

CIVIL COVER SHEET

JS-44 (Rev. 11/2020 DC)

I. (a) PLAINTIFFS REED SMITH LLP DEFENDANTS FOOD AND DRUG ADMINISTRATION (b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF 88888 (EXCEPT IN U.S. PLAINTIFF CASES) COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRMNAME, ADDRESS, AND TELEPHONE NUMBER) James F. Segroves, Reed Smith LLP 1301 K Street, NW, Suite 1000 - East Tower Washington, DC 20005 202.414.9294; jsegroves@reedsmith.com ATTORNEYS (IF KNOWN) Unknown

II. BASIS OF JURISDICTION (PLACE AN X IN ONE BOX ONLY) 1 U.S. Government Plaintiff 2 U.S. Government Defendant 3 Federal Question (U.S. Government Not a Party) 4 Diversity (Indicate Citizenship of Parties in item III) III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN X IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) FOR DIVERSITY CASES ONLY! PTF DFT PTF DFT Citizen of this State 1 1 Incorporated or Principal Place of Business in This State 4 4 Citizen of Another State 2 2 Incorporated and Principal Place of Business in Another State 5 5 Citizen or Subject of a Foreign Country 3 3 Foreign Nation 6 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT (Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

A. Antitrust 410 Antitrust B. Personal Injury/Malpractice 310 Airplane 315 Airplane Product Liability 320 Assault, Libel & Slander 330 Federal Employers Liability 340 Marine 345 Marine Product Liability 350 Motor Vehicle 355 Motor Vehicle Product Liability 360 Other Personal Injury 362 Medical Malpractice 365 Product Liability 367 Health Care/Pharmaceutical Personal Injury Product Liability 368 Asbestos Product Liability C. Administrative Agency Review 151 Medicare Act Social Security 861 HIA (1395ff) 862 Black Lung (923) 863 DIWC/DIWW (405(g)) 864 SSID Title XVI 865 RSI (405(g)) Other Statutes 891 Agricultural Acts 893 Environmental Matters 890 Other Statutory Actions (If Administrative Agency is Involved) D. Temporary Restraining Order/Preliminary Injunction Any nature of suit from any category may be selected for this category of case assignment. *(If Antitrust, then A governs)*

E. General Civil (Other) OR F. Pro Se General Civil Real Property 210 Land Condemnation 220 Foreclosure 230 Rent, Lease & Ejectment 240 Torts to Land 245 Tort Product Liability 290 All Other Real Property Personal Property 370 Other Fraud 371 Truth in Lending 380 Other Personal Property Damage 385 Property Damage Product Liability Bankruptcy 422 Appeal 27 USC 158 423 Withdrawal 28 USC 157 Prisoner Petitions 535 Death Penalty 540 Mandamus & Other 550 Civil Rights 555 Prison Conditions 560 Civil Detainee - Conditions of Confinement Property Rights 820 Copyrights 830 Patent 835 Patent - Abbreviated New Drug Application 840 Trademark 880 Defend Trade Secrets Act of 2016 (DTSA) Federal Tax Suits 870 Taxes (US plaintiff or defendant) 871 IRS-Third Party 26 USC 7609 Forfeiture/Penalty 625 Drug Related Seizure of Property 21 USC 881 690 Other Other Statutes 375 False Claims Act 376 Qui Tam (31 USC 3729(a)) 400 State Reapportionment 430 Banks & Banking 450 Commerce/ICC Rates/etc 460 Deportation 462 Naturalization Application 465 Other Immigration Actions 470 Racketeer Influenced & Corrupt Organization 480 Consumer Credit 485 Telephone Consumer Protection Act (TCPA) 490 Cable/Satellite TV 850 Securities/Commodities/Exchange 896 Arbitration 899 Administrative Procedure Act/Review or Appeal of Agency Decision 950 Constitutionality of State Statutes 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

<input type="radio"/> G. Habeas Corpus/ 2255 <input type="checkbox"/> 530 Habeas Corpus – General <input type="checkbox"/> 510 Motion/Vacate Sentence <input type="checkbox"/> 463 Habeas Corpus – Alien Detainee	<input type="radio"/> H. Employment Discrimination <input type="checkbox"/> 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	<input checked="" type="radio"/> I. FOIA/Privacy Act <input checked="" type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	<input type="radio"/> J. Student Loan <input type="checkbox"/> 152 Recovery of Defaulted Student Loan (excluding veterans)
<input type="radio"/> K. Labor/ERISA (non-employment) <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 740 Labor Railway Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	<input type="radio"/> L. Other Civil Rights (non-employment) <input type="checkbox"/> 441 Voting (if not Voting Rights Act) <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 445 Americans w/Disabilities – Employment <input type="checkbox"/> 446 Americans w/Disabilities – Other <input type="checkbox"/> 448 Education	<input type="radio"/> M. Contract <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 153 Recovery of Overpayment of Veteran’s Benefits <input type="checkbox"/> 160 Stockholder’s Suits <input type="checkbox"/> 190 Other Contracts <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<input type="radio"/> N. Three-Judge Court <input type="checkbox"/> 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN
 1 Original Proceeding
 2 Removed from State Court
 3 Remanded from Appellate Court
 4 Reinstated or Reopened
 5 Transferred from another district (specify)
 6 Multi-district Litigation
 7 Appeal to District Judge from Mag. Judge
 8 Multi-district Litigation – Direct File

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)
 Action seeking disclosure of agency records under the Freedom of Information Act, 5 U.S.C. § 552.

VII. REQUESTED IN COMPLAINT	<input type="checkbox"/> CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23	DEMAND \$ _____	JURY DEMAND: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>
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VIII. RELATED CASE(S) IF ANY	(See instruction)	YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	If yes, please complete related case form
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DATE: January 4, 2022	SIGNATURE OF ATTORNEY OF RECORD: /s/ James F. Segroves
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INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
 Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil coversheet. These tips coincide with the Roman Numerals on the cover sheet.

- I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.
- III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.
- IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.
- VI. CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.
- VIII. RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk’s Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.