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RECEIVED & FILED  
SUPERIOR COURT  
2007 MAY -8 PM 12:15  
CIVIL DIVISION

DAVID OLAGUNJU  
*Plaintiff,*  
  
v.  
  
NOVARTIS PHARMACEUTICALS  
CORPORATION  
*Defendants.*

SUPERIOR COURT OF NEW JERSEY  
MORRIS COUNTY  
LAW DIVISION  
DOCKET NO.  
  
*CIVIL ACTION*  
**COMPLAINT AND JURY DEMAND**

Plaintiff, David Olagunju, of full age by way of complaint against Defendant does hereby say:

1. Plaintiff is a citizen of the State of New Jersey and resides in the Township of Randolph, County of Morris, and State of New Jersey.
2. Defendant Novartis Pharmaceuticals Corporation maintains a principle place of business in the Town of Florham Park, County of Morris, and State of New Jersey and registered to do business in the State of New Jersey.

**STATEMENT OF THE CASE**

Plaintiff brings this action against Novartis Pharmaceutical Corporation for violating his protected rights as a whistleblower under the New Jersey Conscientious Employee Protection Act and retaliating against him for disclosing and refusing to participate in illegal and unethical activities regarding the testing and reporting of human drug study results concerning Tasigna (ANM), Novartis' new cancer drug. As Global Director of Oncology Statistical Reporting and Standards Reporting (SRS), plaintiff disclosed to Novartis' senior management the existence of

improper statistical data being reported to the United States Food and Drug Administration (FDA), violations of established ethical standards concerning the recording and reporting of data, the failure to follow proper statistical protocols when reporting drug study data and violations of policies and procedures established to safeguard drug study participants and consumers of pharmaceutical products. In response to Plaintiff's complaints and in retaliation for his refusal to take part in Novartis' illegal activities and violations of public policy, he was harassed, threatened and ultimately terminated from his position at Novartis. Plaintiff seeks an Order compelling an audit of all drug study data compiled by Novartis and provided to the FDA concerning Tasigna or any other drugs utilizing Novartis's current clinical trial safety reporting system, otherwise known as Standard Tables and Listings (STL). Plaintiff also seeks compensatory and punitive damages as a result of Novartis' willful and intentional actions and inactions.

#### **GENERAL ALLEGATIONS**

1. When Plaintiff began his employment with Novartis in October of 2004, he believed Novartis was an ethical pharmaceutical company committed to developing high quality and safe pharmaceutical products. It was Plaintiff's understanding that Novartis would strictly adhere to all of the laws, rules, regulations and ethical standards which govern the pharmaceutical industry. Had he thought otherwise, he never would have left his home in the State of Washington to become employed with Novartis.
2. During Plaintiff's first year at Novartis, he worked as the Global Director of Biostatistics and Statistical Reporting Standards. Plaintiff reported directly to the Global Executive Director of Statistical Reporting. In December of 2005, Novartis decentralized its Biostatistics and Statistical Reporting functions relating to Oncology to the Oncology Business Unit. In February,

2006, plaintiff was offered and accepted the position of Global Director of Oncology Statistical Reporting and Standards (SRS). Although he resided in Randolph, New Jersey and worked out of Novartis' Florham Park, New Jersey offices, Plaintiff's duties included responsibility for company activities throughout the United States, Switzerland, India and Japan.

3. In May of 2006, Kannan Natarajan was hired by Novartis as Vice President of Oncology Biostatistics & Statistical Reporting and became Plaintiff's immediate supervisor. Although he had previously served as Director of Cardiovascular Statistics at Bristol Meyers Squibb, Natarajan had little or no experience in managing statistical reporting or oncology statistics. Statistical reporting requires a thorough understanding of the technology, programming and processes for capturing, storing and extracting and reporting data derived from clinical trials. Due in part to his inexperience and the dismantling of the centralized B&SR department at Novartis, the amount of oversight needed to accumulate reliable and valid data was negatively impacted and compliance with proper protocol and FDA standards was not enforced.

4. Between May of 2006 and September of 2006, Plaintiff met with Natarajan and other Novartis officials on various occasions to discuss numerous violations in the hope of rectifying data errors and placing the various ongoing drug studies in compliance with FDA regulations.

5. On several occasions, Plaintiff discussed his concerns with Natarajan about the processing of drug study safety data within Novartis' Safety Reporting System (also known as the "STL") that was not formally validated prior to commissioning into production and generating data errors (i.e. empty files, poor documentation, incorrect date imputation for adverse events, wrong variables, and mismatched items). These issues have serious impact on the reporting of safety data and have negative impact all of Novartis' clinical trials, not just the clinical trials for Tasigna. Novartis was advised as early as 2004 by their Global Director of

Safety Reporting, that the “STL was not fully validated as per 21 CFR Part 11 guidelines”. To date the system is obsolete and still generating inaccurate safety data that is being submitted to the FDA.

6. At the same time that Plaintiff was disclosing the reporting of improper safety data to Novartis officials, a contract programmer within the Oncology Business Unit complained of being forced to alter the calculation of duration of adverse side effects to enhance the appearance of Tasigna’s safety in the clinical trials. It had become apparent amongst study team members that Tasigna had numerous cardiovascular side effects. By compressing the duration of adverse effects, Novartis has exposed the public to a serious danger if this drug were to be approved. When the contractor complained about being instructed to compress the safety data, Natarajan retaliated against him by withdrawing his offer of employment under the pretext that he did not get along with the study team. When Plaintiff objected to Natarajan’s retaliatory action against the contractor, Natarajan threatened Plaintiff with termination.

7. Plaintiff also objected to the fraudulent attempt by Novartis’ Development Leadership Team (DLT) to exaggerate Tasigna’s Summary of Clinical Efficacy (SCE) and Summary of Clinical Safety (SCS) which are designed to demonstrate to the FDA the efficacy and safety of the drug. The DLT’s actions were enhanced through a last minute redefinition of Tasigna’s Intent to Treat (ITT). Any deviation from the pre-defined statistical methodology negotiated with the FDA, including the definition of ITT, is improper. Nevertheless, the DLT (which consisted of a group of Vice Presidents, chaired by a Sr. Vice President of Oncology Development at Novartis) redefined the details of how patients were randomly assigned to treatment drugs, how the effect of the drugs were measured, reported statistically and negotiated with the FDA a few days prior to locking the data base. As a result of the actions of the DLT, the data provided to the

FDA was not in accordance with the statistical protocol required by the FDA, and the FDA was not advised of these fundamental changes. Any changes or modifications to the FDA's protocol should result in a protocol amendment, approved and renegotiated with the FDA. Failure to do so could be considered fraud.

8. On March 31, 2006, the lead statistician for clinical pharmacology instructed a contract programmer to "hard code" the randomization codes for certain specified subjects of one of the Tasigna studies in a SAS program. This practice not only calls the validity of the study into serious doubt, it is in direct contradiction to the established procedures at Novartis, which state:

"No hard-coding is permitted in any programs used for the creation of analysis data sets, tables, listing or analyses that are intended for external reporting after data base lock { i.e. Clinical Study Reports (all phases), Publications, Abstracts, Clinical summaries { e.g. SCE, SCS, etc.}. ***B&SR is responsible to report the data on the data base and not to correct it.*** [emphasis in original]"

The type of study at issue in this particular instance was a SCS study relating to Tasigna. Pursuant to Novartis' own guidelines, the data should not have been manipulated.

9. Plaintiff became aware of the hard coding of the study's randomization codes and voiced his concerns and objections to Natarajan and his Leadership Team. Natarajan expressed his frustration to Plaintiff that the contractor who was instructed to manipulate the randomization codes had the audacity to voice his opinion on what should or should not be done in a Novartis clinical trial. He seemed more upset however, that the contractor had documented the hard coding event and that Plaintiff was agreeing that the contractor was right in voicing his objections.

10. Plaintiff also voiced his concern regarding Novartis' failure to allocate resources sufficient to comply with legal standards and good clinical practice. Contrary to industry standards, Natarajan populated the department with many more statisticians than programmers.

Programmers and other department personnel were allocated to multiple projects and were pressured to neglect standards and procedures. As a result, the integrity of the data and reports suffered. Novartis was non responsive to Plaintiff's concerns.

11. Plaintiff also voiced concern to his superiors concerning changes to the Analysis Plan by the DLT without obtaining the required approvals or completing the necessary "RAP Change Request Approval Form". Novartis' standard operating procedure requires that any changes to the analysis plan be approved. When they are not approved it suggests to the FDA that Novartis may be altering the analysis as the scientists look at the data, see the results and change the methodology. Such a procedure is improper because these changes affect the numbers that are submitted to the FDA. Even over the objections of Plaintiff and other project team members who voiced their concern that such changes contradicted their ethical obligations, Novartis enforced their decision to modify analysis plan and data items. As a result, the veracity of the data submitted to the FDA was impacted.

12. The Lead Biostatistician on the Tasigna project affirmed many of Plaintiff's complaints to Novartis management, but still nothing changed at Novartis. As a result the danger to the public is substantial as Novartis continues to seek approval for Tasigna, a drug whose efficacy and safety design, data, and analysis were not well thought out, not validated and were hastily compiled. The same is so for all other Novartis drugs utilizing the same Safety Reporting System used in the Tasigna clinical trials.

13. The same lead Biostatistician also affirmed that the clinical data base for Tasigna was locked even though there were still pending data issues. He elaborated his concerns to Natarajan who continued to disregard this serious data integrity and reliability issue and permitted data of questionable reliability to be transmitted to the FDA.

14. After several unsuccessful attempts to resolve the issues outlined above with Novartis management, Plaintiff filed a Complaint with Novartis' Corporate Compliance Department. Since Natarajan had already threatened him with termination in the event he did not "keep quiet" and "stop complaining", Plaintiff also reported Natarajan's behavior to his Supervisor, Alexandro Riva, Sr. Vice President of Oncology Development.

15. On or about October 6, 2006, Plaintiff was contacted by Tracie Hill of the Human Resources Department concerning his complaint to Riva. Plaintiff met with her and explained what had been happening, but it was clearly apparent that she did not comprehend the seriousness of what was being related to her. She remarked, "We know we have had some 'data issues' with [Tasigna]" and then asked Plaintiff for his "ideal solution".

16. Plaintiff informed Tracie Hill of his belief that Oncology SRS should go back to reporting to the Global Statistical Reporting which was independent and isolated from the business pressures being imposed by the Oncology Business Unit. Kathy Mellars, the Executive Director of Global Statistical Reporting, was a person who understood the need to provide the FDA with reliable, valid and uncorrupted data.

17. In response to Plaintiff's suggestion, Ms. Hill proposed a meeting with her, Natarajan and the Plaintiff to "define expectations". Plaintiff believed that Hill was going to assist him in ensuring compliance with Novartis' expectations of following proper policies, regulations and procedures.

18. On or about October 18, 2006 during his regularly scheduled one-on-one meeting with Natarajan, a person Plaintiff had never seen before showed up at the meeting. She introduced herself as Lakshmi Mahadevan, a Human Relations leadership program associate, on rotation from Basel, Switzerland. She handed Plaintiff a document entitled "Performance Feedback and

Expectations”. Plaintiff was humiliated and devastated by the false accusations and blatant manipulations contained in the document. Ms. Mahadevan announced “I am here to tell you what the organization wants you to do. Read the document and let us know immediately, if you still want to remain with the Company”. This ridicule and harassment continued for the next several one-on-one weekly meetings with Ms Mahadevan and Natarajan both present.

19. During this same time period, Voss Volk from Novartis’ United States Corporate Compliance Office telephoned Plaintiff to discuss his complaints. He pleaded with Mr. Volk to keep his identity confidential and secret, but Plaintiff was told that it may be difficult at his level within the Company. Plaintiff informed Volk that he was already being subjected to internal harassment and retaliation.

20. Volk also involved Novartis’ Clinical Quality Assurance Department and Plaintiff met with a Mr. Grant Simon from that department in mid October. Mr. Simon informed Plaintiff that he had received complaints similar to Plaintiff’s and that the people who complained from Oncology were typically nervous about losing their jobs. He also indicated that some employees actually resigned from the Company because of this type of issues. He described Oncology as “untouchable” within Novartis and wondered aloud if Volk had enough resources to hire an independent auditor. Plaintiff sent him information that he requested and then never heard from Simon again.

21. On or about November 6, 2006 Plaintiff met once again with Natarajan and Mahadevan at his weekly supervisory meeting. Mahadevan handed him a revised version of the “Performance Feedback and Expectations” document and informed him that the “Organization” had decided that he should consider the document a Performance Improvement Plan (PIP) and that he had no choice in the matter. Plaintiff was further informed that the performance

improvement period would last for 90 days and would end on January 31, 2007 despite the fact that Natarajan had already approved his vacation for December 18<sup>th</sup> through January 6th. Established procedures for imposing a PIP were not followed.

22. From that point forward, Mahadevan was present in every one-on-one meeting Plaintiff had with Natarajan. He was subject to embarrassment and intimidation. Even though he was still functioning at a Director's level, he was compelled by the Human Resources associate to take minutes, distribute the minutes and prepare agendas.

23. On December 2, 2006 Plaintiff was asked to update the document entitled "Performance Feedback and Expectations: Response and Clarification" to capture what he had achieved during the PIP period to date. Both Mahadevan and Natarajan promised to provide their updates also, but they never did.

24. On December 8, Linda Finelli, Natarajan's secretary sent Plaintiff an email informing him that his annual performance evaluation would take place during his December 11<sup>th</sup> one-on-one meeting with Natarajan. This contradicted Novartis' Performance Evaluation Timeline. Annual performance evaluations are typically done between January and February after final approvals from Senior Management concerning bonus and stock options are obtained. Natarajan provided Plaintiff's performance evaluation without any numerical rating. Natarajan did not allow Plaintiff to include his employee comments on the evaluation and the evaluation was not signed. Most of his comments were negative and contradicted the mid year evaluation he provided to Plaintiff in August, prior to Plaintiff's voicing numerous complaints about Novartis' statistical reporting practices. The negative comments were also contradicted by the annual performance evaluation Plaintiff received in 2005 from Kathy Mellars, his former supervisor.

25. On January 22<sup>nd</sup>, Plaintiff was approached by Natarajan, Hills and Mahadevan and was informed that his employment had been terminated. While the severance package he was handed was still being discussed, Natarajan sent out email to the global organization, misrepresenting to Plaintiff's co-workers that he had decided to take another opportunity outside of Novartis, and that in light of this decision, he was no longer with the organization.

### **COUNT ONE**

#### **New Jersey Conscientious Employee Protection Act**

26. The Plaintiff repeats paragraphs 1 through 25 of the Complaint as if fully set forth herein at length.

27. The actions and inactions of Defendant have caused and will continue to cause a serious risk of harm to drug study participants and the ultimate users of the Drugs developed, tested and/or reported through Novartis' Oncology Business Unit.

28. Plaintiff also engaged in actions which were protected under the New Jersey Conscientious Employee Protection Act, N.J.S.A. 34:19-1 *et seq.* These actions included, but are not limited to, his objections to and refusal to participate in activities he reasonably believed were in violation of law and/or public policy.

29. Defendant retaliated against Plaintiff for engaging in protected activities under the New Jersey Conscientious Employee Protection Act.

30. As a direct and proximate result of the Plaintiffs' voicing his objection to and refusal to participate in what he believed were violations of public policy and/or illegal acts, he was systematically and repeatedly retaliated against.

31. As a direct and proximate result of the Defendant's actions, the Plaintiff has suffered and continues to suffer damages including severe emotional distress.

32. Defendant's actions were intentional, knowing and in reckless disregard of the harm incurred by Plaintiff, and the harm or potential harm to drug study participants and the general public.

**WHEREFORE**, Plaintiff demands judgment against the Defendant as follows:

1. Enjoining Defendant from providing the FDA with fraudulent, misleading, corrupted or manipulated data relating to their clinical drug trials and compelling Novartis' compliance with all FDA procedures, protocols and regulations;
2. Compelling an audit of all data submitted to the FDA from the clinical trials of Novartis' cancer drug Tasigna and all data submitted to the FDA on all Novartis' clinical drug trials utilizing Novartis' Safety Reporting System;
3. Reinstatement of the Plaintiff and awarding damages including compensatory, hedonic, punitive damages, front pay, back pay, attorney's fees, interest, cost of suit and for such other relief as the Court may deem just and proper.

### **JURY DEMAND**

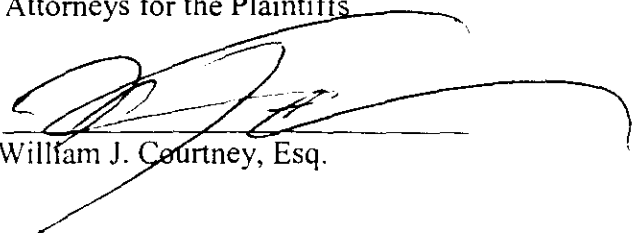
Plaintiff hereby demands a trial by jury on all issues so triable.

### **TRIAL ATTORNEY DESIGNATION**

In accordance with R. 4:25-4 William J. Courtney is hereby designated as trial counsel for Plaintiff David Olagunju.

Law Offices of William J. Courtney, L.L.C.  
Attorneys for the Plaintiffs

By:

  
William J. Courtney, Esq.

Dated: May 7, 2007

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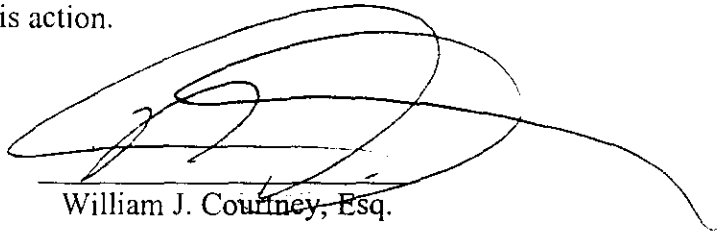
**CERTIFICATION PURSUANT TO R. 4:5-1**

2007/MAY -8 PM 12:35

CIVIL DIVISION

Pursuant to Rule 4:5-1, the undersigned certifies that to the best of his knowledge, the within matters in controversy are not the subject of any other action pending in any other Court or of a pending arbitration proceeding nor is any action or arbitration proceeding contemplated nor are other parties required to be joined in this action.

Dated: May 7, 2007



William J. Courtney, Esq.



# CIVIL CASE INFORMATION STATEMENT

## (CIS)

Use for initial Law Division  
 Civil Part pleadings (not motions) under Rule 4:5-1  
**Pleading will be rejected for filing, under Rule 1:5-6(c),  
 if information above the black bar is not completed or  
 if attorney's signature is not affixed.**

FOR USE BY CLERK'S OFFICE ONLY

PAYMENT TYPE: CK [ ] CG [ ] CA [ ]

CHECK NO. 2007 MAY 8 PM 12:15

AMOUNT:  
OVERPAYMENT: CIVIL DIVISION

BATCH NUMBER:

ATTORNEY/PRO SE NAME William J. Courtney, Esq.		TELEPHONE NUMBER (908) 782-5900	COUNTY OF VENUE MORRIS
FIRM NAME (If applicable) Law Offices of William J. Courtney, LLC		DOCKET NUMBER (When available)	
OFFICE ADDRESS 2 Main Street, PO Box 112 Flemington, NJ 08822		DOCUMENT TYPE Complaint	
		JURY DEMAND <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
NAME OF PARTY (e.g., John Doe, Plaintiff) David Olagunju		CAPTION David Olagunju v. Novartis Pharmaceuticals Corporation	
CASE TYPE NUMBER (See reverse side for listing) 616	IS THIS A PROFESSIONAL MALPRACTICE CASE? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO IF YOU HAVE CHECKED "YES," SEE N.J.S.A. 2A:53A-27 AND APPLICABLE CASE LAW REGARDING YOUR OBLIGATION TO FILE AN AFFIDAVIT OF MERIT.		
RELATED CASES PENDING? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	IF YES, LIST DOCKET NUMBERS		
DO YOU ANTICIPATE ADDING ANY PARTIES (arising out of same transaction or occurrence)? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	NAME OF DEFENDANT'S PRIMARY INSURANCE COMPANY, IF KNOWN <input type="checkbox"/> NONE <input checked="" type="checkbox"/> UNKNOWN		

**THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE.**

### CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

DO PARTIES HAVE A CURRENT, PAST OR RECURRENT RELATIONSHIP? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	IF YES, IS THAT RELATIONSHIP <input checked="" type="checkbox"/> EMPLOYER-EMPLOYEE <input type="checkbox"/> FRIEND/NEIGHBOR <input type="checkbox"/> OTHER (explain) <input type="checkbox"/> FAMILIAL <input type="checkbox"/> BUSINESS
DOES THE STATUTE GOVERNING THIS CASE PROVIDE FOR PAYMENT OF FEES BY THE LOSING PARTY? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
USE THIS SPACE TO ALERT THE COURT TO ANY SPECIAL CASE CHARACTERISTICS THAT MAY WARRANT INDIVIDUAL MANAGEMENT OR ACCELERATED DISPOSITION:	

DO YOU OR YOUR CLIENT NEED ANY DISABILITY ACCOMMODATIONS? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	IF YES, PLEASE IDENTIFY THE REQUESTED ACCOMMODATION:
---	--

WILL AN INTERPRETER BE NEEDED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	IF YES, FOR WHAT LANGUAGE:
--	----------------------------

ATTORNEY SIGNATURE



# CIVIL CASE INFORMATION STATEMENT (CIS)

Use for initial pleadings (not motions) under *Rule 4:5-1*

**CASE TYPES** (Choose one and enter number of case type in appropriate space on the reverse side.)

**Track I — 150 days' discovery**

- 151 NAME CHANGE
- 175 FORFEITURE
- 302 TENANCY
- 399 REAL PROPERTY (other than Tenancy, Contract, Condemnation, Complex Commercial or Construction)
- 502 BOOK ACCOUNT (debt collection matters only)
- 505 OTHER INSURANCE CLAIM (INCLUDING DECLARATORY JUDGMENT ACTIONS)
- 506 PIP COVERAGE
- 510 UM or UIM CLAIM
- 511 ACTION ON NEGOTIABLE INSTRUMENT
- 512 LEMON LAW
- 801 SUMMARY ACTION
- 802 OPEN PUBLIC RECORDS ACT (SUMMARY ACTION)
- 999 OTHER (Briefly describe nature of action)

**Track II — 300 days' discovery**

- 305 CONSTRUCTION
- 509 EMPLOYMENT (other than CEPA or LAD)
- 599 CONTRACT/COMMERCIAL TRANSACTION
- 603 AUTO NEGLIGENCE – PERSONAL INJURY
- 605 PERSONAL INJURY
- 610 AUTO NEGLIGENCE – PROPERTY DAMAGE
- 699 TORT – OTHER

**Track III — 450 days' discovery**

- 005 CIVIL RIGHTS
- 301 CONDEMNATION
- 602 ASSAULT AND BATTERY
- 604 MEDICAL MALPRACTICE
- 606 PRODUCT LIABILITY
- 607 PROFESSIONAL MALPRACTICE
- 608 TOXIC TORT
- 609 DEFAMATION
- 616 WHISTLEBLOWER / CONSCIENTIOUS EMPLOYEE PROTECTION ACT (CEPA) CASES
- 617 INVERSE CONDEMNATION
- 618 LAW AGAINST DISCRIMINATION (LAD) CASES

**Track IV — Active Case Management by Individual Judge / 450 days' discovery**

- 156 ENVIRONMENTAL/ENVIRONMENTAL COVERAGE LITIGATION
- 303 MT. LAUREL
- 508 COMPLEX COMMERCIAL
- 513 COMPLEX CONSTRUCTION
- 514 INSURANCE FRAUD
- 701 ACTIONS IN LIEU OF PREROGATIVE WRITS

**Mass Tort (Track IV)**

- |   |                                |
|---|--------------------------------|
| 240 REDUX/PHEN-FEN (formerly "DIET DRUG") | 271 ACCUTANE                   |
| 241 TOBACCO                               | 272 BEXTRA/CELEBREX            |
| 248 CIBA GEIGY                            | 274 RISPERDAL/SEROQUEL/ZYPREXA |
| 264 PPA                                   | 601 ASBESTOS                   |
| 266 HORMONE REPLACEMENT THERAPY (HRT)     | 619 VIOXX                      |
| 268 MANUFACTURED GAS PLANT (MGP)          |                                |

If you believe this case requires a track other than that provided above, please indicate the reason on Side 1, in the space under "Case Characteristics."

Please check off each applicable category:

Verbal Threshold

Putative Class Action

Title 59