**October 31, 2012**

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| **Drug Name** | **Active Ingredient** | **Dosage Form/Route** | **Sponsor** | **Submission Type** |
| [Advicor](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&107&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=021249&source=govdelivery) | lovastatin; niacin | Tablet, Extended Release; Oral | Abbvie | Labeling Revision |
| [Altoprev](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&108&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=021316&source=govdelivery) | lovastatin | Tablet, Extended Release; Oral | Andrx Labs Llc | Labeling Revision |
| [Caduet](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&109&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=021540&source=govdelivery) | amlodipine besylate; atorvastatin calcium | Tablet; Oral | Pfizer | Labeling Revision |
| [Crestor](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&110&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=021366&source=govdelivery) | rosuvastatin calcium | Tablet; Oral | Ipr | Labeling Revision |
| [Fenoglide](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&111&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=022118&source=govdelivery) | fenofibrate | Tablet; Oral | Santarus | Labeling Revision |
| [Fosrenol](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&112&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=021468&source=govdelivery) | lanthanum carbonate | Tablet, Chewable; Oral | Shire Llc | Labeling Revision |
| [Juvisync](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&113&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=202343&source=govdelivery) | simvastatin; sitagliptin phosphate | Tablet; Oral | Merck Sharp Dohme | Labeling Revision |
| [Lescol](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&114&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=020261&source=govdelivery) | fluvastatin sodium | Capsule; Oral | Novartis | Labeling Revision |
| [Lescol Xl](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&115&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=021192&source=govdelivery) | fluvastatin sodium | Tablet, Extended Release; Oral | Novartis | Labeling Revision |
| [Lipitor](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&116&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=020702&source=govdelivery) | atorvastatin calcium | Tablet; Oral | Pfizer | Labeling Revision |
| [Livalo](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&117&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=022363&source=govdelivery) | pitavastatin calcium | Tablet; Oral | Kowa Co | Labeling Revision |
| [Mevacor](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&118&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=019643&source=govdelivery) | lovastatin | Tablet; Oral | Merck | Labeling Revision |
| [Plendil](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&119&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=019834&source=govdelivery) | felodipine | Tablet, Extended Release; Oral | Astrazeneca | Labeling Revision |
| [Pravachol](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&120&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=019898&source=govdelivery) | pravastatin sodium | Tablet; Oral | Bristol Myers Squibb | Labeling Revision |
| [Simcor](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&121&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=022078&source=govdelivery) | niacin; simvastatin | Tablet, Extended Release; Oral | Abbvie | Labeling Revision |
| [Stendra](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&122&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=202276&source=govdelivery) | avanafil | Tablet; Oral | Vivus | Labeling Revision |
| [Tenoretic 100](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&123&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=018760&source=govdelivery) | atenolol; chlorthalidone | Tablet; Oral | Astrazeneca | Labeling Revision |
| [Tenoretic 50](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&123&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=018760&source=govdelivery) | atenolol; chlorthalidone | Tablet; Oral | Astrazeneca | Labeling Revision |
| [Tenormin](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&124&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=018240&source=govdelivery) | atenolol | Tablet; Oral | Astrazeneca | Labeling Revision |
| [Toprol-Xl](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&125&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=019962&source=govdelivery) | metoprolol succinate | Tablet, Extended Release; Oral | Astrazeneca | Labeling Revision |
| [Vytorin](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&126&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=021687&source=govdelivery) | ezetimibe; simvastatin | Tablet; Oral | Msd Intl | Labeling Revision |
| [Zestoretic](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&127&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=019888&source=govdelivery) | hydrochlorothiazide; lisinopril | Tablet; Oral | Astrazeneca | Labeling Revision |
| [Zestril](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&128&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=019777&source=govdelivery) | lisinopril | Tablet; Oral | Astrazeneca | Labeling Revision |
| [Zocor](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTAyLjExNjg4MjExJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwMi4xMTY4ODIxMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTc4NzYzJmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&129&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=019766&source=govdelivery) | simvastatin | Tablet; Oral | Merck | Labeling Revision |