

<u>Nominations of Difficult to Compound Drugs *</u>	<u>Specific Dosage Form and/or Delivery Mechanism As Identified By the Nominator</u>	<u>Nominator</u>
Advair Diskus® (fluticasone propionate and salmeterol xinafoate)	Inhalation Powder	GlaxoSmithKline (GSK)
Advair HFA® (fluticasone propionate and salmeterol xinafoate)	Inhalation Aerosol	GlaxoSmithKline (GSK)
Alprostadil	Injectable	Auxilium Pharmaceuticals
Ampyra® (dalfampridine)	ER tablets	Acorda Therapeutics
Anoro™ Ellipta® (umeclidinium bromide; and vilanterol trifenate)	Inhalation Aerosol	GlaxoSmithKline (GSK)
Atropine	None Identified	Nephron Compounding Ctr
Avandamet® (rosiglitazone maleate and metformin hydrochloride)	Tablet	GlaxoSmithKline (GSK)
Avandaryl® (rosiglitazone maleate and glimepiride)	Tablet	GlaxoSmithKline (GSK)
Avandia® (rosiglitazone maleate)	Tablet	GlaxoSmithKline (GSK)
Avodart® (dutasteride)	Capsules	GlaxoSmithKline (GSK)
Azithromycin	Intravenous	Nephron Compounding Ctr
Baclofen	Intrathecal Implantable Pump	Mallinckrodt Pharmaceuticals
Beconase AQ® (beclomethasone dipropionate, monohydrate)	Nasal Spray	GlaxoSmithKline (GSK)
Bio-identical hormone	Pellets	Kenneth Woliner, MD; Gary Donovitz, MD; Leila Martin
Biologic products	Injectable	Biotechnology Industry Organization
Breo® Ellipta® (fluticasone furoate and vilanterol trifenate)	Inhalation Powder	GlaxoSmithKline (GSK)
Collagenase SANTYL® 250 units/g	Topical ointment	Smith & Newpew Inc.
Coreg CR® (carvedilol phosphate)	ER Capsule	GlaxoSmithKline (GSK)
Diclofenac Sodium	Topical solution	Mallinckrodt Pharmaceuticals
Drug products subject to a Risk Evaluation and Mitigation strategy (REMS) with elements to assure safe use (ETASU)	None Identified	Biotechnology Industry Organization
Drugs manufactured by extrusion or nanotechnology	Extrusion/Nanotech	AbbVie
Drugs utilizing transdermal drug delivery systems	None Identified	AbbVie
Dry powder inhaler (DPI) products (non-exempt under 503A and 503B)	Dry Powder	Public Citizen
Enteric-coated preparations (non-exempt under 503A and 503B)	None Identified	Public Citizen
Estradiol	Oral and topical	Wulf Utian MB BCh, PhD, DSc(Med), FRCOG, FACOG, FICS
Estriol	Individual Drug	Carolyn Quist, DO, PA
Flonase® (fluticasone propionate)	Nasal Spray	GlaxoSmithKline (GSK)
Flovent Diskus® (fluticasone propionate)	Inhalation Powder	GlaxoSmithKline (GSK)
Flovent HFA® (fluticasone propionate)	Inhalation Powder	GlaxoSmithKline (GSK)
Heparin	None Identified	Nephron Compounding Ctr
High potency drugs	None Identified	AbbVie
Human chorionic gonadotropin (HCG)	Individual Drug	Kenneth Woliner, MD
Hyaluronidase	Injectable	Halozyme Therapeutics
Hygroscopic, light sensitive, temperature-controlled drug products	None Identified	AbbVie

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Itraconazole (Sporanox®)	Individual Drug	Kenneth Woliner, MD
Jalyn® (dutasteride and tamsulosin HCl)	Capsules	GlaxoSmithKline (GSK)
Kenalog® (Triamcinolone Acetonide)	Injectable - epidural	Dennis Haney
Lamictal® (lamotrigine)	Chewable Dispersible Tablet	GlaxoSmithKline (GSK)
Lamictal® XR (lamotrigine)	ER Tablet	GlaxoSmithKline (GSK)
Low dose drugs	None Identified	AbbVie
Metered dose inhaler (MDI) products (non-exempt under 503A and 503B)	Aerosolized	Public Citizen's Health Research Group
Methylprednisolone Acetate	Injectable - epidural	Terri Anderson, Arachnoiditis Society for Awareness and Prevention
Modified release drug products	MR Capsules or Tablets	AbbVie
Morphine	Implantable Pump	Mallinckrodt Pharmaceuticals
Narrow Therapeutic Index Drugs	None Identified	Biotechnology Industry Organization; AbbVie
Nitroglycerin Ointment	Ointment	Aptalis Pharma US, Inc.
Nonsterile-to-sterile compounding (non-exempt under 503A only)	Injectables, Infusions or Implants, Aqueous- based Inhalation Solutions, and Ophthalmic Products	Public Citizen's Health Research Group; Sarah Sellers, PharmD
Papaverine	Injectable	Auxilium Pharmaceuticals
Potiga™ (ezogabine)	Tablet	GlaxoSmithKline (GSK)
Products susceptible to oxidation	None Identified	AbbVie
Progesterone	Oral and topical	Wulf Utian MB BCH, PhD, DSc(Med), FRCOG, FACOG, FICS
Progesterone with estradiol	Oral and topical	Wulf Utian MB BCH, PhD, DSc(Med), FRCOG, FACOG, FICS
Promacta® (eltrombopag olamine)	Tablet	GlaxoSmithKline (GSK)
Relenza® (zanamivir)	Inhalation Powder	GlaxoSmithKline (GSK)
Requip XL® (ropinirole hydrochloride)	ER Tablet	GlaxoSmithKline (GSK)
Rythmol SR® (propafenone hydrochloride)	ER Capsule	GlaxoSmithKline (GSK)
Serevent® Diskus® (salmeterol xinafoate)	Inhalation Powder	GlaxoSmithKline (GSK)
Soriatane® (acitretin)	Capsules	GlaxoSmithKline (GSK)
Sterile drugs	Injectable	AbbVie
Sterile products for ophthalmic use	None Identified	FaegreBD Consulting
Sustained or time-release dosage forms (non-exempt under 503A and 503B)	None Identified	Public Citizen's Health Research Group
Tafinlar® (dabrafenib mesylate)	Capsules	GlaxoSmithKline (GSK)
Tecfidera® (dimethyl fumarate)	ER Capsule	Biogen Idec
Testosterone	Pellets	Abraham Morgentaler; Auxilium Pharmaceuticals; Men's Health Network
Transdermal Delivery Systems (TDSs) (non-exempt under 503A and 503B)	Transdermal	Public Citizen
Veltin® (clindamycin phosphate and tretinoin)	Gel	GlaxoSmithKline (GSK)
Ventolin® HFA (albuterol sulfate)	Inhalation Aerosol	GlaxoSmithKline (GSK)
Veramyst® (fluticasone furoate)	Nasal Spray	GlaxoSmithKline (GSK)
Votrient® (pazopanib)	Tablets	GlaxoSmithKline (GSK)

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Wellbutrin® SR (bupropion hydrochloride)	SR Tablet	GlaxoSmithKline (GSK)
Zyban® (bupropion hydrochloride)	SR Tablet	GlaxoSmithKline (GSK)

DPI = Dry Powder Inhaler

ER = Extended Release

MR = Modified Release

SR = Sustained Release

* product nominations have been edited for spelling as
identified by Drugs@FDA