**November 5, 2012**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Drug Name** | **Active Ingredient** | **Dosage Form/Route** | **Sponsor** | **Submission Type** |
| [Levemir](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA3LjExODU0OTUxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwNy4xMTg1NDk1MSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgxNjc5JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&105&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=021536&source=govdelivery) | insulin detemir recombinant | Injectable; Subcutaneous | Novo Nordisk Inc | Labeling Revision |
| [Novolog](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA3LjExODU0OTUxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwNy4xMTg1NDk1MSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgxNjc5JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&106&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=020986&source=govdelivery) | insulin aspart recombinant | Injectable; Subcutaneous | Novo Nordisk Inc | Labeling Revision |
| [Sildenafil Citrate](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA3LjExODU0OTUxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwNy4xMTg1NDk1MSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgxNjc5JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&107&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=202506&source=govdelivery) | sildenafil citrate | Tablet; Oral | Watson Labs | Tentative Approval |
| [Xarelto](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA3LjExODU0OTUxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwNy4xMTg1NDk1MSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgxNjc5JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&108&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=202439&source=govdelivery) | rivaroxaban | Tablet; Oral | Janssen Pharms | Labeling Revision |