

**Product Titles in Highlights of Prescribing Information Consistent with Recommendations in Draft  
Guidance for Industry: [Product Title and Initial U.S. Approval in the Highlights of Prescribing  
Information for Human Prescription Drug and Biological Products - Content and Format](#)**

<p><b>TABLETS</b></p>	<p><b>“tablets”</b>            LEVITRA (vardenafil hydrochloride) tablets, for oral use            INVOKANA (canagliflozin) tablets, for oral use            LIPTRUZET (ezetimibe and atorvastatin) tablets, for oral use            CLOZARIL (clozapine) tablets, for oral use            SEROQUEL (quetiapine fumarate) tablets, for oral use            LATUDA (lurasidone hydrochloride) tablets, for oral use            ONFI (clobazam) tablets, for oral use, CIV            LUNESTA (eszopiclone) tablets, for oral use, CIV            ZOMIG (zolmitriptan) tablets, for oral use            CADUET (amlodipine besylate and atorvastatin calcium) tablets, for oral use            ELIQUIS (apixaban) tablets, for oral use            REVATIO (sildenafil) tablets, for oral use            CYCLOPHOSPHAMIDE tablets, for oral use            VIEKIRA PAK (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets), co-packaged for oral use            KISQALI FEMARA CO-PACK (ribociclib tablets; letrozole tablets), co-packaged for oral use</p> <p><b>“extended-release tablets”</b>            UCERIS (budesonide) extended-release tablets, for oral use            INTUNIV (guanfacine) extended-release tablets, for oral use            OXTELLAR XR (oxcarbazepine) extended-release tablets, for oral use            APLENZIN (bupropion hydrobromide) extended-release tablets, for oral use            ENVARUS XR (tacrolimus extended-release tablets), for oral use</p> <p><b>“orally disintegrating tablets”</b>            FAZACLO (clozapine) orally disintegrating tablets            STAXYN (vardenafil hydrochloride) orally disintegrating tablets            ZOMIG-ZMT (zolmitriptan) orally disintegrating tablets            MAXALT-MLT (rizatriptan benzoate) orally disintegrating tablets</p> <p><b>“sublingual tablets”</b>            INTERMEZZO (zolpidem tartrate) sublingual tablets, CIV</p> <p><b>“buccal tablets”</b>            FENTORA (fentanyl buccal tablets), CII</p> <p><b>“tablets for oral suspension”</b>            AFINITOR DISPERZ (everolimus tablets for oral suspension)</p>
<p><b>CAPSULES</b></p>	<p><b>“capsules”</b>            BRISDELLE (paroxetine) capsules, for oral use            ABSORICA (isotretinoin) capsules, for oral use            VYVANSE (lisdexamfetamine dimesylate) capsules, for oral use, CII</p> <p><b>“extended-release capsules”</b>            AMRIX (cyclobenzaprine hydrochloride extended-release capsules), for oral use            XIMINO (minocycline hydrochloride) extended-release capsules, for oral use            FETZIMA (levomilnacipran) extended-release capsules, for oral use            EQUETRO (carbamazepine) extended-release capsules, for oral use</p> <p><b>“delayed-release capsules”</b>            TECFIDERA (dimethyl fumarate) delayed-release capsules, for oral use            CYMBALTA (duloxetine delayed-release capsules), for oral use</p>
<p><b>ORAL SOLUTION</b></p>	<p><b>“oral solution”</b>            NYMALIZE (nimodipine) oral solution</p>

	<p>HEMANGEOL (propranolol hydrochloride oral solution)          XYREM (sodium oxybate) oral solution, CIII          KEPPRA (levetiracetam) oral solution</p> <p><b>“for oral solution”</b>          MOVIPREP (polyethylene glycol 3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid for oral solution)          PREPOPIK (sodium picosulfate, magnesium oxide, and anhydrous citric acid) for oral solution          ORALTAG (iohexol) for oral solution</p>
<p><b>ORAL          SUSPENSION</b></p>	<p><b>“oral suspension”</b>          ONFI (clobazam) oral suspension, CIV          PURIXAN (mercaptapurine) oral suspension</p> <p><b>“for oral suspension”</b>          REVATIO (sildenafil) for oral suspension          ISENTRESS (raltegravir) for oral suspension</p> <p><b>“for extended-release oral suspension”</b>          QUILLIVANT XR (methylphenidate hydrochloride) for extended-release oral suspension, CII</p> <p><b>“for delayed-release oral suspension”</b>          NEXIUM (esomeprazole magnesium) for delayed-release oral suspension</p>
<p><b>INJECTION</b></p>	<p><b>“injection”</b></p> <p><u>Drug Products</u>          PHENYLEPHRINE HYDROCHLORIDE injection, for intravenous use          BREVIBLOC (esmolol hydrochloride) injection, for intravenous use          LANOXIN (digoxin) injection, for intravenous or intramuscular use          REVATIO (sildenafil) injection, for intravenous use          CYCLOPHOSPHAMIDE injection, for intravenous use          DOXORUBICIN HYDROCHLORIDE injection, for intravenous use          KYBELLA (deoxycholic acid) injection, for subcutaneous use          JEVTANA (cabazitaxel) injection, for intravenous use          CEFAZOLIN injection, for intravenous use          KYBELLA (deoxycholic acid) injection, for subcutaneous use          INTEGRILIN (eptifibatide) injection, for intravenous use          COPAXONE (glatiramer acetate injection), for subcutaneous use          TRESIBA (insulin degludec injection), for subcutaneous use          BASAGLAR (insulin glargine injection), for subcutaneous use          DEXTROSE injection, for intravenous use</p> <p><u>Biological Products</u>          TALTZ (ixekizumab) injection, for subcutaneous use          SILIQ (brodalumab) injection, for subcutaneous use          DUPIXENT (dupilumab) injection, for subcutaneous use          NAGLAZYME (galsulfase) injection, for intravenous use          ELAPRASE (idursulfase) injection, for intravenous use          TYSABRI (natalizumab) injection, for intravenous use          SIMPONI (golimumab) injection, for subcutaneous use          STELARA (ustekinumab) injection, for subcutaneous use          ILARIS (canakinumab) injection, for subcutaneous use          AVONEX (interferon beta-1a) injection, for intramuscular use          COSENTYX (secukinumab) injection, for subcutaneous use          HUMIRA (adalimumab) injection, for subcutaneous use          DARZALEX (daratumumab) injection, for intravenous use</p> <p><b>Other Dosage Forms</b></p> <p>INVEGA SUSTENNA (paliperidone palmitate) extended-release injectable suspension, for intramuscular use          ABILIFY MAINTENA (aripiprazole) for extended-release injectable suspension, for intramuscular use          ARISTADA (aripiprazole lauroxil) extended-release injectable suspension, for intramuscular use</p>

	<p><b>NETSPOT (kit for the preparation of gallium Ga 68 dotatate injection), for intravenous use</b>  <b>CINVANTI (aprepitant) injectable emulsion, for intravenous use</b></p>
<b>FOR INJECTION</b>	<p><u>Biological Products</u>  <b>BOTOX (onabotulinumtoxinA) for injection, for intramuscular, intradetrusor, or intradermal use</b>  <b>BOTOX COSMETIC (onabotulinumtoxinA) for injection, for intramuscular use</b>  <b>AMEVIVE (alefacept) for injection, for intramuscular use</b>  <b>ELELYSO (taliglucerase alfa) for injection, for intravenous use</b>  <b>XIAFLEX (collagenase clostridium histolyticum) for injection, for intralesional use</b>  <b>BETASERON (interferon beta-1b) for injection, for subcutaneous use</b>  <b>GLUCAGON for injection, for intravenous or intramuscular use</b>  <b>COSENTYX (secukinumab) for injection, for subcutaneous use</b>  <b>EMPLICITI (elotuzumab) for injection, for intravenous use</b></p> <p><u>Drug Products</u>  <b>DOXORUBICIN HYDROCHLORIDE for injection, for intravenous use</b>  <b>CAVERJECT IMPULSE (alprostadil) for injection, for intracavernosal use</b>  <b>VIDAZA (azacitidine for injection), for subcutaneous or intravenous use</b>  <b>TREANDA (bendamustine hydrochloride) for injection, for intravenous use</b>  <b>ANGIOMAX (bivalirudin) for injection, for intravenous use</b>  <b>KENGREAL (cangrelor) for injection, for intravenous use</b>  <b>CANCIDAS (casposfungin acetate) for injection, for intravenous use</b>  <b>KYPROLIS (carfilzomib) for injection, for intravenous use</b>  <b>MAXIPIME (cefepime hydrochloride) for injection, for intravenous or intramuscular use</b>  <b>AVYCAZ (ceftazidime and avibactam) for injection, for intravenous use</b>  <b>LOLAN (epoprostenol sodium) for injection, for intravenous use</b></p>
<b>TRANSDERMAL SYSTEMS</b>	<p><b>OXYTROL (oxybutynin transdermal system)</b>  <b>IONSYS (fentanyl iontophoretic transdermal system), CII</b></p>
<b>DOSAGE FORMS FOR TOPICAL USE</b>	<p><b>ULESFIA (benzyl alcohol) lotion, for topical use</b>  <b>CENTANY (mupirocin) ointment, for topical use</b>  <b>XERESE (acyclovir and hydrocortisone) cream, for topical use</b>  <b>ESKATA (hydrogen peroxide) topical solution</b>  <b>ULESFIA (benzyl alcohol) lotion, for topical use</b>  <b>PLIAGLIS (lidocaine and tetracaine) cream, for topical use</b>  <b>BACTROBAN (mupirocin calcium) cream, for topical use</b>  <b>RHOFADE (oxymetazoline hydrochloride) cream, for topical use</b>  <b>XEPI (ozenoxacin) cream, for topical use</b>  <b>MIRVASO (brimonidine) topical gel</b></p>
<b>OTHER DOSAGE FORMS</b>	<p><b>GLIADEL WAFER (carmustine implant), for intracranial use</b>  <b>ADASUVE (loxapine) inhalation powder, for oral inhalation use</b>  <b>DULERA (mometasone furoate and formoterol fumarate dihydrate) inhalation aerosol, for oral inhalation use</b>  <b>KITABIS PAK (tobramycin inhalation solution), for oral inhalation use</b>  <b>OMNARIS (ciclesonide) nasal spray</b>  <b>CIPRODEX (ciprofloxacin and dexamethasone) otic suspension</b></p>