

CIVIL COVER SHEET

JS-44 (Rev. 11/2020 DC)

<b>I. (a) PLAINTIFFS</b> Vanda Pharmaceuticals Inc.	<b>DEFENDANTS</b> Food and Drug Administration
(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF <u>11001</u> (EXCEPT IN U.S. PLAINTIFF CASES)	COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____ (IN U.S. PLAINTIFF CASES ONLY) <small>NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED</small>
(c) ATTORNEYS (FIRMNAME, ADDRESS, AND TELEPHONE NUMBER) Paul W. Hughes McDermott Will & Emery LLP 500 North Capitol St NW, Washington, DC 20001 202-756-8000	ATTORNEYS (IF KNOWN)

<b>II. BASIS OF JURISDICTION</b> (PLACE AN x IN ONE BOX ONLY)	<b>III. CITIZENSHIP OF PRINCIPAL PARTIES</b> (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) <b>FOR DIVERSITY CASES ONLY!</b>																								
<input type="radio"/> 1 U.S. Government Plaintiff <input checked="" type="radio"/> 2 U.S. Government Defendant <input type="radio"/> 3 Federal Question (U.S. Government Not a Party) <input type="radio"/> 4 Diversity (Indicate Citizenship of Parties in item III)	<table style="width:100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">PTF</th> <th style="text-align: center;">DFT</th> <th></th> <th style="text-align: center;">PTF</th> <th style="text-align: center;">DFT</th> </tr> </thead> <tbody> <tr> <td>Citizen of this State</td> <td style="text-align: center;"><input type="radio"/> 1</td> <td style="text-align: center;"><input type="radio"/> 1</td> <td>Incorporated or Principal Place of Business in This State</td> <td style="text-align: center;"><input type="radio"/> 4</td> <td style="text-align: center;"><input type="radio"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td style="text-align: center;"><input type="radio"/> 2</td> <td style="text-align: center;"><input type="radio"/> 2</td> <td>Incorporated and Principal Place of Business in Another State</td> <td style="text-align: center;"><input type="radio"/> 5</td> <td style="text-align: center;"><input type="radio"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td style="text-align: center;"><input type="radio"/> 3</td> <td style="text-align: center;"><input type="radio"/> 3</td> <td>Foreign Nation</td> <td style="text-align: center;"><input type="radio"/> 6</td> <td style="text-align: center;"><input type="radio"/> 6</td> </tr> </tbody> </table>		PTF	DFT		PTF	DFT	Citizen of this State	<input type="radio"/> 1	<input type="radio"/> 1	Incorporated or Principal Place of Business in This State	<input type="radio"/> 4	<input type="radio"/> 4	Citizen of Another State	<input type="radio"/> 2	<input type="radio"/> 2	Incorporated and Principal Place of Business in Another State	<input type="radio"/> 5	<input type="radio"/> 5	Citizen or Subject of a Foreign Country	<input type="radio"/> 3	<input type="radio"/> 3	Foreign Nation	<input type="radio"/> 6	<input type="radio"/> 6
	PTF	DFT		PTF	DFT																				
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Citizen or Subject of a Foreign Country	<input type="radio"/> 3	<input type="radio"/> 3	Foreign Nation	<input type="radio"/> 6	<input type="radio"/> 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)

<input type="radio"/> <b>A. Antitrust</b>  <input type="checkbox"/> 410 Antitrust	<input type="radio"/> <b>B. Personal Injury/Malpractice</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Medical Malpractice <input type="checkbox"/> 365 Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Product Liability	<input type="radio"/> <b>C. Administrative Agency Review</b>  <input type="checkbox"/> 151 Medicare Act  <u>Social Security</u> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <u>Other Statutes</u> <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 890 Other Statutory Actions (If Administrative Agency is Involved)	<input type="radio"/> <b>D. Temporary Restraining Order/Preliminary Injunction</b>  Any nature of suit from any category may be selected for this category of case assignment.  *(If Antitrust, then A governs)*
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<input type="radio"/> <b>E. General Civil (Other)</b>		OR	<input type="radio"/> <b>F. Pro Se General Civil</b>	
<u>Real Property</u> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent, Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property  <u>Personal Property</u> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<u>Bankruptcy</u> <input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157  <u>Prisoner Petitions</u> <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Conditions <input type="checkbox"/> 560 Civil Detainee – Conditions of Confinement  <u>Property Rights</u> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent – Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <input type="checkbox"/> 880 Defend Trade Secrets Act of 2016 (DTSA)	<u>Federal Tax Suits</u> <input type="checkbox"/> 870 Taxes (US plaintiff or defendant) <input type="checkbox"/> 871 IRS-Third Party 26 USC 7609  <u>Forfeiture/Penalty</u> <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other  <u>Other Statutes</u> <input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 430 Banks & Banking <input type="checkbox"/> 450 Commerce/ICC Rates/etc <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 462 Naturalization Application	<input type="checkbox"/> 465 Other Immigration Actions <input type="checkbox"/> 470 Racketeer Influenced & Corrupt Organization <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 485 Telephone Consumer Protection Act (TCPA) <input type="checkbox"/> 490 Cable/Satellite TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes <input type="checkbox"/> 890 Other Statutory Actions (if not administrative agency review or Privacy Act)	

<input type="radio"/> <b>G. Habeas Corpus/ 2255</b>  <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"/> <b>H. Employment Discrimination</b>  <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"/> <b>I. FOIA/Privacy Act</b>  <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"/> <b>J. Student Loan</b>  <input type="checkbox"/> 152 Recovery of Defaulted Student Loan (excluding veterans)
<input type="radio"/> <b>K. Labor/ERISA (non-employment)</b>  <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"/> <b>L. Other Civil Rights (non-employment)</b>  <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"/> <b>M. Contract</b>  <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"/> <b>N. Three-Judge Court</b>  <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.)**  
 Freedom of Information Act, 5 U.S.C. 552 - order the production of agency records improperly withheld

<b>VII. REQUESTED IN COMPLAINT</b>	<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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<b>VIII. RELATED CASE(S) IF ANY</b>	(See instruction)	YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	If yes, please complete related case form
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DATE: <u>2/6/2024</u>	SIGNATURE OF ATTORNEY OF RECORD <u>/s/ Paul W. Hughes</u>
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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.