**November 6, 2012**

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| --- | --- | --- | --- | --- |
| **Drug Name** | **Active Ingredient** | **Dosage Form/Route** | **Sponsor** | **Submission Type** |
| [Norethindrone and Ethinyl Estradiol](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA4LjExOTEzNjAxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwOC4xMTkxMzYwMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgyNDI2JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&106&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=078376&source=govdelivery) | ethinyl estradiol; norethindrone | Tablet; Oral-28 | Vintage Pharms | Approval |
| [Sildenafil Citrate](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA4LjExOTEzNjAxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwOC4xMTkxMzYwMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgyNDI2JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&107&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=091379&source=govdelivery) | sildenafil citrate | Tablet; Oral | Apotex Corp | Approval |
| [Sildenafil Citrate](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA4LjExOTEzNjAxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwOC4xMTkxMzYwMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgyNDI2JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&108&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=091479&source=govdelivery) | sildenafil citrate | Tablet; Oral | Torrent Pharms Ltd | Approval |
| [Sildenafil Citrate](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA4LjExOTEzNjAxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwOC4xMTkxMzYwMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgyNDI2JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&109&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=202503&source=govdelivery) | sildenafil citrate | Tablet; Oral | Watson Labs Inc | Approval |
| [Sildenafil Citrate](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA4LjExOTEzNjAxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwOC4xMTkxMzYwMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgyNDI2JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&110&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=202598&source=govdelivery) | sildenafil citrate | Tablet; Oral | Dr Reddys Labs Ltd | Approval |
| [Xeljanz](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA4LjExOTEzNjAxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwOC4xMTkxMzYwMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgyNDI2JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&111&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=203214&source=govdelivery) | tofacitinib | Tablet; Oral | Pfizer Inc | Approval |