

## FDA Citizen Petitions requesting A rating for 505(b)(2) drugs

Docket ID	CP post date	Drug	Route of administration	Drug class	NDA Number	505(b)(2) approval date	Rating requested
FDA-2017-P-3329	2017-05-30	Voriconazole for injection	Intravenous	Antifungal	208562	2017-03-09	AP
FDA-2018-P-1197	2018-03-20	Palonosetron hydrochloride injection	Intravenous	Antiemetic	207963	2016-08-22	AP
FDA-2018-P-3176	2018-08-16	Sodium chloride injection in a plastic syringe	Intravenous, intramuscular, subcutaneous	Fluids, Electrolytes	202832	2012-01-06	AP
FDA-2018-P-3666	2018-09-27	Indomethacin injection	Intravenous	Anti-Inflammatory	22536	2010-03-17	AP
FDA-2018-P-4664	2018-12-10	Palonosetron hydrochloride injection	Intravenous	Antiemetic	208109	2017-11-21	AP
FDA-2019-P-1560	2019-04-03	Vancomycin injection	Intravenous	Antibacterial	211962	2019-02-15	AP
FDA-2019-P-1678	2019-04-08	Glycopyrrolate injection	Intravenous, intramuscular	Anticholinergic	210997	2018-07-11	AP
FDA-2019-P-2590	2019-05-29	Fulvestrant injection	Intramuscular	Antineoplastic	210326	2019-05-20	AP
FDA-2019-P-2687	2019-06-04	Argatroban in sodium chloride injection	Intravenous	Anticoagulant	209552	2018-11-27	AP
FDA-2019-P-3937	2019-08-21	Fulvestrant injection	Intramuscular	Antineoplastic	210063	2019-08-29	AO
FDA-2019-P-4155	2019-09-06	Fosaprepitant dimeglumine injection	Intravenous	Antiemetic	210064	2019-09-05	AP
FDA-2019-P-4962	2019-10-24	Glucagon injection	Intravenous, intramuscular, subcutaneous	Hypoglycemic	201849	2015-05-08	AP
FDA-2020-P-1066	2020-03-13	Cefazolin and dextrose	Intravenous	Antibiotic	50779	2000-07-27	AP
FDA-2020-P-1067	2020-03-14	Cefepime and dextrose in duplex container	Intravenous	Antibiotic	50821	2010-05-06	AP
FDA-2020-P-1068	2020-03-15	Cefotetan and dextrose in duplex container	Intravenous	Antibiotic	65430	2007-08-09	AP
FDA-2020-P-1069	2020-03-16	Ceftazidime in dextrose container	Intravenous	Antibiotic	50823	2011-06-13	AP
FDA-2020-P-1070	2020-03-17	Meropenem and sodium chloride in duplex container	Intravenous	Antibiotic	202106	2015-04-30	AP
FDA-2020-P-1071	2020-03-18	Sodium chloride	Intravenous	Fluids, Electrolytes	19635	1988-03-09	AP
FDA-2020-P-1246	2020-04-03	Acetaminophen injection	Intravenous	Analgesic	204767	2015-10-28	AP
FDA-2021-P-0278	2021-03-10	Acetaminophen injection	Intravenous	Analgesic	204957	2021-02-18	AB

Source: Data on Citizen Petitions pulled from regulations.gov. Drug characteristics and approval dates are pulled from the Drugs@FDA database. Indications come from First Databank.

Note: Full Citizen Petitions and responses can be found by searching the docket numbers at [regulations.gov](https://www.regulations.gov). Detailed drug information can be found by searching NDA numbers at [www.accessdata.fda.gov/scripts/cder/daf/index.cfm](https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm).

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FDA-2021-P-0308	2021-03-19	Nicardipine hydrochloride injection	Intravenous	Antihypertensive	22276	2008-07-24	AP
FDA-2022-P-0287	2022-03-04	Neostigmine methylsulfate injection	Intravenous	Antimyasthenic, cholinergic	203629	2015-01-08	AB
FDA-2022-P-0290	2022-03-04	Calcium gluconate in sodium chloride injection	Intravenous	Calcium	208418	2017-06-15	AP
FDA-2022-P-0329	2022-03-14	Lanreotide acetate	Subcutaneous	Somatostatin	215395	2021-12-17	AP
FDA-2022-P-1656	2022-07-22	Glycopyrrolate injection	Intravenous, intramuscular	Anticholinergic	214919	2022-04-21	AP
FDA-2022-P-2075	2022-08-31	Paclitaxel protein-bound particles for injectable suspension	Intravenous	Antineoplastic	211875	2022-07-27	AP
FDA-2022-P-2498	2022-10-12	Argatroban in sodium chloride injection	Intravenous	Anticoagulant	209552	2018-11-27	AP

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