



PRESCRIPTION DRUGS AND BIOLOGICS

2025 FDA ADVERTISING & PROMOTION ENFORCEMENT LETTERS

Date (Hyperlink to Letter)	Letter Type	Drug Name	Therapeutic Area / Indication	Boxed Warning Present? (Y/N)	Promotional Material (Hyperlink where available)	Target Audience	Alleged Violation Type
02/03/2025	UL	HEMADY (dexamethasone tablets)	Multiple Myeloma (MM)	N	Exhibit booth panel	Professional	<p>Unsubstantiated Efficacy Claims (unsubstantiated superiority)</p> <p>Omission of Risk Information (complete omission)</p>
03/21/2025	UL	LYTGOBI (futibatinib)	intrahepatic Cholangiocarcinoma (iCCA)	N	Webpage	Professional	<p>Unsubstantiated Efficacy Claims (time-to-event efficacy endpoints that could not be established through a single-arm trial)</p>
04/25/2025	WL	SOAANZ (torsemide)	Edema associated with heart failure or renal disease	N	Webpages, pamphlet, exhibit booth panel	Professional	<p>Unsubstantiated Efficacy Claims (unsubstantiated superiority)</p> <p>Omission of Risk Information (complete omission of risk information in exhibit panel)</p> <p>Minimization of Risk Information (minimization of specific risks on webpages)</p> <p>Omission of Material Facts (omission of full indication)</p> <p>Failure to Submit Form FDA-2253</p>

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04/28/2025	UL	NEXTSTELLIS (drospirenone and estetrol tablets)	Contraception	Y	Speaker slide deck with speaker notes	Professional	<p>Misleading Presentation of Risk (unsubstantiated comparative safety claim)</p> <p>Minimization of Risk Information</p> <p>Omission of Risk Information (omission of material information regarding specific risks)</p>
05/29/2025	WL	ADDYI (flibanserin)	Acquired hypoactive sexual desire disorder (HSDD)	Y	Social media (Instagram) post by CEO	Consumer	<p>Omission of Risk Information (complete omission of risk information)</p> <p>Omission of Material Facts (omission of information from the indication and limitations of use)</p> <p>Failure to Submit Form FDA-2253</p>
09/09/2025	UL	LINZESS (linaclotide)	Irritable bowel syndrome with constipation (IBS-C); chronic constipation; functional constipation	Y	DTC TV ad	Consumer	<p>Minimization of Risk Information (frequent scene changes and compelling and attention-grabbing visuals during the presentation of the major statement)</p>

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09/09/2025	UL	QULIPTA (atogepant)	Migraines	N	DTC TV ad	Consumer	<p>Unsubstantiated Efficacy Claims (claims implying complete migraine prevention)</p> <p>Minimization of Risk Information (frequent scene changes and compelling and attention-grabbing visuals during the presentation of the major statement)</p>
09/09/2025	UL	ULTOMIRIS (ravulizumab-cwvz)	Generalized myasthenia gravis (gMG)	Y	DTC TV ad	Consumer	<p>Unsubstantiated Efficacy Claims (claims suggesting continuous symptom control)</p> <p>Minimization of Risk Information (frequent scene changes and compelling and attention-grabbing visuals during the presentation of the major statement)</p>
09/09/2025	UL	AMVUTTRA (vutrisiran)	Cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM)	N	DTC TV ad	Consumer	<p>Unsubstantiated Efficacy Claims (overstatement of efficacy -onset of effect and quality of life (QOL) claims)</p>
09/09/2025	WL	RELEXXII (methylphenidate hydrochloride extended-release tablets)	ADHD	Y	Sponsored links	Consumer	<p>Omission of Risk Information (complete omission of risk information)</p>

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09/09/2025	UL	NEFFY (epinephrine nasal spray)	Allergic reactions (anaphylaxis)	N	DTC TV Ad	Consumer	Unsubstantiated Efficacy Claims (overstatement of efficacy - claims implying complete resolution of concerns over allergic reactions and needle use)
09/09/2025	UL	CALQUENCE (acalabrutinib)	Chronic lymphocytic leukemia	N	DTC TV Ad	Consumer	Minimization of Risk Information (active lifestyle depicted in the ad downplays the drug's serious side effects) Minimization of Risk Information (compelling and attention-grabbing visuals during the presentation of the major statement)
09/09/2025	UL	FASENRA (benralizumab)	Asthma	N	DTC TV Ad 1	Consumer	Unsubstantiated Efficacy Claims (quality of life (QOL) claims) Minimization of Risk Information (major statement fails to meet dual modality standard)
09/09/2025	UL	FASENRA (benralizumab)	Asthma	N	DTC TV Ad 2	Consumer	Unsubstantiated Efficacy Claims (overstatement of efficacy) Unsubstantiated Efficacy Claim (quality of life (QOL) claims) Minimization of Risk Information (major statement fails to meet dual modality standard)

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09/09/2025	UL	FASENRA (benralizumab)	Asthma	N	DTC TV Ad 3	Consumer	<p>Unsubstantiated Efficacy Claims (quality of life (QOL) claims)</p> <p>Minimization of Risk Information (major statement fails to meet dual modality standard)</p> <p>Minimization of Risk Information (competing and attention-grabbing visuals and music during the presentation of the major statement)</p>
09/09/2025	UL ¹	FLUMIST	Influenza	N	DTC TV Ad	Consumer	<p>Minimization of Risk Information (competing and attention-grabbing visuals and music during the presentation of the major statement)</p> <p>Minimization of Risk Information (presentation of the major statement on-screen SUPERS)</p> <p>Otherwise Misleading (imagery misleadingly suggests minors can order and self-administer FLUMIST)</p>
09/09/2025	UL	TRUQAP (capiwasertib)	HR-positive, HER2-negative, locally advanced or metastatic breast cancer	N	DTC TV Ad	Consumer	<p>Minimization of Risk Information (frequent scene changes and compelling and attention-grabbing visuals during the presentation of the major statement)</p>

¹ Untitled Letter issued by CBER's Advertising and Promotion Labeling Branch (APLB).

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09/09/2025	UL	AUVELITY (dextromethorphan hydrobromide and bupropion hydrochloride)	Major Depressive Disorder (MDD)	Y	DTC Print Ad	Consumer	Unsubstantiated Efficacy Claims (specific symptom improvement)
09/09/2025	WL	ADZENYS XR-ODT (amphetamine)	ADHD	Y	Sponsored links	Consumer	Omission of Risk Information (complete omission of risk information) Failure to Use Required Established Name Failure to Submit Form FDA-2253
09/09/2025	WL	Cotempla XR-ODT (methylphenidate extended-release orally disintegrating tablets)	ADHD	Y	Sponsored links	Consumer	Misleading Efficacy Claims (claims suggesting therapeutic equivalence to another treatment) Omission of Risk Information (complete omission of risk information) Failure to Submit Form FDA-2253
09/09/2025	UL	FYARRO (sirolimus protein-bound particles for injectable suspension)	Locally advanced or metastatic malignant perivascular epithelioid cell tumor (PEComa)	N	Webpage	Professional	Unsubstantiated Efficacy Claims (time-to-event efficacy endpoints could not be established through a single-arm trial)

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09/09/2025	UL	JUBLIA (efinaconazole)	Onychomycosis (toenail fungus)	N	DTC TV Ad	Consumer	Unsubstantiated Efficacy Claims (overstatement of efficacy - claims of complete resolution and immediate treatment results)
09/09/2025	UL	JARDIANCE (empagliflozin tablets)	Type 2 diabetes	N	DTC TV AD 1	Consumer	<p>Minimization of Indication Statement and Limitations of Use (compelling and attention-grabbing visuals, frequent scene changes, and music during presentation of the indication and limitations of use)</p> <p>Minimization of Risk Information (compelling and attention-grabbing visuals and frequent scene changes during the presentation of the major statement)</p> <p>Minimization of Risk Information (presentation of the major statement on-screen SUPERS)</p>

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9/9/2025	UL	JARDIANCE (empagliflozin tablets)	Type 2 diabetes	N	DTC TV Ad 2	Consumer	<p>Minimization of Indication Statement and Limitations of Use (compelling and attention-grabbing visuals, frequent scene changes, and music during presentation of the indication and limitations of use)</p> <p>Minimization of Risk Information (compelling and attention-grabbing visuals and frequent scene changes during the presentation of the major statement)</p> <p>Minimization of Risk Information (presentation of the major statement on-screen SUPERS)</p>
09/09/2025	UL	JARDIANCE (empagliflozin tablets)	Type 2 diabetes	N	DTC TV Ad 3	Consumer	<p>Minimization of Indication Statement and Limitations of Use (compelling and attention-grabbing visuals, frequent scene changes, and music during presentation of the indication and limitations of use)</p> <p>Minimization of Risk Information (compelling and attention-grabbing visuals and frequent scene changes during the presentation of the major statement)</p> <p>Minimization of Risk Information (presentation of the major statement on-screen SUPERS)</p>

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09/09/2025	UL	ATTRUBY (acoramidis)	Cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM)	N	DTC TV Ad	Consumer	Unsubstantiated Efficacy Claims (quality of life (QOL) claims)
09/09/2025	UL	CAMZYOS (mavacamten)	Obstructive hypertrophic cardiomyopathy (HCM)	Y	DTC TV Ad	Consumer	<p>Unsubstantiated Efficacy Claims (overstatement of efficacy and unsubstantiated quality of Life (QOL) claims)</p> <p>Misleading Efficacy Claims (mechanism of action)</p> <p>Omission of Risk Information (omission of material information from the major statement)</p> <p>Minimization of Risk Information (compelling and attention-grabbing visuals and frequent scene changes during the presentation of the major statement)</p> <p>Minimization of Risk Information (presentation of the major statement on-screen SUPERS)</p>

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09/09/2025	UL	OPDIVO QVANTIG (nivolumab and hyaluronidase-nvhy)	Renal Cancer	N	DTC TV Ad	Consumer	<p>Unsubstantiated Efficacy Claims (overstatement of efficacy)</p> <p>Minimization of Risk Information (attention-grabbing visuals and frequent scene changes during the presentation of the major statement)</p>
09/09/2025	UL	OPDIVO (nivolumab); YERVOY (ipilimumab)	Non-Small Cell Lung Cancer	N	DTC TV Ad	Consumer	<p>Unsubstantiated Efficacy Claims (overstatement of efficacy and unsubstantiated quality of life (QOL) claims)</p> <p>Minimization of Risk Information (attention-grabbing visuals and frequent scene changes during the presentation of the major statement)</p>
09/09/2025	WL ²	HIZENTRA (Immune Globulin Subcutaneous (Human))	Primary immunodeficiency	Y	DTC TV Ad	Consumer	<p>Unsubstantiated Efficacy Claims (overstatement of efficacy)</p> <p>Minimization of Risk Information (attention-grabbing visuals and frequent scene changes during the presentation of the major statement)</p> <p>Minimization of Risk Information (presentation of the major statement on-screen SUPERS)</p>

² Warning Letter issued by CBER's Advertising and Promotion Labeling Branch (APLB).

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09/09/2025	UL	SKYRIZI (risankizumab-rzaa)	Crohn's disease	N	Webpage	Professional	Unsubstantiated Efficacy Claims (unsubstantiated superiority)
9/9/2025	WL	ZEPBOUND (tirzepatide)	Obesity / Overweight	Y	Promotional video (Dayton 24/7 Now)	Consumer	Omission of Risk Information (complete omission of risk information) Omission of Material Facts (omission of limitations of use) Failure to Submit FDA Form-2253
09/09/2025	WL	ZEPBOUND (tirzepatide)	Obesity / Overweight	Y	Promotional video interview (OKC Fox 25)	Consumer	Omission of Risk Information (complete omission of risk information) Omission of Material Facts (omission of limitations of use) Failure to Submit FDA Form-2253
09/09/2025	WL	ZEPBOUND (tirzepatide); MOUNJARO (tirzepatide)	Obesity / Overweight	Y	Promotional video interview (Oprah special)	Consumer	Omission of Risk Information (omission of specific risks) Minimization of Risk (statements minimizing risks; lack of fair balance) Failure to Submit FDA Form-2253

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09/09/2025	UL	ANKTIVA (nogapendekin alfa inbakicept-pmln)	Bladder cancer	N	Webpage	Professional	Unsubstantiated Efficacy Claims (time-to-event efficacy endpoints could not be established through a single-arm trial)
09/09/2025	UL	NEMLUVIO (nemolizumab-ilto)	Moderate-to-severe eczema (atopic dermatitis)	N	DTC TV Ad	Consumer	Omission of Material Facts (omission of information from the indication) Misleading Efficacy Claims (claims misleadingly suggest use as a single agent; overstatement of efficacy)
09/09/2025	UL	IMDELLTRA (tarlatamab-dlle)	Extensive stage small cell lung cancer (ES-SCLC)	Y	Webpage	Professional	Unsubstantiated Efficacy Claims (efficacy endpoints could not be established through a single-arm trial)
09/09/2025	UL	DANZITEN (nilotinib)	Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML)	Y	Professional and DTC TV skin background and video	Consumer, Professional	Omission of Risk Information (omission of specific risks) Minimization of Risk Information (video fails to present risk information in order of severity) Omission of Material Fact (omission of information from the indication)

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09/09/2025	UL	JEUVEAU (prabotulinumtoxinA-xvfs)	Moderate to severe glabellar lines	Y	Newsletter	Professional	<p>Unsubstantiated Efficacy Claims (unsubstantiated superiority claims regarding benefits of manufacturing and formulation)</p> <p>Minimization of Risk</p>
09/09/2025	UL	CONTRAVE (naltrexone hydrochloride and bupropion hydrochloride)	Obesity / Overweight	Y	DTC TV Ad	Consumer	<p>Misleading Efficacy Claims (mechanism of action)</p> <p>Omission of Risk Information (omission of specific risks from the major statement)</p>
09/09/2025	UL	INGREZZA (valbenazine)	Tardive dyskinesia (TD)	Y	DTC TV Ad	Consumer	<p>Unsubstantiated Efficacy Claims (overstatement of efficacy)</p> <p>Misleading Efficacy Claims (claims regarding onset of action and patient satisfaction)</p>
09/09/2025	UL	KESIMPTA (ofatumumab)	Relapsing forms of multiple sclerosis	N	DTC TV Ad	Consumer	<p>Misleading Claims (misleading claims regarding administration time and process)</p> <p>Minimization of Risk Information (attention-grabbing visuals during the presentation of the major statement)</p>

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9/9/2025	UL	KISQALI (ribociclib)	HR-positive, HER2-negative metastatic breast cancer	N	DTC TV Ad	Consumer	<p>Unsubstantiated Efficacy Claims (exploratory analysis of overall survival data)</p> <p>Misleading Efficacy Claims (material information and limitations presented at high speed and with competing modalities)</p>
09/09/2025	UL	PLUVICTO (lutetium Lu 177 vipivotide tetraxetan)	Prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC)	N	DTC TV Ad	Consumer	<p>Unsubstantiated Efficacy Claims (overstatement of efficacy)</p> <p>Omission of Material Fact (omission of information from the indication)</p> <p>Minimization of Risk (attention-grabbing visuals and frequent scene changes during the presentation of the major statement)</p>
09/09/2025	WL	WEGOVY (semaglutide) OZEMPIC (semaglutide) VICTOZA (liraglutide)	Obesity / Overweight	Y	Promotional video interview (Oprah special)	Consumer	<p>Omission of Risk Information (omission of specific risks)</p> <p>Minimization of Risk (statements minimizing risks; lack of fair balance)</p> <p>Failure to Submit FDA Form-2253</p>

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09/09/2025	UL	VELSIPITY (etrasimod)	Ulcerative colitis (UC)	N	DTC TV Ad	Consumer	Unsubstantiated Efficacy Claims (overstatement of efficacy) Minimization of Risk (attention-grabbing visuals during the presentation of the major statement)
09/09/2025	UL	VOQUEZNA (vonoprazan)	Gastroesophageal Reflux Disease (GERD)	N	DTC video interview (<i>The Culture Shift</i> and YouTube)	Consumer	Omission of Risk Information (complete omission of risk information)
09/09/2025	UL	VOQUEZNA (vonoprazan)	GERD	N	DTC video interview (<i>The Dan Le Batard Show with Stugotz</i> and YouTube)	Consumer	Omission of Risk Information (complete omission of risk information)
09/09/2025	UL	VOQUEZNA (vonoprazan)	GERD	N	DTC video interview (<i>Rolling Out</i> and YouTube)	Consumer	Omission of Risk Information (complete omission of risk information)

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09/09/2025	UL	PEMAZYRE (pemigatinib)	Locally advanced or metastatic cholangiocarcinoma; relapsed or refractory myeloid/ lymphoid neoplasms	N	Sales Aid	Professional	Unsubstantiated Efficacy Claims (single-arm study not capable of supporting cited endpoints)
09/09/2025	UL	TAZVERIK (tazemetostat)	Follicular lymphoma	N	Webpage	Professional	Unsubstantiated Efficacy Claims (single-arm study not capable of supporting cited endpoints)
09/09/2025	UL	TZIELD (teplizumab-mzwv)	Type 1 diabetes	N	DTC TV Ad	Consumer	Unsubstantiated Efficacy Claims (quality of life (QOL) claims) Minimization of Risk (compelling and attention-grabbing visuals and frequent scene changes during the presentation of the major statement)
09/09/2025	UL	PHOTOFRIN (porfimer sodium)	Esophageal cancer	N	Tradeshaw booth exhibit panel	Professional	Omission of Risk Information (complete omission of risk information)

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09/09/2025	UL	QELBREE (viloxazine extended-release capsules)	ADHD	Y	DTC TV Ad 1	Consumer	<p>Unsubstantiated Efficacy Claims (overstatement of efficacy - implied claims of complete resolution of symptoms)</p> <p>Minimization of Risks (frequent scene changes during the presentation of the major statement; happy, smiling people during the presentation of serious risks)</p>
09/09/2025	UL	QELBREE (viloxazine extended-release capsules)	ADHD	Y	DTC TV Ad 2	Consumer	<p>Unsubstantiated Efficacy Claims (overstatement of efficacy - implied claims of complete resolution of symptoms)</p> <p>Minimization of Risks (frequent scene changes during the presentation of the major statement; happy, smiling people during the presentation of serious risks)</p>
09/09/2025	UL	PHOTOFRIN (porfimer sodium)	Non-small-cell lung cancer (NSCLC)	N	Tradeshaw booth exhibit panel	Professional	Omission of Risk Information (complete omission of risk information)
09/09/2025	UL	ICLUSIG (ponatinib)	Chronic myeloid leukemia (CML)	Y	Webpage	Professional	Unsubstantiated Efficacy Claims (single-arm study not capable of supporting cited endpoints)

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09/09/2025	UL	FRUZAQLA (fruquintinib)	Metastatic colorectal cancer (mCRC)	N	DTC TV Ad	Consumer	Omission of Risk Information (omission of specific risk) Minimization of Risk Information (attention-grabbing visuals during the presentation of the major statement)
09/09/2025	UL	FRUZAQLA (fruquintinib)	Metastatic colorectal cancer (mCRC)	N	Webpage	Consumer	Unsubstantiated Efficacy Claims (quality of life (QOL) claims)
09/09/2025	UL	AUSTEDO XR (deutetrabenazine)	Tardive dyskinesia	Y	DTC TV Ads	Consumer	Unsubstantiated Efficacy Claims (overstatement of efficacy - implied claims of complete resolution of symptoms)
09/09/2025	UL	AUSTEDO XR (deutetrabenazine)	Tardive dyskinesia	Y	DTC TV Ad	Consumer	Unsubstantiated Efficacy Claims (overstatement of efficacy - implied claims of complete resolution of symptoms)
09/09/2025	UL	BIMZELX (bimekizumab-bkzx)	Hidradenitis suppurativa	N	DTC TV Ad	Consumer	Unsubstantiated Efficacy Claims (quality of life (QOL) claims) Minimization of Risk Information (attention-grabbing visuals and frequent scene changes during the presentation of the major statement)

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09/09/2025	UL	BIMZELX (bimekizumab-bkzx)	Plaque psoriasis	N	DTC TV Ad	Consumer	<p>Unsubstantiated Efficacy Claims (quality of life (QOL) claims)</p> <p>Minimization of Risk Information (attention-grabbing visuals and frequent scene changes during the presentation of the major statement)</p>
09/09/2025	UL	BIMZELX (bimekizumab-bkzx)	Psoriatic arthritis	N	DTC TV Ad	Consumer	<p>Unsubstantiated Efficacy Claims (quality of life (QOL) claims; claims overstating symptom resolution)</p>
09/09/2025	UL	RYSTIGGO (rozanolixizumab-noli)	Generalized myasthenia gravis (gMG)	N	Webpages	Professional	<p>Unsubstantiated Efficacy Claims (overstatement of efficacy - implied claims of rapid and near-complete resolution of symptoms)</p>
09/09/2025	UL	APRETUDE (cabotegravir extended-release injectable suspension)	HIV Pre-exposure prophylaxis (PrEP)	Y	DTC TV Ad	Consumer	<p>Minimization of Risk Information (claims and sexually suggestive images create a misleading impression regarding the risk of sexually transmitted infections (STIs))</p> <p>Minimization of Risk Information (frequent scene changes and attention-grabbing visuals during the presentation of the major statement)</p>

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09/23/2025	UL	FABHALTA (iptacopan)	Paroxysmal nocturnal hemoglobinuria	Y	DTC TV Ad	Consumer	<p>Misleading Efficacy Claims (material information and limitations presented at high speed and with competing modalities)</p> <p>Minimization of Risk Information (compelling and attention-grabbing visuals, frequent scene changes, and music during the presentation of the major statement)</p>
09/23/2025	UL	FARXIGA (dapagliflozin)	Chronic kidney disease; heart failure	N	DTC TV Ad	Consumer	Omission of Material Information (failure to communicate material information from the indication)
09/30/2025	UL	KETAMINE HYDROCHLORIDE	Anesthesia	N	Corporate Website	Consumer	<p>Omission of Risk Information (complete omission of risk information)</p> <p>Omission of Material Information (omission of material information from the indication)</p> <p>Failure to Submit FDA Form-2253</p>
9/30/2025	UL	XCOPRI (cenobamate tablets)	Seizures	N	DTC TV Ad	Consumer	<p>Omission of Risk Information (omission of specific risks from the major statement)</p> <p>Minimization of Risk Information (major statement fails to meet dual modality standard)</p>

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11/24/2025	UL	TURALIO (pexidartinib)	Tenosynovial giant cell tumor (TGCT)	Y	Patient Testimonial Video	Consumer	Unsubstantiated Efficacy Claims (overstatement of efficacy - implied claims of complete resolution of symptoms; quality of life (QOL) claims)
12/15/2025	UL	COBENFY (xanomeline and trospium chloride)	Schizophrenia	N	DTC TV Ad	Consumer	Unsubstantiated Efficacy Claims Misleading Efficacy Claims (misleading statements regarding the drug class) Minimization of Risk Information (compelling and attention-grabbing visuals during the presentation of the major statement)
12/17/2025	UL	TEVIMBRA (tislelizumab-jsgr)	Esophageal cancer; gastric cancer; gastroesophageal junction cancer	N	Branded Microsoft Teams Backgrounds	Consumer	Omission of Material Information (omission of material information from the indication) Omission of Risk Information (complete omission of risk information)
12/19/2025	UL	NEXLIZET (bempedoic acid and ezetimibe)	Heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease	N	DTC TV Ad	Consumer	Misleading Efficacy Claim (misleading “only” claim) Minimization of Risk Information (compelling and attention-grabbing visuals during the presentation of the major statement)