IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA
WEST PALM BEACH DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

LGM PHARMA LLC, a limited liability company,

and

PRASAD RAJE and SHAILESH VENGURLEKAR, individuals,

Defendants.

COMPLAINT FOR PERMANENT INJUNCTION

The United States of America, Plaintiff, by and through its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act" or the "FDCA"), 21 U.S.C. § 332(a), to permanently enjoin and restrain LGM Pharma LLC ("LGM Pharma"), a limited liability company, and Prasad Raje and Shailesh Vengurlekar, individuals (collectively, "Defendants") from: (a) violating 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); and (b) violating 21 U.S.C. § 331(k) by causing articles of drug to become

adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this District is proper under 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant LGM Pharma is a Delaware limited liability company. LGM Pharma's corporate headquarters office is located in Boca Raton, Florida (the "Headquarters Facility"), within the jurisdiction of this Court.

5. LGM Pharma is engaged in the importation and distribution of drugs, including active pharmaceutical ingredients ("API"), manufactured primarily by companies operating outside the United States. API are used in the manufacture of finished drug products. LGM Pharma receives API at, and distributes API from, a facility located in Erlanger, Kentucky (the "Kentucky Facility").

6. Defendant Prasad S. Raje is the Chief Executive Officer of LGM Pharma and a part owner of the company. Defendant Raje is responsible for all aspects of the company's operations, including the LGM Pharma Kentucky Facility, capital decisions, employee hiring and firing, with input from human resources personnel, and senior management supervision. Defendant Raje participated in FDA's 2022 inspections of the Headquarters and Kentucky Facilities. FDA issued two Lists of Inspectional Observations ("FDA Form 483"), which detailed the FDA investigators' inspectional observations at the Kentucky and Headquarters Facilities, to Mr. Raje, as the most responsible person at the company.

7. Since May 2019, Defendant Shailesh Vengurlekar has been the Senior Vice President of Quality and Regulatory Affairs at LGM Pharma and has an ownership stake in the company. Mr. Vengurlekar reports directly to Mr. Raje and is responsible for the quality team overseeing LGM Pharma's API supply chain. He also has authority over hiring and firing decisions, with human resources input, as well as certain financial decisions, with senior leadership team input.

8. During their regular course of business, Defendants receive, hold, and distribute articles of drug, within the meaning of 21 U.S.C. § 321(g)(1), in interstate commerce, including thousands of API, imported from hundreds of suppliers located primarily outside the United States, and that are further distributed by LGM Pharma to its customers located throughout the United States.

DEFENDANTS UNLAWFULLY DISTRIBUTE ADULTERATED DRUGS

9. Products that are intended "for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" or "to affect the structure or any function of the body" in humans are drugs within the meaning of 21 U.S.C. § 321(g)(1)(B) and (C). In addition, "articles intended for use as a component of any article specified" in 21 U.S.C. § 321(g)(1)(B) and (C) are also drugs. 21 U.S.C. § 321(g)(1)(D).

10. The API that Defendants receive, hold, and distribute to customers are intended to be incorporated as a component of finished drug products. Defendants' API are drugs under the Act, because they are intended to be used as components of articles that are intended to cure, mitigate, treat, or prevent disease, or to affect the structure or function of the body.

11. The Act requires drugs to be manufactured, processed, packed, and held in accordance with current good manufacturing practice ("CGMP"). 21 U.S.C. § 351(a)(2)(B). The

Act deems a drug adulterated if "the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with [CGMP] to assure that [it] meets the requirements of [the] Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess," regardless of whether the drug is actually defective in some way.

12. FDA inspected the LGM Pharma Kentucky and Headquarters Facilities during March and April 2022 (the "2022 Inspections"). These inspections revealed multiple instances in which Defendants failed to adhere to CGMP for receiving, holding, and distributing drugs. Following the 2022 Inspections, FDA issued FDA Forms 483 enumerating multiple observations of quality control issues that pose a serious and on-going risk to the public. Moreover, as set forth in greater detail below, many of the CGMP violations observed during the 2022 Inspections are similar to violations observed previously during FDA's 2018 inspection of the Kentucky Facility.

13. Defendants' significant deviations from CGMP observed during the 2022 Inspections include, but are not limited to, the following:

A. Failure to adequately investigate and resolve quality related complaints. For example, a customer of LGM Pharma reported out-of-specification ("OOS") test results concerning unidentified impurities in cromolyn sodium, a drug used to treat bronchial asthma and certain allergic conditions, it had purchased from LGM Pharma. LGM Pharma did not quarantine remaining product from the compromised lot while it investigated the OOS complaint, in violation of its own Standard Operating Procedures ("SOPs"). Instead, LGM shipped quantities of the remaining API to two additional customers without informing them of the OOS results until the 2022 Inspections were underway, more than a year after LGM Pharma was apprised of the

OOS test results. LGM Pharma's investigation into this issue was inadequate, and not compliant with its SOPs, in that LGM Pharma did not assess the scope of the issue or its risk, or properly document its investigation. Similarly, LGM Pharma failed to take appropriate action in conformity with its SOPs when it learned of multiple OOS test results relating to impurities/potential low potency for multiple lots of estriol, an estrogen hormone, that LGM Pharma purchased from a Chinese supplier and distributed to six different customers in the U.S.

B. Failure to accurately perform quality control measures. For example, LGM Pharma's quality unit reviewed and approved a checklist used to determine whether a batch of sodium thiosulfate API met its requirements for distribution in the U.S. that contained significant errors.

C. Failure to qualify API suppliers in accordance with established SOPs. For example, LGM Pharma ordered and received hundreds of API from multiple suppliers between late 2018 and early 2022 that were not qualified and approved pursuant to LGM Pharma's own SOPs. Moreover, inconsistent with CGMP as well as LGM Pharma's SOPs, LGM Pharma's finance department oversees the relationships and transactions the company has with many of its API suppliers rather than its quality personnel.

D. Failure to establish adequate SOPs for distribution of products after manufacturer disqualification and to follow existing SOPs for distribution of such product. LGM Pharma's vendor qualification SOP is inadequate because, for example, it allows the company to distribute inventory from a vendor that has been disqualified without requiring the company to undertake an assessment of the product's quality and risk prior to distribution. Moreover, LGM Pharma failed to follow its existing SOPs when it distributed multiple shipments of API inventory

from a supplier after LGM Pharma had disqualified the supplier without any written justification for the distribution, as required by the company's vendor qualification SOPs.

E. Failure to follow established SOPs for registering API manufacturers with FDA. For example, LGM Pharma registered foreign suppliers with FDA without the supplier's knowledge and authorization, and with inaccurate information, including incorrect supplier contact information.

F. Failure to properly document investigations into deviations and complaints. LGM Pharma's investigation documentation is deficient in numerous respects, including but not limited to, that it lacks significant details such as dates of discovery, investigation start dates, product impact assessments, and product dispositions.

14. Defendants violated 21 U.S.C. § 331(a) by introducing and causing to be introduced, or delivering and causing to be delivered for introduction, into interstate commerce articles of drug that were adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

DEFENDANTS CAUSE ADULTERATION OF DRUGS WHILE HELD FOR SALE

15. Through the actions set forth above, Defendants cause drugs to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), while they are held for sale after shipment of one or more of their components in interstate commerce, in violation of 21 U.S.C. § 331(k).

DEFENDANTS DISTRIBUTED ADULTERATED DRUGS IN INTERSTATE COMMERCE

16. Defendants distribute API to customers across the United States. Defendants import the majority of the API it distributes from manufacturers or brokers outside the United States. Thus, Defendants' activities satisfy the interstate commerce element of 21 U.S.C. § 331 and 21 U.S.C. § 331(k). *See, e.g.*, 21 U.S.C. § 321(a)(2) ("The term 'interstate commerce' means (1) commerce between any State . . . and any place outside thereof"); *United States v. Food*, 2,998

Cases, 64 F.3d 984, 989 (5th Cir. 1995) (importation of goods into the U.S. satisfies statutory introduction into interstate commerce requirement).

DEFENDANTS' HISTORY OF VIOLATIVE CONDUCT

17. Defendants have a history of noncompliance with the Act, have failed to adequately remedy violations, and continue to violate the Act.

18. At the close of the 2022 Inspections, FDA investigators issued FDA Forms 483 to Defendant Raje, collectively listing six inspectional observations (four at the Kentucky Facility and two at the Headquarters Facility), and discussed the observed deviations with LGM Pharma management, including Defendants Raje and Vengurlekar. FDA subsequently received responses to the FDA Forms 483 that did not adequately address the identified violations.

19. FDA previously inspected the Kentucky Facility in 2018 (the "2018 Inspection"). At the close the 2018 Inspection, FDA investigators issued an FDA Form 483 listing 11 inspectional observations and discussed the observed deviations with LGM Pharma management, including Defendant Raje. FDA subsequently received a series of responses to the FDA Form 483 that did not adequately address the identified violations. The following are among the CGMP violations observed during the 2018 Inspection, many of which are the same as, or similar to, violations observed during the 2022 Inspections:

A. Failure to justify re-labeling of drugs. Defendants re-labeled API received from a foreign manufacturer as a different drug without investigating and documenting whether the re-labeling was justified. Specifically, Defendants imported two shipments of the antiviral drug, cidofovir, from a broker in China, that were labeled as tranexamic acid, a blood-clotting agent. Defendants re-labeled the product as cidofovir without any verification or testing of the content to confirm that the substance was, in fact, cidofovir. Defendants distributed one shipment

of the API to several customers in the U.S. This departure from CGMP was especially problematic because cidofovir and tranexamic acid cannot be distinguished upon visual inspection.

B. Failure to adequately investigate and resolve quality complaints. For example, Defendants received multiple complaints from customers that lots of porcine thyroid powder API, used to treat underactive thyroid conditions, were OOS for lack of homogeneity, an issue that can lead to inconsistent potency, potentially resulting in sub-potent or super-potent individual doses. Rather than quarantining the product pending an investigation into the cause for the OOS testing results, Defendants accepted returns of the rejected product from customers, stripped any indication the drug had been previously distributed, and shipped it to other customers. LGM has persisted in this non-compliant conduct as set forth in paragraph 13(A) above.

C. Failure to adequately qualify API suppliers. For example, LGM Pharma imported API from suppliers placed on FDA Import Alerts, which inform FDA's field staff and the public that the agency has enough evidence to detain imported drugs that appear to be in violation of the FDCA, and imported two shipments of cidofovir API that were manufactured by a Chinese company that had not been evaluated and qualified by Defendants. As set forth in paragraph 13(C) above, LGM Pharma's supplier qualification procedures remain non-compliant.

D. Failure to have an adequate quality unit. For example, individuals within the production and commercial units of LGM Pharma made quality control decisions, rather than personnel from an independent quality unit. As set forth in paragraph 13(C) above, LGM Pharma remains non-compliant in this area, because the company's finance department, rather than

quality personnel, oversees relationships and transactions with many of LGM Pharma's API supply vendors.

E. Failure to properly register suppliers with FDA. For example, Defendants registered a Chinese company with FDA, incorrectly identifying it as the manufacturer of asparaginase API imported by Defendants. In addition, LGM Pharma undertook this registration and listing without the foreign company's knowledge or authorization. As set forth in paragraph 13(E) above, LGM Pharma continued its practice of inaccurate and unauthorized registration of suppliers after the 2018 Inspection.

20. Based on the foregoing, despite repeated notifications, Defendants remain unable or unwilling to comply with the Act. Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests that the Court:

I. Issue an injunction restraining and enjoining Defendants, and each and all of their directors, officers, agents, employees, representatives, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, pursuant to 21 U.S.C. § 332(a) and the inherent equitable authority of the Court, from doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce drugs, as defined in 21 U.S.C. § 321(g), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); and

B. Violating 21 U.S.C. § 331(k), by causing drugs to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), while they are held for sale after shipment of one or more of their components in interstate commerce;

II. Issue an injunction requiring Defendants to undertake actions to ensure that their methods and controls for receiving, labeling, holding, and/or distributing drugs, including quality controls, are established and operate in a manner that conforms with the Act and its regulations, and in a manner that has been found acceptable by FDA, and to ensure that Defendants' drugs are not adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); and

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receiving, holding, and distributing of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

DATED January 11, 2023

Respectfully submitted,

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Acting Assistant Attorney General
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JS 44 (Rev. 10/20) FLSD Revised 02/12/2021

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service 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. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)* **NOTICE: Attorneys MUST Indicate All Re-filed Cases Below.**

I. (a) PLAINTIFFS

United States of America

DEFENDANTS

LGM Pharma LLC, Prasad Raje, Shailesh Vengu

(b) County of Residence of First Listed Plaintiff *(EXCEPT IN U.S. PLAINTIFF CASES)*

County of Residence of First Listed Defendant West Palm Beach County *(IN U.S. PLAINTIFF CASES ONLY)*

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Ann Entwistle, U.S. Justice Department 450 5th St. NW, Washington, I

Attorneys *(If Known)*

Eric Sussman, Barnes & Thornberg LLP

(d) Check County Where Action Arose: ■ MIAMI- DADE ☐ MONROE ☐ BROWARD ☐ PALM BEACH ☐ MARTIN ☐ ST. LUCIE ☐ INDIAN RIVER ☐ OKEECHOBEE ☐ HIGHLANDS

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ■ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 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	DEF		PTF	DEF
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. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 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 Personal Injury - Med. Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent – Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729 (a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act (TCPA)
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ■ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence

Other:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee – Conditions of Confinement

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

V. ORIGIN *(Place an "X" in One Box Only)*

■ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Re-filed **(See VI below)** ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district *(specify)* ☐ 6 Multidistrict Litigation Transfer ☐ 7 Appeal to District Judge from Magistrate Judgment ☐ 8 Multidistrict Litigation – Direct File ☐ 9 Remanded from Appellate Court

VI. RELATED/ RE-FILED CASE(S)

(See instructions): a) Re-filed Case ☐YES ☐ NO b) Related Cases ☐YES ■ NO

JUDGE: **DOCKET NUMBER:**

VII. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing and Write a Brief Statement of Cause ***(Do not cite jurisdictional statutes unless diversity)***:

21 U.S.C. §§ 331(a), 331(k), and 332(a)

LENGTH OF TRIAL via days estimated (for both sides to try entire case)

VIII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☐ Yes ■ No

ABOVE INFORMATION IS TRUE & CORRECT TO THE BEST OF MY KNOWLEDGE

DATE 1/11/2023

SIGNATURE OF ATTORNEY OF RECORD /s Ann Entwistle

FOR OFFICE USE ONLY : RECEIPT # **AMOUNT** IFP JUDGE MAG JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM 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 service of pleading 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. The attorney filing a case should complete the form as follows:

I. (a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked. Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Refiled (3) Attach copy of Order for Dismissal of Previous case. Also complete VI.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

Remanded from Appellate Court. (8) Check this box if remanded from Appellate Court.

VI. Related/Refiled Cases. This section of the JS 44 is used to reference related pending cases or re-filed cases. Insert the docket numbers and the corresponding judges name for such cases.

VII. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity**. Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VIII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

Date and Attorney Signature. Date and sign the civil cover sheet.