

Product Titles in Highlights of Prescribing Information Consistent with Requirements Under 21 CFR 201.57(a)(2) and Recommendations in Draft Guidance for Industry: [Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products -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](#)

TABLETS

“tablets”

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
 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
 ELIQUIS (apixaban) tablets, for oral use
 REVATIO (sildenafil) tablets, for oral use
 CYCLOPHOSPHAMIDE tablets, for oral use
 BIKTARVY (bictegravir, emtricitabine, and tenofovir alafenamide) 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

“delayed-release tablets”

ACIPHEX (rabeprazole sodium) delayed-release tablets, for oral use
 ASACOL HD (mesalamine) delayed-release tablets, for oral use

“extended-release tablets”

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
 ENVARSUS XR (tacrolimus extended-release tablets), for oral use

“orally disintegrating tablets”

FAZACLO (clozapine) orally disintegrating tablets
 STAXYN (vardenafil hydrochloride) orally disintegrating tablets
 ZOMIG-ZMT (zolmitriptan) orally disintegrating tablets
 MAXALT-MLT (rizatriptan benzoate) orally disintegrating tablets

“delayed-release orally disintegrating tablets”

PREVACID SOLUTAB (lansoprazole) delayed-release orally disintegrating tablets

“extended-release orally disintegrating tablets”

COTEMPLA XR-ODT (methylphenidate extended-release orally disintegrating tablets), CII
 ADZENYS XR-ODT (amphetamine) extended-release orally disintegrating tablets, CII

“buccal tablets”

FENTORA (fentanyl buccal tablets), CII
 SITAVIG (acyclovir) buccal tablets

“chewable tablets”

VYVANSE (lisdexamfetamine dimesylate) chewable tablets, for oral use, CII
 SUPRAX (cefixime) chewable tablets, for oral use
 ISENTRESS (raltegravir) chewable tablets, for oral use

“sublingual tablets”

INTERMEZZO (zolpidem tartrate) sublingual tablets, CIV

“tablets for oral suspension”

	<p>AFINITOR DISPERZ (everolimus tablets for oral suspension) TRACLEER (bosentan) tablets for oral suspension</p> <p>“effervescent tablets for oral solution” BINOSTO (alendronate sodium) effervescent tablets for oral solution</p>
<p>CAPSULES</p>	<p>“capsules” BRISDELLE (paroxetine) capsules, for oral use ABSORICA (isotretinoin) capsules, for oral use VYVANSE (lisdexamfetamine dimesylate) capsules, for oral use, CII NUEDEXTA (dextromethorphan hydrobromide and quinidine sulfate) capsules, for oral use LITHIUM CARBONATE capsules, for oral use</p> <p>“delayed-release capsules” TECFIDERA (dimethyl fumarate) delayed-release capsules, for oral use CYMBALTA (duloxetine delayed-release capsules), for oral use PREVACID (lansoprazole) delayed-release capsules, for oral use</p> <p>“extended-release capsules” 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 ASTAGRAF XL (tacrolimus extended-release capsules), for oral use</p>
<p>ORAL SOLUTION</p>	<p>“oral solution” NYMALIZE (nimodipine) oral solution HEMANGEOL (propranolol hydrochloride oral solution) XYREM (sodium oxybate) oral solution, CIII KEPPRA (levetiracetam) oral solution</p> <p>“for oral solution” 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 ZERIT (stavudine) for oral solution</p>
<p>ORAL SUSPENSION</p>	<p>“oral suspension” ONFI (clobazam) oral suspension, CIV PURIXAN (mercaptapurine) oral suspension FYCOMPA (perampanel) oral suspension, CIII EMFLAZA (deflazacort) oral suspension LEXIVA (fosamprenavir calcium) oral suspension</p> <p>“for oral suspension” REVATIO (sildenafil) for oral suspension ISENTRESS (raltegravir) for oral suspension LOKELMA (sodium zirconium cyclosilicate) for oral suspension VFEND (voriconazole) for oral suspension LOKELMA (sodium zirconium cyclosilicate) for oral suspension</p> <p>“extended-release oral suspension” ADZENYS ER (amphetamine) extended-release oral suspension, CII DYANAVEL XR (amphetamine) extended-release oral suspension, CII TUZISTRA XR (codeine polistirex and chlorpheniramine polistirex) extended-release oral suspension, CIII</p> <p>“for delayed-release oral suspension” NEXIUM (esomeprazole magnesium) for delayed-release oral suspension PRILOSEC (omeprazole magnesium) for delayed-release oral suspension</p> <p>“for extended-release oral suspension” QUILLIVANT XR (methylphenidate hydrochloride) for extended-release oral suspension, CII</p>

“injection”

Drug Products

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

Biological Products

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
TROGARZO (ibalizumab-uiyk) injection, for intravenous use
ILUMYA (tildrakizumab-asmn) injection, for subcutaneous use
CRYSVITA (burosumab-twza) injection, for subcutaneous use
AIMOVIG (erenumab-aooe) injection, for subcutaneous use
PALYNZIQ (pegvaliase-pqpz) injection, for subcutaneous use
POTELIGEO (mogamulizumab-kpkc) injection, for intravenous use
TAKHZYRO (lanadelumab-flyo) injection, for subcutaneous use
LUMOXITI (moxetumomab pasudotox-tdfk) for injection, for intravenous use
AJOVY (fremanezumab-vfrm) injection, for subcutaneous use
EMGALITY (galcanezumab-gnlm) injection, for subcutaneous use
LIBTAYO (cemiplimab-rwlc) injection, for intravenous use
REVCovi (elapegedemase-lvlr) injection, for intramuscular use
NIVESTYM (filgrastim-aafi) injection, for subcutaneous or intravenous use
HYRIMOZ (adalimumab-adaz) injection, for subcutaneous use
UDENYCA (pegfilgrastim-cbqv) injection, for subcutaneous use

Pre-Mixed Drug Products

LEVETIRACETAM IN SODIUM CHLORIDE injection, for intravenous use
MAGNESIUM SULFATE IN DEXTROSE injection, for intravenous use
CARDENE IV (nicardipine hydrochloride in sodium chloride injection), for intravenous use
CALCIUM GLUCONATE IN SODIUM CHLORIDE injection, for intravenous use
INFUGEM (gemcitabine in sodium chloride injection), for intravenous use

Radiopharmaceuticals

NETSPOT (kit for the preparation of gallium Ga 68 dotatate injection), for intravenous use
LUTATHERA (lutetium Lu 177 dotatate) injection, for intravenous use

INJECTION

**FOR
INJECTION**

Biological Products

BOTOX (onabotulinumtoxinA) for injection, for intramuscular, intradetrusor, or intradermal use
BOTOX COSMETIC (onabotulinumtoxinA) for injection, for intramuscular use
AMEVIVE (alefacept) for injection, for intramuscular use
ELELYSO (taliglucerase alfa) for injection, for intravenous use
XIAFLEX (collagenase clostridium histolyticum) for injection, for intralesional use

	<p>BETASERON (interferon beta-1b) for injection, for subcutaneous use GLUCAGON for injection, for intravenous or intramuscular use COSENTYX (secukinumab) for injection, for subcutaneous use EMPLICITI (elotuzumab) for injection, for intravenous use</p> <p><u>Drug Products</u> DOXORUBICIN HYDROCHLORIDE for injection, for intravenous use CAVERJECT IMPULSE (alprostadil) for injection, for intracavernosal use VIDAZA (azacitidine for injection), for subcutaneous or intravenous use TREANDA (bendamustine hydrochloride) for injection, for intravenous use ANGIOMAX (bivalirudin) for injection, for intravenous use KENGREAL (cangrelor) for injection, for intravenous use CANCIDAS (caspofungin acetate) for injection, for intravenous use KYPROLIS (carfilzomib) for injection, for intravenous use AVYCAZ (ceftazidime and avibactam) for injection, for intravenous use LOLAN (epoprostenol sodium) for injection, for intravenous use</p>
OTHER INJECTION DOSAGE FORMS	<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 CINVANTI (aprepitant) injectable emulsion, for intravenous use OMEGAVEN (fish oil triglycerides) injectable emulsion, for intravenous use CLINOLIPID (lipid injectable emulsion), for intravenous use VARITHENA (polidocanol injectable foam), for intravenous use SIGNIFOR LAR (pasireotide) for injectable suspension, for intramuscular use VARITHENA (polidocanol injectable foam), for intravenous use</p>
TRANSDERMAL SYSTEMS	<p>OXYTROL (oxybutynin transdermal system) IONSYS (fentanyl iontophoretic transdermal system), CII MINIVELLE (estradiol transdermal system) NEUPRO (rotigotine transdermal system) EMSAM (selegiline transdermal system)</p>
DOSAGE FORMS FOR TOPICAL USE	<p>ULESFIA (benzyl alcohol) lotion, for topical use CENTANY (mupirocin) ointment, for topical use XERESE (acyclovir and hydrocortisone) cream, for topical use ESKATA (hydrogen peroxide) topical solution ULESFIA (benzyl alcohol) lotion, for topical use PLIAGLIS (lidocaine and tetracaine) cream, for topical use BACTROBAN (mupirocin calcium) cream, for topical use RHOFADE (oxymetazoline hydrochloride) cream, for topical use XEPI (ozenoxacin) cream, for topical use MIRVASO (brimonidine) topical gel PANDEL (hydrocortisone probutate) cream, for topical use DUOBRII (halobetasol propionate and tazarotene) lotion, for topical use LEXETTE (halobetasol propionate) topical foam ALTRENO (tretinoin) lotion, for topical use</p>
DOSAGE FORMS FOR INHALATION USE	<p>RELENZA (zanamivir inhalation powder), for oral inhalation use TRELEGY ELLIPTA (fluticasone furoate, umeclidinium, and vilanterol inhalation powder), for oral inhalation use ADASUVE (loxapine) inhalation powder, for oral inhalation use DULERA (mometasone furoate and formoterol fumarate dihydrate) inhalation aerosol, for oral inhalation use KITABIS PAK (tobramycin inhalation solution), for oral inhalation use</p>
OTHER DOSAGE FORMS	<p>GLIADEL WAFER (carmustine implant), for intracranial use OMNARIS (ciclesonide) nasal spray NITROLINGUAL PUMPSPRAY (nitroglycerin) lingual spray CIPRODEX (ciprofloxacin and dexamethasone) otic suspension OTOVEL (ciprofloxacin and fluocinolone acetonide) otic solution ANNOVERA (segestrone acetate and ethinyl estradiol vaginal system) SYMPAZANTM (clobazam) oral film, CIV BELBUCA (buprenorphine buccal film), CIII KALYDECO (ivacaftor) oral granules SOLOSEC (secnidazole) oral granules IMVEXXY (estradiol vaginal inserts) INTRAROSA (prasterone) vaginal inserts CANASA (mesalamine) suppositories, for rectal use NORVIR (ritonavir) oral powder</p>