY YS-1-7706G WHITE                              | ORAL             | TABLET                                | 22.50 mg           |
| Q4 2019 | OPASPRAY K-1-4731 PURPLE                             | ORAL             | TABLET                                | 0.5 mg             |
| Q3 2019 | OPASPRAY K-1-4731 PURPLE                             | ORAL             | TABLET                                | 0.5 ml             |
| Q4 2019 | POLYETHYLENE GLYCOL 1600                             | DENTAL           | GEL                                   | 5.00 %w/w          |
| Q3 2019 | POLYETHYLENE GLYCOL 1500                             | DENTAL           | GEL                                   | 5.00 %w/w          |
| Q4 2019 | POLYETHYLENE GLYCOL 1600                             | DENTAL           | PASTE                                 | 4.96 %w/w          |
| Q3 2019 | POLYETHYLENE GLYCOL 1500                             | DENTAL           | PASTE                                 | 4.96 %w/w          |
| Q4 2019 | POLYETHYLENE GLYCOL 1600                             | ORAL             | TABLET                                | 1.20 mg            |
| Q3 2019 | POLYETHYLENE GLYCOL 1500                             | ORAL             | TABLET                                | 1.20 mg            |
| Q4 2019 | POLYETHYLENE GLYCOL 1600                             | ORAL             | TABLET, COATED                        | NA                 |
| Q3 2019 | POLYETHYLENE GLYCOL 1500                             | ORAL             | TABLET, COATED                        | NA                 |
| Q4 2019 | POLYETHYLENE GLYCOL 1600                             | RECTAL           | SUPPOSITORY                           | 0.30 mg/mg         |
| Q3 2019 | POLYETHYLENE GLYCOL 1500                             | RECTAL           | SUPPOSITORY                           | 0.30 mg/mg         |
| Q4 2019 | POLYETHYLENE GLYCOL 1600                             | TOPICAL          | SOLUTION                              | 29.70 %w/w         |

|         |                             |                          |                                                |                     |
|---------|-----------------------------|--------------------------|------------------------------------------------|---------------------|
| Q3 2019 | POLYETHYLENE GLYCOL 1500    | TOPICAL                  | SOLUTION                                       | 29.70 %w/w          |
| Q4 2019 | POLYSORBATE 20              | INTRAVENOUS              | INJECTION, POWDER, FOR SOLUTION                | 0.011 %w/v          |
| Q3 2019 | POLYSORBATE 20              | INTRAVENOUS              | INJECTION, POWDER, FOR SOLUTION                | 0.44 mg             |
| Q4 2019 | POLYSORBATE 80              | RECTAL                   | SUPPOSITORY                                    | 72.15 mg            |
| Q3 2019 | POLYSORBATE 80              | RECTAL                   | SUPPOSITORY                                    | 100.00 mg           |
| Q4 2019 | POLYSORBATE 80              | ORAL                     | POWDER                                         | NA                  |
| Q3 2019 | POLYSORBATE 80              | ORAL                     | POWDER                                         | 0.22 mg             |
| Q4 2019 | PROSOLV SMCC HD 90          | ORAL                     | CAPSULE                                        | 199.11 mg           |
| Q3 2019 | PROSOLV HD 90               | ORAL                     | CAPSULE                                        | 199.11 mg           |
| Q4 2019 | PROSOLV SMCC HD 90          | ORAL                     | TABLET                                         | 351.30 mg           |
| Q3 2019 | PROSOLV HD 90               | ORAL                     | TABLET                                         | 351.30 mg           |
| Q4 2019 | PROSOLV SMCC HD 90          | ORAL                     | TABLET, DELAYED RELEASE                        | 148.73 mg           |
| Q3 2019 | PROSOLV HD 90               | ORAL                     | TABLET, DELAYED RELEASE                        | 148.73 mg           |
| Q4 2019 | PROSOLV SMCC HD 90          | ORAL                     | TABLET, EXTENDED RELEASE                       | 352.00 mg           |
| Q3 2019 | PROSOLV HD 90               | ORAL                     | TABLET, EXTENDED RELEASE                       | 352.00 mg           |
| Q4 2019 | PROSOLV SMCC HD 90          | ORAL                     | TABLET, FILM COATED                            | 375.52 mg           |
| Q3 2019 | PROSOLV HD 90               | ORAL                     | TABLET, FILM COATED                            | 375.52 mg           |
| Q4 2019 | PROSOLV SMCC HD 90          | ORAL                     | TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE | 37.62 mg            |
| Q3 2019 | PROSOLV HD 90               | ORAL                     | TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE | 37.62 mg            |
| Q4 2019 | PROPYLPARABEN SODIUM        | ORAL                     | POWDER, FOR SUSPENSION                         | 0.246 mg/ml         |
| Q3 2019 | PROPYLPARABEN SODIUM        | ORAL                     | POWDER, FOR SUSPENSION                         | 1 mg                |
| Q4 2019 | SACCHARIN SODIUM ANHYDROUS  | ORAL                     | LIQUID                                         | 1.50 mg/ 5.00 ml    |
| Q3 2019 | SACCHARIN SODIUM ANHYDROUS  | ORAL                     | LIQUID                                         | 50.00 mg/ 120.00 ml |
| Q4 2019 | SHELLAC                     | ORAL                     | CAPSULE                                        | 34.48 mg            |
| Q3 2019 | SHELLAC                     | ORAL                     | CAPSULE                                        | 330.88 mg           |
| Q4 2019 | SIMETHICONE EMULSION        | ORAL                     | TABLET                                         | 0.50 mg             |
| Q3 2019 | SIMETHICONE EMULSION        | ORAL                     | TABLET                                         | 0.70 mg             |
| Q4 2019 | SIMETHICONE EMULSION        | ORAL                     | POWDER, FOR SUSPENSION                         | 5 mg/ml             |
| Q3 2019 | SIMETHICONE EMULSION        | ORAL                     | POWDER, FOR SUSPENSION                         | 20 mg               |
| Q4 2019 | SODIUM CHLORIDE             | ORAL                     | SOLUTION                                       | 9.00 mg             |
| Q3 2019 | SODIUM CHLORIDE             | ORAL                     | SOLUTION                                       | 27.00 mg            |
| Q4 2019 | SODIUM CHLORIDE             | RESPIRATORY (INHALATION) | INHALANT                                       | 3 mg                |
| Q3 2019 | SODIUM CHLORIDE             | RESPIRATORY (INHALATION) | INHALANT                                       | 8.6 mg/ml           |
| Q4 2019 | SODIUM ACETATE              | TOPICAL                  | SOLUTION                                       | NA                  |
| Q3 2019 | SODIUM ACETATE              | TOPICAL                  | SOLUTION                                       | 0.36 %w/w           |
| Q4 2019 | SOLVENT ORANGE 2            | RECTAL                   | SUPPOSITORY                                    | NA                  |
| Q3 2019 | SOLVENT ORANGE 2            | RECTAL                   | SUPPOSITORY                                    | 0.35 mg             |
| Q4 2019 | SORBITOL                    | ORAL                     | POWDER                                         | 0.05 mg/mg          |
| Q3 2019 | SORBITOL                    | ORAL                     | POWDER                                         | 185.78 mg/ml        |
| Q4 2019 | SORBITAN TRIOLEATE          | ORAL                     | CAPSULE                                        | NA                  |
| Q3 2019 | SORBITAN TRIOLEATE          | ORAL                     | CAPSULE                                        | 0.02 ml             |
| Q4 2019 | SUCROSE                     | INTRAVENOUS              | INJECTION, POWDER, FOR SOLUTION                | 5 %w/v              |
| Q3 2019 | SUCROSE                     | INTRAVENOUS              | INJECTION, POWDER, FOR SOLUTION                | 200 mg              |
| Q4 2019 | SUCROSE                     | ORAL                     | GRANULE                                        | NA                  |
| Q3 2019 | SUCROSE                     | ORAL                     | GRANULE                                        | 604.84 mg/ml        |
| Q4 2019 | SUCROSE                     | RECTAL                   | SUPPOSITORY                                    | NA                  |
| Q3 2019 | SUCROSE                     | RECTAL                   | SUPPOSITORY                                    | 400 mg              |
| Q4 2019 | SULFURIC ACID               | RESPIRATORY (INHALATION) | SOLUTION                                       | 1.5 %w/v            |
| Q3 2019 | SULFURIC ACID               | RESPIRATORY (INHALATION) | SOLUTION                                       | 40 %v/v             |
| Q4 2019 | SURELEASE E-7-7050          | ORAL                     | CAPSULE, DELAYED RELEASE                       | 23.33 mg            |
| Q3 2019 | SURELEASE E-7-7050          | ORAL                     | CAPSULE, DELAYED RELEASE                       | 28.33 mg            |
| Q4 2019 | LIGHT MINERAL OIL           | ORAL                     | CAPSULE                                        | 0.8 mg              |
| Q3 2019 | LIGHT MINERAL OIL           | ORAL                     | CAPSULE                                        | 1.29 ml             |
| Q4 2019 | MAGNESIUM TRISILICATE       | ORAL                     | POWDER, FOR SUSPENSION                         | 0.3 mg/ml           |
| Q3 2019 | MAGNESIUM TRISILICATE       | ORAL                     | POWDER, FOR SUSPENSION                         | 70 mg               |
| Q4 2019 | MENTHA SPICATA OIL          | DENTAL                   | PASTE, DENTIFRICE                              | 27.60 %w/w          |
| Q3 2019 | SPEARMINT OIL               | DENTAL                   | PASTE, DENTIFRICE                              | 27.60 %w/w          |
| Q4 2019 | MENTHA SPICATA OIL          | ORAL                     | CAPSULE                                        | NA                  |
| Q3 2019 | SPEARMINT OIL               | ORAL                     | CAPSULE                                        | NA                  |
| Q4 2019 | MENTHA SPICATA OIL          | ORAL                     | SOLUTION                                       | NA                  |
| Q3 2019 | SPEARMINT OIL               | ORAL                     | SOLUTION                                       | NA                  |
| Q4 2019 | MENTHA SPICATA OIL          | ORAL                     | SUSPENSION                                     | 0.59 mg/ 20.00 ml   |
| Q3 2019 | SPEARMINT OIL               | ORAL                     | SUSPENSION                                     | 0.59 mg/ 20.00 ml   |
| Q4 2019 | MENTHA SPICATA OIL          | ORAL                     | SYRUP                                          | 0.12 mg/ 5.00 ml    |
| Q3 2019 | SPEARMINT OIL               | ORAL                     | SYRUP                                          | 0.12 mg/ 5.00 ml    |
| Q4 2019 | MENTHA SPICATA OIL          | SUBLINGUAL               | TABLET                                         | 0.40 mg             |
| Q3 2019 | SPEARMINT OIL               | SUBLINGUAL               | TABLET                                         | 0.40 mg             |
| Q4 2019 | MENTHA SPICATA OIL          | TOPICAL                  | OINTMENT                                       | NA                  |
| Q3 2019 | SPEARMINT OIL               | TOPICAL                  | OINTMENT                                       | NA                  |
| Q4 2019 | TALC                        | ORAL                     | SUSPENSION                                     | 2.55 mg/ml          |
| Q3 2019 | TALC                        | ORAL                     | SUSPENSION                                     | 2.55 mg             |
| Q4 2019 | TITANIUM DIOXIDE            | ORAL                     | POWDER                                         | 2 mg                |
| Q3 2019 | TITANIUM DIOXIDE            | ORAL                     | POWDER                                         | 3.25 mg/ml          |
| Q4 2019 | TRISODIUM CITRATE DIHYDRATE | INTRAVENOUS              | INJECTION, POWDER, FOR SOLUTION                | 1.29 %w/v           |

|         |                             |             |                                 |             |
|---------|-----------------------------|-------------|---------------------------------|-------------|
| Q3 2019 | TRISODIUM CITRATE DIHYDRATE | INTRAVENOUS | INJECTION, POWDER, FOR SOLUTION | 51.76 mg    |
| Q4 2019 | WHITE WAX                   | ORAL        | CAPSULE                         | 18.36 mg    |
| Q3 2019 | WHITE WAX                   | ORAL        | CAPSULE                         | 40.00 mg    |
| Q4 2019 | XANTHAN GUM                 | ORAL        | POWDER                          | 0.008 mg/mg |
| Q3 2019 | XANTHAN GUM                 | ORAL        | POWDER                          | 1 mg/ml     |

Data Through 09/27/2019

# Quarter 4 - October 2019 Deleted Records

| Q4 2019<br>Change Log                                   |                          |                                      | 149<br>Deletions              |
|---------------------------------------------------------|--------------------------|--------------------------------------|-------------------------------|
| Deleted Records                                         |                          |                                      |                               |
| Inactive Ingredient                                     | Route of Administration  | Dosage Form                          | Maximum Potency per Unit Dose |
| ACETIC ACID                                             | OPHTHALMIC               | POWDER, FOR SOLUTION                 | ADJ PH                        |
| ACETIC ACID                                             | ORAL                     | INJECTION                            | ADJ PH                        |
| ACETIC ACID                                             | ORAL                     | INJECTION, SOLUTION                  | ADJ PH                        |
| ACRYLATES COPOLYMER                                     | TOPICAL                  | CREAM                                | 13.60 %w/w                    |
| ACRYLATES COPOLYMER                                     | TOPICAL                  | GEL                                  | 3.79 %w/w                     |
| ADVANTIA PRIME 190100BA01 WHITE                         | ORAL                     | TABLET                               | 3.00 mg                       |
| ALCOHOL                                                 | ORAL                     | CAPSULE, COATED                      | 25.00 mg                      |
| ANHYDROUS LACTOSE                                       | ORAL                     | GRANULE                              | 86.60 mg/ml                   |
| ANHYDROUS TRISODIUM CITRATE                             | ORAL                     | GRANULE                              | 80.00 mg/ml                   |
| APAFURANE                                               | INHALATION               | AEROSOL, METERED                     | 98 %w/w                       |
| BENZYL ALCOHOL                                          | TOPICAL                  | RINSE                                | 10.00 %w/w                    |
| BETADEX SULFOBUTYL ETHER SODIUM                         | INTRAVENOUS              | POWDER                               | 270.00 mg/ml                  |
| BORIC ACID                                              | OPHTHALMIC               | POWDER, FOR SOLUTION                 | 0.06 %w/w                     |
| BUTYLATED HYDROXYTOLUENE                                | TOPICAL                  | RINSE                                | 0.10 %w/w                     |
| BUTYLPARABEN                                            | ORAL                     | LIQUID                               | 6.00 mg/ 120.00 ml            |
| BUTYLPARABEN                                            | RECTAL                   | LIQUID                               | 0.01 %w/v                     |
| CALCIUM CARBONATE                                       | RESPIRATORY (INHALATION) | INJECTION, SOLUTION                  | 4.02 %w/v                     |
| CALCIUM CHLORIDE                                        | OPHTHALMIC               | POWDER, FOR SOLUTION                 | 0.05 %w/w                     |
| CALCIUM CHLORIDE                                        | ORAL                     | TABLET                               | 0.50 mg/ml                    |
| CARAMEL                                                 | ORAL                     | GRANULE                              | 0.50 mg/ml                    |
| CARAMEL                                                 | ORAL                     | POWDER, FOR SOLUTION                 | NA                            |
| CARAMEL                                                 | RECTAL                   | LIQUID                               | NA                            |
| CARAMEL                                                 | RECTAL                   | POWDER, FOR SOLUTION                 | NA                            |
| CARBOMER 1382                                           | TOPICAL                  | GEL                                  | 0.90 %w/w                     |
| CARBOMER 980                                            | TOPICAL                  | GEL                                  | 1.40 %w/w                     |
| CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSI | TOPICAL                  | CREAM, AUGMENTED                     | 0.20 %w/v                     |
| CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL OR / | ORAL                     | TABLET, EXTENDED RELEASE             | 30.00 mg                      |
| CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKEI  | VAGINAL                  | GEL                                  | 2.00 %w/w                     |
| CARBOXYMETHYLCELLULOSE SODIUM                           | TOPICAL                  | PASTE, DENTIFRICE                    | 16.63 %w/w                    |
| CETOSTEARYL ALCOHOL                                     | TOPICAL                  | RINSE                                | 3.00 %w/w                     |
| CHLOROBUTANOL                                           | OPHTHALMIC               | POWDER, FOR SOLUTION                 | 0.55 %w/w                     |
| CITRIC ACID MONOHYDRATE                                 | INTRAVENOUS              | POWDER                               | ADJ PH                        |
| CITRIC ACID MONOHYDRATE                                 | ORAL                     | GRANULE                              | 1.25 mg/ml                    |
| CITRIC ACID MONOHYDRATE                                 | ORAL                     | INHALANT                             | 0.31 mg/ml                    |
| CROSCARMELOSE SODIUM                                    | ORAL                     | TABLET, SUGAR COATED                 | 2.50 mg                       |
| DETOSU/TRIETHYLENE GLYCOL/TRIETHYLENE GLYCOL POLYGLYCO  | SUBCUTANEOUS             | INJECTION                            | 392 mg/0.4 ml                 |
| DEXTRAN                                                 | INTRAVENOUS              | INJECTION, SOLUTION                  | 9.10 mg/ml                    |
| EDETATE DISODIUM                                        | ORAL                     | INHALANT                             | 0.10 mg/ml                    |
| EDETATE DISODIUM                                        | RESPIRATORY (INHALATION) | INHALANT                             | 0.11 mg/ml                    |
| EDETIC ACID                                             | ORAL                     | INJECTION, SOLUTION                  | 0.50 mg/ 1.70 ml              |
| ETHYLCELLULOSE DISPERSION TYPE B                        | ORAL                     | CAPSULE, DELAYED RELEASE             | 58.33 mg                      |
| ETHYLCELLULOSE DISPERSION TYPE B                        | ORAL                     | CAPSULE, EXTENDED RELEASE            | 165.45 mg                     |
| ETHYLCELLULOSE DISPERSION TYPE B                        | ORAL                     | GRANULE                              | 0.03 mg/mg                    |
| ETHYLCELLULOSE DISPERSION TYPE B                        | ORAL                     | GRANULE, FOR SUSPENSION              | 2.12 mg/ml                    |
| ETHYLCELLULOSE DISPERSION TYPE B                        | ORAL                     | TABLET                               | NA                            |
| ETHYLCELLULOSE DISPERSION TYPE B                        | ORAL                     | TABLET, EXTENDED RELEASE             | 26.40 mg                      |
| FD&C RED NO. 3                                          | ORAL                     | GRANULE                              | 0.05 mg/ml                    |
| FD&C YELLOW NO. 6                                       | TOPICAL                  | RINSE                                | NA                            |
| FLAVOR PEPPERMINT 104                                   | ORAL                     | TABLET                               | 2.00 mg/ml                    |
| GELATIN                                                 | TOPICAL                  | PASTE, DENTIFRICE                    | 16.63 %w/w                    |
| GELATIN                                                 | VAGINAL                  | INSERT                               | NA                            |
| GLYCERIN                                                | ORAL                     | INJECTION                            | 25.00 mg/ 1.00 ml             |
| GLYCERIN                                                | VAGINAL                  | INSERT                               | NA                            |
| GLYCERYL MONOSTEARATE                                   | TOPICAL                  | SUPPOSITORY                          | 0.05 mg/mg                    |
| HEXYLENE GLYCOL                                         | TOPICAL                  | RINSE                                | 10.00 %w/w                    |
| HYDROCHLORIC ACID                                       | INTRAVENOUS              | POWDER                               | ADJ PH                        |
| HYDROCHLORIC ACID                                       | OPHTHALMIC               | POWDER, FOR SOLUTION                 | ADJ PH                        |
| HYDROCHLORIC ACID                                       | RECTAL                   | LIQUID                               | ADJ PH                        |
| HYDROGEN PEROXIDE                                       | INTRAVENOUS              | INJECTION                            | 33.00 %w/w                    |
| HYDROXYETHYL CELLULOSE                                  | BUCCAL                   | FILM, SOLUBLE                        | 39.88 mg                      |
| HYDROXYETHYL CELLULOSE                                  | NASAL                    | SPRAY                                | 0.10 mg/ 0.20 ml              |
| HYDROXYETHYL CELLULOSE                                  | ORAL                     | CAPSULE                              | 2.98 mg                       |
| HYDROXYETHYL CELLULOSE                                  | ORAL                     | POWDER, FOR SUSPENSION               | 70.00 mg                      |
| HYDROXYETHYL CELLULOSE                                  | TOPICAL                  | SPRAY                                | 0.05 %w/w                     |
| HYDROXYETHYL CELLULOSE                                  | TOPICAL                  | SUSPENSION                           | 0.69 %w/w                     |
| HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%)               | TOPICAL                  | RINSE                                | 1.10 %w/w                     |
| HYPROMELLOSE 2208 (100 MPA.S)                           | BUCCAL                   | TABLET, EXTENDED RELEASE             | 17.25 mg                      |
| INK FINE BLACK 2202C                                    | ORAL                     | TABLET                               | NA                            |
| ISOSTEARIC ACID                                         | TRANSDERMAL              | GEL                                  | 0.20 %w/w                     |
| LACTOSE                                                 | ORAL                     | GRANULE                              | 102.50 mg/ml                  |
| LACTOSE MONOHYDRATE                                     | RESPIRATORY (INHALATION) | INHALANT                             | NA                            |
| LACTOSE MONOHYDRATE - CELLULOSE, MICROCRYSTALLINE       | ORAL                     | TABLET, EXTENDED RELEASE             | 121.50 mg                     |
| LEMON OIL                                               | ORAL                     | TABLET                               | NA                            |
| LIGHT MINERAL OIL                                       | VAGINAL                  | INSERT                               | 1464.90 mg                    |
| LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED    | ORAL                     | CAPSULE, DELAYED RELEASE             | 20.00 mg                      |
| LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED    | ORAL                     | TABLET, DELAYED RELEASE PARTICLES    | 15.00 mg                      |
| LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED    | ORAL                     | TABLET, EXTENDED RELEASE             | 11.66 mg                      |
| LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED    | ORAL                     | TABLET, MULTILAYER, EXTENDED RELEASE | 63.00 mg                      |
| MAGNESIUM ALUMINUM SILICATE                             | ORAL                     | GRANULE                              | 2.50 mg/ml                    |
| MAGNESIUM CHLORIDE                                      | OPHTHALMIC               | POWDER, FOR SOLUTION                 | 0.03 %w/w                     |
| MAGNESIUM STEARATE                                      | BUCCAL                   | TABLET, EXTENDED RELEASE             | 0.58 mg                       |
| MAGNESIUM STEARATE                                      | RESPIRATORY (INHALATION) | INHALANT                             | 0.08 mg                       |
| MAGNESIUM STEARATE                                      | TRANSMUCOSAL             | TABLET                               | 1.50 mg                       |
| MANNITOL                                                | OPHTHALMIC               | POWDER, FOR SOLUTION                 | 1.20 %w/w                     |
| MANNITOL                                                | ORAL                     | INJECTION, SOLUTION                  | 50.00 ma/ 1.70 ml             |

|                                           |                          |                          |                   |
|-------------------------------------------|--------------------------|--------------------------|-------------------|
| MANNITOL                                  | TRANSMUCOSAL             | TABLET                   | 180.19 mg         |
| MEDIUM-CHAIN TRIGLYCERIDES                | VAGINAL                  | INSERT                   | NA                |
| METHYLPARABEN                             | ORAL                     | GRANULE                  | 1.60 mg/ml        |
| METHYLPARABEN                             | RECTAL                   | LIQUID                   | 0.13 %w/v         |
| MICROCRYSTALLINE CELLULOSE                | BUCCAL                   | TABLET, EXTENDED RELEASE | 18.04 mg          |
| MICROCRYSTALLINE CELLULOSE                | ORAL                     | TABLET, SUGAR COATED     | 4.64 mg           |
| MILK PROTEIN CONCENTRATE                  | BUCCAL                   | TABLET, EXTENDED RELEASE | 23.00 mg          |
| MONOSODIUM CITRATE                        | ORAL                     | POWDER                   | 11.92 mg/ml       |
| N-METHYLPERFLUOROOCTANESULFONAMIDOETHANOL | TOPICAL                  | AEROSOL, FOAM            | 56.09 %w/w        |
| OLEIC ACID                                | TOPICAL                  | GEL                      | 2.50 %w/w         |
| OPACODE S-1-8100-HV BLACK                 | ORAL                     | TABLET, SUGAR COATED     | 0.09 mg           |
| OPADRY YS-1-4241 BLUE                     | ORAL                     | TABLET, FILM COATED      | 6.00 mg           |
| OPAGLOS GS 2-0310                         | ORAL                     | TABLET, SUGAR COATED     | 0.76 mg           |
| OPALUX AS 4258 BLUE                       | ORAL                     | TABLET                   | NA                |
| OPALUX BLUE                               | ORAL                     | TABLET                   | NA                |
| PECTIN                                    | TOPICAL                  | PASTE, DENTIFRICE        | 16.63 %w/w        |
| PEPPERMINT OIL                            | ORAL                     | TABLET                   | 1908.00 mg        |
| PETROLATUM                                | VAGINAL                  | INSERT                   | 27.00 mg          |
| PHENOL                                    | ORAL                     | INJECTION                | 5.00 mg/ 1.00 ml  |
| POLYETHYLENE OXIDE 7000000                | ORAL                     | TABLET                   | 132.66 mg         |
| POLYOXYL 20 CETOSTEARYL ETHER             | TOPICAL                  | RINSE                    | 0.90 %w/w         |
| POLYSORBATE 80                            | ORAL                     | GRANULE                  | 4.80 mg/ml        |
| POLYSORBATE 80                            | ORAL                     | INHALANT                 | 0.20 mg/ml        |
| POLYSORBATE 80                            | ORAL                     | POWDER, FOR SOLUTION     | NA                |
| POLYSORBATE 80                            | RECTAL                   | POWDER, FOR SOLUTION     | NA                |
| POTASSIUM BICARBONATE                     | TRANSMUCOSAL             | TABLET                   | 8.00 mg           |
| POTASSIUM CHLORIDE                        | OPHTHALMIC               | POWDER, FOR SOLUTION     | 0.08 %w/w         |
| POVIDONES                                 | BUCCAL                   | TABLET, EXTENDED RELEASE | 0.50 mg           |
| PROPYLENE GLYCOL                          | TOPICAL                  | RINSE                    | 3.00 %w/w         |
| PROPYLENE GLYCOL MONOPALMITOSTEARATE      | RECTAL                   | SUPPOSITORY              | 1150.00 mg        |
| PROPYLPARABEN                             | RECTAL                   | LIQUID                   | 0.02 %w/v         |
| SACCHARIN SODIUM                          | ORAL                     | POWDER                   | 0.22 mg/ml        |
| SACCHARIN SODIUM ANHYDROUS                | RECTAL                   | LIQUID                   | 0.04 %w/v         |
| SILICON DIOXIDE                           | BUCCAL                   | TABLET, EXTENDED RELEASE | 0.46 mg           |
| SILICON DIOXIDE                           | ENDOCERVICAL             | GEL                      | 8.00 %w/w         |
| SILICON DIOXIDE                           | ORAL                     | TABLET, SUGAR COATED     | 0.80 mg           |
| SIMETHICONE                               | ORAL                     | GRANULE                  | 0.80 mg/ml        |
| SODIUM ACETATE                            | OPHTHALMIC               | POWDER, FOR SOLUTION     | 0.39 %w/w         |
| SODIUM ACETATE                            | ORAL                     | INJECTION                | ADJ PH            |
| SODIUM ACETATE                            | ORAL                     | INJECTION, SOLUTION      | 1.36 mg/ 1.70 ml  |
| SODIUM BENZOATE                           | ORAL                     | POWDER                   | 1.08 mg/ml        |
| SODIUM BICARBONATE                        | ORAL                     | SUSPENSION               | 5.00 mg/ 5.00 ml  |
| SODIUM CARBONATE                          | INTRAVENOUS              | POWDER                   | 575.00 mg         |
| SODIUM CARBONATE                          | ORAL                     | INJECTION                | 23.96 mg/ 1.00 ml |
| SODIUM CHLORIDE                           | ORAL                     | INHALANT                 | 8.50 mg/ml        |
| SODIUM HYDROXIDE                          | INTRAMUSCULAR            | POWDER                   | ADJ PH            |
| SODIUM HYDROXIDE                          | OPHTHALMIC               | POWDER, FOR SOLUTION     | ADJ PH            |
| SODIUM HYDROXIDE                          | RESPIRATORY (INHALATION) | INJECTION, SOLUTION      | ADJ PH            |
| SODIUM LAURYL SULFATE                     | BUCCAL                   | TABLET, EXTENDED RELEASE | 5.18 mg           |
| SODIUM STARCH GLYCOLATE TYPE A POTATO     | TRANSMUCOSAL             | TABLET                   | 10.00 mg          |
| STARCH                                    | ORAL                     | TABLET, SUGAR COATED     | 43.25 mg          |
| STARCH, PREGELATINIZED                    | ORAL                     | TABLET, SUGAR COATED     | 9.40 mg           |
| STEARALKONIUM CHLORIDE                    | TOPICAL                  | RINSE                    | 4.20 %w/w         |
| STEARIC ACID                              | ORAL                     | TABLET, SUGAR COATED     | 0.90 mg           |
| SUCROSE                                   | ORAL                     | TABLET, SUGAR COATED     | 73.18 mg          |
| SULFURIC ACID                             | NASAL                    | SOLUTION                 | 75.00 mg/ 5.00 ml |
| SULFURIC ACID                             | RESPIRATORY (INHALATION) | INHALANT                 | ADJ PH            |
| TITANIUM DIOXIDE                          | VAGINAL                  | SUPPOSITORY              | NA                |
| TRISODIUM CITRATE DIHYDRATE               | ORAL                     | INHALANT                 | 0.50 mg/ml        |
| TRISODIUM CITRATE DIHYDRATE               | RESPIRATORY (INHALATION) | INHALANT                 | 2.00 mg/ml        |
| XANTHAN GUM                               | ORAL                     | GRANULE                  | 2.00 mg/ml        |
| XYLITOL 300                               | ORAL                     | TABLET, EXTENDED RELEASE | 72.00 mg          |
| ZINC                                      | ORAL                     | POWDER                   | NA                |
| ZINC OXIDE                                | RESPIRATORY (INHALATION) | INJECTION, SOLUTION      | 3.11 %w/v         |

Data Through 09/27/2019