

1 Ryan M. Sandrock (SBN 251781)
rsandrock@sidley.com
2 SIDLEY AUSTIN LLP
555 California Street
3 Suite 2000
San Francisco, CA 94104
4 Telephone: +1 415 772 1200
Facsimile: +1 415 772 7400

5
6 Richard D. Raskin (*pro hac vice* motion forthcoming)
rraskin@sidley.com
7 SIDLEY AUSTIN LLP
One South Dearborn
Chicago, Illinois 60603
8 Telephone: +1 312 853 7000
Facsimile: +1 312 853 7036

9
10 Benjamin M. Mundel (*pro hac vice* motion forthcoming)
bmundel@sidley.com
11 SIDLEY AUSTIN LLP
1501 K Street NW
Washington, DC 20005
12 Telephone: +1 202 736 8157
Facsimile: +1 202 736 8711

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14 Attorneys for Defendant
EXELTIS USA, INC.

15 UNITED STATES DISTRICT COURT
16 NORTHERN DISTRICT OF CALIFORNIA
17 SAN FRANCISCO DIVISION

18 EXELTIS USA, INC., a New Jersey Corporation,
19 Plaintiff,
20 vs.
21 FIRST DATABANK, INC., a Missouri
22 Corporation,
23 Defendant.

Case No. 17-4810

COMPLAINT

JURY TRIAL DEMANDED

24
25 **COMPLAINT FOR INJUNCTIVE, DECLARATORY, AND OTHER RELIEF**

26 Plaintiff Exeltis USA bring this Complaint against Defendant First Databank, Inc., seeking
27 injunctive, declaratory, and other relief.
28

1 **NATURE OF THE ACTION**

2 1. This case is about ensuring women have access to doctor-prescribed prenatal vitamins
3 that prevent serious and deadly birth defects. Defendant First Databank, the most widely used drug-
4 coding database, has correctly coded prescription prenatal vitamins as “prescription” for decades.
5 But First Databank has announced that, beginning September 15, 2017, it will code prescription
6 prenatal vitamins as “Non-Rx” or over-the-counter. This new coding is false and deceptive. It will
7 deny pregnant women—particularly those covered by Medicaid—access to necessary prenatal
8 vitamins that prevent spina bifida and other devastating neural tube birth defects. It will also
9 devastate Exeltis’s business.

10 2. First Databank is a gatekeeper for prescription drug reimbursement. It creates and
11 sells drug databases that are used by the majority of state Medicaid programs and private insurance
12 plans (payors) to make reimbursement decisions. As relevant here, many payors cover prescription
13 products, but not over-the-counter products. To identify whether a product is “prescription” or over-
14 the-counter, payors depend on drug databases (most commonly First Databank) and use their coding
15 to make reimbursement decisions. Thus, First Databank’s “prescription” or “Non-Rx” coding has the
16 practical effect of determining whether a product is covered by many state Medicaid programs and
17 private insurance plans.

18 3. While some prenatal vitamins are sold over-the-counter and are classified
19 accordingly, a number of manufacturers, including Exeltis, sell prenatal vitamins *by prescription*
20 *only*. By making their product available only if a physician authorizes their use, physicians are
21 empowered to select the prenatal vitamin with the medically appropriate formula of vitamins and
22 minerals for a particular patient’s needs. First Databank has recognized this for decades and correctly
23 coded these latter products as “prescription.” The federal government’s drug data file and all other
24 private drug databases similarly code these products as “prescription.” This coding is consistent with
25 federal law, which requires Medicaid plans to cover “prescription prenatal vitamins.” When these
26 products are correctly coded as “prescription,” Medicaid plans are able to identify them and properly
27 cover them. Millions of women have thus had access to prescription prenatal vitamins for free (or a
28 nominal copay).

1 4. Even though neither the law nor the marketing of these products has changed, First
2 Databank has decided suddenly to code prescription prenatal vitamins as “Non-Rx” or “over-the-
3 counter”—all at the behest of a few First Databank customers (who are third-party payors) that want
4 to save money. First Databank’s new coding is equivalent to coding a two-week stay in the intensive
5 care unit as an “out-patient procedure” or coding oxycodone as a “mild pain reliever.” To code
6 prescription prenatal vitamins, including Exeltis’s, as Non-Rx or over-the-counter is false and
7 deceptive, and will lead to widespread denial of Medicaid and insurance coverage for these products.

8 5. Many women will be unable to afford prescription prenatal vitamins out-of-pocket if
9 state Medicaid programs and private insurance plans do not cover them. As a result, these women—
10 and their developing children—will not receive necessary nutrients during one of the most important
11 stages of a child’s development. Exeltis’s business will also be harmed.

12 6. First Databank’s false and deceptive coding will cause devastating public health
13 consequences. Among their most important benefits, prescription prenatal vitamins—specifically, the
14 folic acid in them—prevent serious neural tube birth defects, such as anencephaly and spina bifida.
15 Babies born with anencephaly die shortly after birth. Babies with spina bifida often live, but have
16 severe disabilities including paralysis and the inability to control their bodily functions. Prenatal folic
17 acid supplementation prevents 70 percent of neural tube defects. According to the Centers for
18 Disease Control (“CDC”), each year approximately 1,300 babies—who would otherwise die or have
19 a crippling birth defect—are born healthy because of folic acid supplementation and fortification.

20 7. Indeed, federal public health agencies universally recognize how important folic acid
21 prenatal vitamins are. The National Institutes of Health (“NIH”), the U.S. Food and Drug
22 Administration (“FDA”), the U.S. Preventative Health Services Task Force, and the CDC *universally*
23 recommend that pregnant women—and any women who may become pregnant—take folic acid. The
24 medical community shares this view: the American College of Obstetricians and Gynecologists, the
25 American Academy of Family Physicians, the American Academy of Pediatrics, the American
26 Academy of Neurology, and the American College of Medical Genetics and Genomics all
27 recommend that women take a prenatal vitamin supplement. And yet—if First Databank makes its
28 proposed change—women, particularly those with fewer financial resources, will be unable to follow

1 this advice.

2 8. While less catastrophic than depriving pregnant women of prenatal vitamins, First
3 Databank's false coding will also damage Plaintiff Exeltis's business. Today, 41% of Exeltis's
4 prenatal vitamin sales are covered by Medicaid and 53% are covered by private insurance. Just 6%
5 are paid for out-of-pocket. First Databank's false coding threatens to immediately eliminate half of
6 Exeltis's sales.

7 **PARTIES**

8 9. Plaintiff Exeltis USA, Inc., is a New Jersey corporation with its principal place of
9 business in Florham Park, New Jersey. Exeltis is a leader in women's health, and supplies innovative
10 and high-quality products to meet the needs of women at different stages of their lives. Exeltis sells
11 eleven different types of prenatal vitamins by prescription only. Each product contains 1 mg of Folic
12 Acid and a number of other key vitamins and minerals.

13 10. Defendant First Databank, Inc., is a Missouri corporation with its principal place of
14 business in San Francisco, California. First Databank creates and publishes electronic databases with
15 drug information that it sells to pharmacies, physicians, pharmacy-benefit managers, Medicaid and
16 Medicare reimbursement entities, and others in the business of paying for drug products. First
17 Databank's largest segment of customers are "Third Party Payors"—private and government parties
18 that provide prescription drug coverage for patients. First Databank's publications include electronic
19 databases and software modules purporting to describe the characteristics of pharmaceutical products
20 accurately. First Databank knows and intends that its subscribers use its databases to make
21 reimbursement decisions. First Databank states that it "go[es] beyond the development and
22 maintenance of drug knowledge to focus on building problem-solving partnerships" with its
23 reimbursement subscribers.

24 **JURISDICTION AND VENUE**

25 11. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a) because the
26 amount in controversy exceeds \$75,000 and the parties are citizens of different states.

27 12. This Court also has subject matter jurisdiction because this action arises under the
28 laws of the United States. 28 U.S.C. §§ 1331, 1367; 15 U.S.C. § 1125(a)(1)(B).

1 19. This form of spina bifida causes nerve damage and other disabilities. Seventy to
2 ninety percent of children with Myelmeningocele have too much fluid on their brains, which causes
3 pressure and swelling. Brain surgery is often required to avoid permanent brain damage. A
4 ventricular shunt—a surgically placed tube that allows fluid in the baby’s brain to drain to his
5 abdomen—is often required.

6 20. Spina bifida causes a number of complications and disabilities including: (1) muscle
7 weakness in the legs, which severely limits mobility and sometimes involves paralysis; (2) bowel and
8 bladder problems; (3) seizures; and (4) orthopedic problems—such as deformed feet, uneven hips,
9 and a curved spine (scoliosis). Some babies develop meningitis, a life threatening infection in the
10 tissues surrounding the brain.

11 21. Additional problems may arise as children with spina bifida get older, including
12 learning disabilities, difficulty paying attention, problems with language and reading comprehension,
13 and trouble learning math.

14 22. Each year, 3,000 babies—or, eight per day—are born in the United States with spina
15 bifida. Rates of spina bifida and anencephaly are highest among Hispanic women.

16 23. The financial costs of spina bifida are also dramatic. According to the CDC, the
17 annual medical care and surgical costs for people with spina bifida exceeds \$200 million. The total
18 lifetime cost for each child born with spina bifida is estimated to be \$791,900.

19 24. Fortunately, there are ways to decrease the risk of neural tube defects, including spina
20 bifida. According to the CDC, folic acid supplementation and fortification have reduced the number
21 of babies born with neural tube defects by 35%—which is 1,300 babies each year.

22 25. Although folic acid supplementation cannot prevent all neural tube defects, it can
23 prevent up to *70 percent* of potential neural tube defects. The CDC estimates that folic acid
24 supplementation and fortification has led to an annual savings of \$508 million for the neural tube-
25 affected births that were prevented.

26 26. Prenatal vitamins provide many other benefits beyond preventing neural tube defects.
27 According to the NIH, folic acid supplementation increases the likelihood of full-term births and
28 lowers the risk of preterm birth.

1 27. The NIH also states that “folic acid, in combination with a multivitamin supplement,
2 helps minimize the risk of congenital heart defects.” For example, one study showed that congenital
3 heart defects were 24 percent less common in the infants of women who took multivitamins than in
4 infants of women who did not take multivitamins. Studies have also found that prenatal vitamins
5 reduce the incidence of urinary tract anomalies, oral facial clefts, limb defects, and hydrocephalus.

6 28. The iron in prenatal vitamins is also important. It supports the baby’s growth and
7 development, and helps prevent anemia in pregnant women. Many pregnant women do not obtain
8 sufficient iron from their diet to meet their body’s increased need during pregnancy, and this iron
9 deficiency can lead to anemia. Preventing iron-deficiency anemia cuts the risk of preterm delivery,
10 low birth weight, and infant mortality.

11 29. Further, calcium in prenatal vitamins helps children grow strong bones and teeth as
12 well as healthy nerves and muscles (including the heart).

13 30. Because many of these vitamins and minerals are most important at the beginning of
14 pregnancy, it is vital that women take a prenatal vitamin before they become pregnant and during the
15 first few weeks of their pregnancy. For example, neural tube defects occur in the first month of
16 pregnancy, before many women find out that they are pregnant. Physicians therefore prescribe
17 prenatal vitamins to women who may become pregnant, in addition to women who are pregnant.

18 **II. Medical Organizations And Government Authorities Recommend That All Women**
19 **Who Are Or May Become Pregnant Take A Prenatal Vitamin With Folic Acid.**

20 31. Leading government authorities recommend that all women who are pregnant, or may
21 become pregnant, take a folic acid prenatal vitamin. For example:
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Organization	Statement ¹
Food and Drug Administration	<p>“If you’re a woman of childbearing age who may become pregnant or is in the first trimester of pregnancy, consume adequate synthetic folic acid daily.”</p> <p>“Taking folic acid before you're pregnant is essential in reducing the risk of birth defects.”</p>
National Institutes of Health	<p>“Taking folic acid regularly before becoming pregnant and during early pregnancy helps prevent neural tube defects in babies. But about half of all pregnancies are unplanned. Therefore, all women and teen girls who could become pregnant should consume 400 mcg of folic acid daily from supplements, fortified foods, or both in addition to the folate they get naturally from foods.”</p>
Centers for Disease Control	<p>“Folic acid . . . can help prevent major birth defects. Take a vitamin with 400 micrograms (mcg) of folic acid every day, before and during pregnancy.”</p>
United States Public Health Service	<p>“[A]ll women of childbearing age consume 400 micrograms (mcg) of folic acid daily to reduce the risk of having a pregnancy affected by birth defects.”</p>
Institute of Medicine	<p>“[W]omen capable of becoming pregnant should take 400 micrograms of synthetic folic acid daily, from fortified foods or supplements or a combination of the two, in addition to consuming food with folate from a varied diet.”</p>

32. The American College of Obstetricians and Gynecologists, American Academy of Family Physicians, American Academy of Pediatrics, American Academy of Neurology, and the American College of Medical Genetics and Genomics all recommend that women who may become pregnant take a prenatal vitamin supplement to ensure that they obtain adequate amounts of folic acid and other nutrients.

¹ <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm118079.htm>;
<https://www.fda.gov/Food/ResourcesForYou/HealthEducators/ucm089330.htm>;
<https://ods.od.nih.gov/factsheets/Folate-Consumer/>; <https://www.cdc.gov/pregnancy/during.html>;
 Department of Health and Human Services, Public Health Service. Recommendations for the Use of Folic Acid to Reduce the Number of Cases of Spina Bifida and other Neural Tube Defects. Mortality and Morbidity Weekly Report. 1992; 41/No.RR-14: 1-7.

1 33. Following these guidelines and recommendations, many physicians in the United
2 States direct their patients take a prenatal vitamin if they are pregnant or may become pregnant.
3 Many of these physicians prescribe a prescription prenatal vitamin so that they can select the prenatal
4 vitamin formula that they think best fits their particular patient’s needs. Physicians also use a
5 prescription product so that they can better monitor patient compliance. Evidence further shows that
6 patients are more likely to comply with this recommendation if the physician prescribes a prescription
7 product and oversees its use.

8 **III. Medicaid Statute And Regulations Require States To Cover Prescription Prenatal**
9 **Vitamins.**

10 34. Medicaid provides health coverage to millions of Americans, including low-income
11 adults, children, pregnant women, elderly adults, and people with disabilities. All states, the District
12 of Columbia, and the U.S. territories have Medicaid programs.

13 35. Federal law give states the option to provide a prescription drug benefit, but if a state
14 decides to provide one (as all fifty states and all federal territories have chosen to do), the program
15 must comply with certain requirements outlined by federal law and regulations. One of these
16 requirements is that state Medicaid plans must reimburse “covered outpatient drugs.”

17 36. Federal law also specifically requires state Medicaid plans to provide coverage for
18 prescription prenatal vitamins. 42 U.S.C. § 1396r-8(d)(2)(F) (2012) (allows states to exclude from
19 coverage “[p]rescription vitamins and mineral products, **except prenatal vitamins**”) (emphasis
20 added).

21 37. Interpreting this statute, the Centers for Medicare & Medicaid Services (“CMS”) have
22 stated that “[w]e read these provisions in context to provide that **prescription prenatal vitamins** ...
23 would qualify as [covered outpatient drugs], [and] **states may not restrict or exclude from**
24 **coverage.**” 81 Fed. Reg. 5170, 5188 (Feb. 1, 2016) (codified at 42 C.F.R. Part 447) (emphasis
25 added)

26 38. In a December 28, 2011 announcement, CMS confirmed that “prescription prenatal
27 vitamins continue to meet the definition of a covered outpatient drug and are rebate-eligible.”
28 Release, Centers for Medicare & Medicaid Services, Use of Utilization Data for Calculation of

1 Annual Branded Prescription Drug Fee (Release No. 159) (Dec. 28, 2011) (attached hereto as Exhibit
2 A). State Medicaid programs must therefore cover prescription prenatal vitamins as covered
3 outpatient drugs. As a result, all fifty states and the federal territories provide coverage for
4 prescription prenatal vitamins.

5 39. Consistent with these state programs, and Congress's mandate, many private
6 insurance plans also provide coverage for prescription prenatal vitamins. The terms of individual
7 drug plans are variable, but many cover *only* prescription prenatal vitamins, and not over-the-counter
8 options.

9 **IV. Exeltis Sells Prescription Prenatal Vitamins That Are Covered Outpatient Drugs And**
10 **Must Be Covered Under State Medicaid Programs.**

11 40. Exeltis and a number of other manufacturers sell their prenatal vitamins through
12 prescription only. Exeltis sells eleven different types of prescription prenatal vitamins, including:
13 Vitafol-One, Vitafol, Select-Ob+DHA, Vitafol-OB+DHA, Vitafol-OB, Vitafol Ultra, Vitafol Nano,
14 Vitafol Fe Plus, Select-OB Chewables Caples, and Vitafol gummies. Each of Exeltis's prescription
15 prenatal vitamins has a variety of vitamins and minerals, including 1 mg of Folic Acid or Folate.

16 41. Physicians across the United States can and do prescribe these Exeltis products. The
17 products cannot be purchased by consumers or sold by pharmacists *without a prescription*. The
18 products are not available at retail stores or on retail shelves.

19 42. In its official drug data file, CMS states that the "Drug Type" is "Rx" or
20 "prescription" for each of Exeltis's products.

21 43. In its official drug data file, CMS states that each of these products as "covered
22 outpatient drugs" because they are "prescription prenatal vitamins," which means that they must be
23 covered by state Medicaid programs.

24 44. After performing a comprehensive review and making revisions to its drug file, CMS
25 has confirmed that Exeltis's products are "prescription prenatal vitamins" and must be covered by
26 Medicaid programs. In December 2011, CMS indicated that "[they] recently bec[a]me aware of
27 some non-prescription (OTC) products" that had been incorrectly labeled as prescription and covered
28 outpatient drugs. Release No. 159 (Ex. A). To correct this problem, CMS "identifie[d] these

1 products for deletion” from their drug data file. *Id.* CMS made clear that only “*prescription prenatal*
2 *vitamins . . . meet the definition of a covered outpatient drug and are rebate-eligible.*” *Id.* After this
3 sweep of their data file, CMS has continued to code Exeltis’s prescription prenatal vitamins as
4 prescription and covered outpatient drugs, because that is what they are.

5 45. Further confirming that Exeltis’s products are covered outpatient drugs, Exeltis has
6 entered into a Medicaid Drug Rebate Agreement with CMS, which is used for manufacturers that sell
7 prescription products covered by Medicaid. This agreement is mutually binding on both parties and
8 requires Exeltis to pay rebates to the states based on the states’ utilization of the manufacturer’s
9 products that qualify as covered outpatient drugs. Exeltis pays rebates to the states on a quarterly
10 basis pursuant to this agreement.

11 **V. For Decades, First Databank Properly Coded Exeltis’s Products As “Prescription” And**
12 **Enabled Medicaid And Private Plans To Cover Them.**

13 46. After a doctor writes a prescription, the patient typically presents the prescription at a
14 pharmacy and the pharmacist submits a claim to the patient’s insurance company (payor) for
15 reimbursement. The pharmacy must quickly determine whether the product is covered by the
16 patient’s insurance, so the pharmacy can determine how much to charge the patient.

17 47. To do this, all pharmacies and payors in the U.S. use a standard and automated
18 computer process: the pharmacy enters the drug’s code into a computer system and that information
19 is sent to the payor, allowing the payor to process the claim. The payor uses a drug compendia—
20 most often First Databank—to adjudicate the claim and determine whether the drug is covered. This
21 adjudication process takes into account a number of drug characteristics, including the prescription
22 status. The system is automated and informs the pharmacy of the result in approximately three
23 seconds.

24 48. First Databank and other industry participants know that one of the first-level rules in
25 the algorithm for many Medicaid and commercial plans is the distinction between “prescription” and
26 “Non-Rx” (or over-the-counter). For many payors, prescription products are covered, and over-the-
27 counter products are not.

28 49. For decades, First Databank has coded prenatal vitamins that are sold by

1 prescription—like Exeltis’s—as “F,” which stands for “prescription.” In particular as shown in the
 2 the screenshot from Databank’s August 2016 MedKnowledge description of codes below, First
 3 Databank describes its “F” code as “indicating the product requires a prescription for dispensing.”

4 • Drug Class (CL) column equals the value of F, indicating the product requires a prescription for
 5 dispensing, and

6 First Databank, FDB MedKnowledge U.S. at 379 (updated Aug. 2016) (excerpts attached hereto as
 7 Exhibit B).

8 First Databank’s long-standing decision to code these prescription prenatal vitamins as
 9 “prescription” matches the official CMS database as well as the code applied by all other private
 10 database companies.

11 50. Indeed recognizing that Congress and common sense require this coding, First
 12 Databank has expressly defined the “F” or “prescription” class code to include “*pregnancy vitamins*
 13 *labeled as prescription.*” This screenshot is taken from First Databank’s August 2016
 14 MedKnowledge description of class codes:

15 FDB MedKnowledge™ U.S. Documentation August 2016 

16

17 **CL**

18 **Class**

19 A one character alphanumeric value that identifies a product’s prescription status.

20 **Valid Values Table**

CL	Description
F	Drugs that are prohibited by federal law from being dispensed without a prescription; bulk drug ingredients for compounding; prenatal vitamins labeled as prescription; or prescription medical devices.
O	Products with no federal legal prescription requirement, including medical foods, nutritional supplements, non-prescription medical devices and over-the-counter drugs.

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26 Ex. B at 2506. Upon information and belief, this First Databank coding document is still in
 27 circulation and the definition has not been revoked or revised.

28 51. Because First Databank properly coded Exeltis’s prescription prenatal vitamins, they

1 have been reimbursed by Medicaid programs and private insurers across the country. Forty-one
2 percent of Exeltis's sales of prenatal vitamins are to Medicaid participants, and most of the remaining
3 sales (53%) are covered by private insurance.

4 **VI. Thousands of Women Rely On Medicaid and Private Insurance Coverage For Their**
5 **Prescription Prenatal Vitamins.**

6 52. Unfortunately all women do not take or have access to prenatal vitamins. In one
7 study, only 78% of pregnant women reported prenatal vitamin use. Usage dropped to just 47%
8 among women who are not pregnant, but could become pregnant.

9 53. One of the most important factors in predicting compliance with prenatal vitamin
10 recommendations is income. Women with higher incomes are far more likely to take prenatal
11 vitamins than women with low incomes.

12 54. Medicaid-eligible women represent nearly half of all pregnancies in the United States.
13 Medicaid coverage of prescription prenatal vitamins is therefore crucial to ensuring that nearly half of
14 all babies receive the proper amount of folic acid and are born without crippling and life-threatening
15 birth defects.

16 55. Each year, Medicaid covers millions of prenatal vitamins prescriptions. With this
17 coverage, Medicaid-eligible woman can obtain prescription prenatal vitamin supplements for free or
18 for a nominal copay of 50 cents to \$5. Medicaid's coverage provides women with access to these
19 life-saving products. Without Medicaid coverage, these women likely cannot afford these
20 prescription or other over-the-counter vitamins, which can cost as much as \$160 per month.

21 56. Race and ethnicity are also closely correlated with folic acid intake. Black and
22 Hispanic women are less likely than white women to have adequate intake of folic acid and other
23 important vitamins and nutrients.

24 57. Even for women with greater financial means, private insurance plays an important
25 part in ensuring access to prescription prenatal vitamins. Each year, private insurance plans cover
26 millions of prenatal vitamin prescriptions as well.

1 **VII. First Databank Announced Plans To Falsely And Deceptively Code Prescription**
2 **Prenatal Vitamins.**

3 58. First Databank announced that on September 15, 2017, it will change the code on all
4 prescription prenatal vitamins—including Exeltis’s prescription prenatal vitamins—from
5 “prescription” (“F”) to “Non-Rx” or over-the-counter (“O”).

6 59. This over-the-counter code is facially false. Exeltis’s prenatal vitamins are sold only
7 by prescription. As the FDA recently stated—in a letter to *First Databank*—“OTC [over-the-
8 counter] drugs . . . can be purchased by consumers without a prescription as they are generally
9 available at the retail level.” See Letter from A. Lotz, Medical Director, Infant Formula and Medical
10 Foods Staff, FDA, to Reem Mohamed, Manager, Editorial Content, First Databank, Inc. (June 29,
11 2017) (obtained pursuant to Freedom of Information Act request) (attached hereto as Exhibit C).
12 Exeltis’s prenatal vitamins do not meet this definition. They *cannot* be purchased without a
13 prescription, and they are *not* available at the retail level.

14 60. First Databank has defended its “Non-Rx” description by arguing that—in its view—
15 federal law does not require the company to sell prenatal vitamins with a prescription. But Congress
16 and CMS have already determined that this is irrelevant for reimbursement and unnecessary to
17 establish the “prescription” status of prenatal vitamins.

18 61. FDA has rejected this argument too. In the same letter to First Databank, FDA
19 explained that it was wrong to call certain medical food products over-the-counter because “although
20 not required by federal law to be dispensed by prescription, physicians can and do write prescriptions
21 for medical foods . . . and [i]mportantly these products cannot simply be obtained from a retail
22 establishment.” Ex. C. Just like medical food products, prescription prenatal vitamins “must be
23 acquired through pharmacies [or] physicians.” *Id.* They are not available at retail, and it is false to
24 describe them as over-the-counter.

25 62. Even First Databank *itself* has rejected that argument. First Databank expressly
26 defines the “F” or “prescription” category to include “prenatal vitamins labeled as prescription.” Ex.
27 B at 2506. Prescription prenatal vitamins must be coded as “prescription” because that is what
28 federal law and common sense requires. First Databank has admitted this and its new attempt to

1 move prescription prenatal vitamins to the “O” category is false even by the plain terms of First
2 Databank’s own documentation.

3 63. First Databank’s over-the-counter description is also deceptive and unfair because, as
4 further explained below, it will cause state Medicaid programs to violate the federal Medicaid statute
5 and delegations. By coding these products *not prescription*, First Databank will cause many Medicaid
6 programs to deny coverage erroneously and, thus, violate federal law.

7 64. Further demonstrating the falsity of First Databank’s proposed coding is the fact that
8 *no other drug coding company is making this change*. The second largest drug database company—
9 Medi-Span—intends to continue coding prescription prenatal vitamins as “prescription.” The third
10 leading database, Gold Standard, will not be making the change either. Indeed, no other drug
11 database has indicated that it will follow First Databank’s false and deceptive change.

12 65. Nor is the government changing its database to match First Databank’s revision.
13 CMS’s drug file will maintain the “Rx” and “prescription” designation for Exeltis’s prescription
14 prenatal vitamins.

15 66. First Databank has made this change simply to do the bidding of its payor customers
16 that want to save money. The change “was prompted by questions from customers,” and on
17 information and belief, these “customers” were commercial payors that did not want to pay for
18 medical foods and dietary supplements, including prescription prenatal vitamins.

19 **REASONS FOR PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF**

20 **VIII. First Databank’s False And Deceptive Coding Will Deny Patients Access To**
21 **Prescription Prenatal Coverage.**

22 67. First Databank’s proposed new coding will cause Third Party Payors—both Medicaid
23 and private insurance plans—erroneously to deny coverage for prescription prenatal vitamins.

24 68. First Databank knows that many Medicaid and private insurance plans cover
25 prescription medical products but do not over-the-counter products. First Databank further knows
26 and intends that claims processors that administer these plans rely on First Databank’s coding of
27 medical products—whether prescription or over-the-counter—to make coverage decisions. By
28 changing the code of Exeltis’s—and all other prescription prenatal products—from “prescription” to

1 “over the counter,” First Databank is knowingly causing these products to go uncovered for the
2 significant number of health plans that do draw a distinction between over the counter and
3 prescription prenatal vitamins.

4 69. On information and belief, First Databank knows that its change will cause denials:
5 FDA has already told the company that denials were caused by a previous “prescription” to “over-
6 the-counter” change that First Databank made. As FDA stated in the context of medical foods, “FDA
7 has been made aware of patients who are losing or have lost insurance coverage for their products
8 marketed as medical foods . . . [because] insurance providers belie[ve] that the products are over the
9 counter” based on First Databank data. Ex. C.

10 70. Similarly, Express Scripts—the largest pharmacy benefit manager in the United
11 States—announced in a letter that, because First Databank “now classifies all medical foods as [over-
12 the-counter] items,” it will deny coverage because “some pharmacy benefit plans do not cover OTC
13 products.” The same will happen if First Databank changes Exeltis’s prescription prenatal vitamins
14 from “prescription” to “over-the-counter.” There will be widespread denials.

15 71. First Databank knows and intends that its data will be used this way. Indeed, First
16 Databank advertises that “[t]he challenge for HMOs, PPOs, PBMs, and other payors is clear: Drug
17 claims processing and adjudication, once just business as ordinary, has become increasingly pivotal. .
18 . . . Leverage the value of highly reliable drug knowledge to provide your decision makers with all the
19 information they need and in precisely the way they need it.” First Databank, *Drug Claims*
20 *Processing*, <http://www.fdbhealth.com/solutions/drug-claims-processing/> (last visited Aug. 15, 2017).

21 72. First Databank also states that its database, “FDB MedKnowledge[,] offers
22 actionable, intuitive, and targeted drug knowledge to facilitate drug . . . reimbursement decisions.”
23 First Databank also advertises that its “[d]etailed product information enables thorough drug-
24 formulary checking . . . to confirm formulary inclusion for Medicare Part D and other private
25 insurers.” First Databank, *FDB MedKnowledge*, [http://www.fdbhealth.com/solutions/fdb-
26 medknowledge/](http://www.fdbhealth.com/solutions/fdb-medknowledge/) (last visited Aug. 15, 2017).

27 73. The impact of First Database’s change will also be far reaching: First Databank
28 claims its databases are “the industry’s most widely used, integrated drug database,” *id.*, and are

1 involved in 1.88 billion retail pharmacy prescriptions and 3.26 billion prescription claims annually.
 2 First Databank claims that its databases are used by eight of the top nine pharmacy benefit managers,
 3 representing 95.9% of total annual prescription volume in the United States, and by the top three
 4 major drug product wholesalers, controlling 85% of the market. Forty-three state Medicaid programs
 5 also use First Databank.

6 **IX. Denying Patients Access To Prenatal Vitamins Will Cause Irreparable Harm To**
 7 **Thousands Of Women And The Plaintiff.**

8 74. If First Databank changes the coding for Exeltis’s prescription prenatal vitamins,
 9 women will be denied coverage. Women would only be able to continue taking the prescription
 10 prenatal vitamin that *they were prescribed* if they pay full price.

11 75. Many women—both those eligible for Medicaid and those who rely on commercial
 12 insurance plans—will be unable to afford the full price for prescription or over-the-counter prenatal
 13 vitamins, and these women will thus not be able to take them. The medical advancements of the past
 14 20 years will begin to reverse, and this will cause more babies to be born with preventable birth
 15 defects. Money damages are insufficient to repair this harm.

16 76. First Databank’s conduct will also cause harm to Exeltis’s business. Its sales, profits,
 17 and goodwill will all suffer. Approximately 40% of Exeltis’s prenatal vitamin sales are to women
 18 who are Medicaid-eligible. Without coverage of prescription prenatal vitamins, these sales will drop
 19 to basically zero, which would destroy Exeltis’s business model and could endanger its viability.

20 **COUNT I**
 21 **LANHAM ACT, 15 U.S.C. § 1125(a)(1)**

22 77. Exeltis incorporates the allegations in Paragraphs 1 through 76 here by reference.

23 78. The Lanham Act, 15 U.S.C. § 1125(a)(1)(B), prohibits the use in commercial
 24 advertising or promotions of “any word, term, name, symbol or device, or any combination thereof,
 25 or any . . . false or misleading description of fact, or false or misleading representation of fact” that
 26 “misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another
 27 person’s goods, services, or commercial activities.” The Lanham Act also authorizes “any person
 28 who believes that he or she is or is likely to be damaged by” such a violation to file a civil action for

1 an injunction and compensatory damages.

2 79. First Databank has and will violate § 1125(a)(1)(B) by falsely and deceptively
3 describing Exeltis's prescription prenatal vitamins as "Non-Rx" or "over-the-counter."

4 80. First Databank has and will violate this statute by misrepresenting the nature,
5 characteristics, and qualities of Exeltis's prescription prenatal vitamins.

6 81. First Databank has misrepresented the nature, characteristics, and qualities of its own
7 drug information resources too. First Databank claims in its commercial advertising and promotion
8 that its drug information resources are accurate, when they clearly are not with respect to prescription
9 prenatal vitamins.

10 82. These statements have all been made in interstate commerce.

11 83. These misrepresentations are material and are reasonably relied on by payors. These
12 representations will cause payors to change reimbursement decisions. The misrepresentations will
13 also cause payors to purchase First Databank's products. Payors would not do so if they knew that
14 First Databank was disseminating inaccurate information that was inconsistent with industry standard
15 practices and federal law.

16 84. These misrepresentations have harmed and will harm Plaintiff in terms of lost
17 revenue and goodwill.

18 85. Exeltis therefore is entitled, under the Lanham Act, to an injunction and damages.

19 **COUNT II**
20 **UNFAIR COMPETITION LAW, Cal. Bus. & Prof Code § 17200 et seq.**

21 86. Exeltis incorporates the allegations in Paragraphs 1 through 85 here by reference.

22 87. California's Unfair Competition Law prohibits "unlawful, unfair, or fraudulent"
23 conduct in business activities.

24 88. First Databank has violated and threatened to violate California's Unfair Competition
25 Law by making materially false and misleading representations about Exeltis's prescription prenatal
26 vitamins and its own databases, particularly by coding Exeltis's prescription prenatal vitamins as
27 over-the-counter.

28 89. First Databank's conduct is unlawful as it violates federal and state law, including the

1 Lanham Act, California False Advertising Law, the California Consumer Legal Remedies Act, and
2 federal Medicaid statutes and regulations.

3 90. First Databank's conduct constitutes an unfair trade practice because its statements
4 are false and misleading. The conduct is also unfair because it will deny women with fewer financial
5 resources access to prescription prenatal vitamins that prevent birth defects. First Databank's conduct
6 is immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers.

7 91. First Databank's conduct is also fraudulent. It will deceive Medicaid programs into
8 violating federal law and deceive private insurance plans into violating their agreements with their
9 customers.

10 92. First Databank's statements are material and relied on by payors. Payors rely on First
11 Databank's representations when determining whether to reimburse a product, which in turn
12 influences whether customers purchase Plaintiff's products. There can be no doubt that First
13 Databank knows and intends that payors use its databases for these purposes. This is why First
14 Databank makes them. First Databank also makes representations about its own databases to induce
15 payors to purchase its products. The coding is also material to patients who cannot (or will not)
16 purchase these products if they are not covered by Medicaid or insurance.

17 93. First Databank's conduct offends public policy and causes substantial injury to
18 consumers by denying women access to prescription prenatal vitamins, a beneficial product relied
19 upon by women across the United States to prevent serious birth defects.

20 94. First Databank's conduct causes substantial injury to Exeltis by misrepresenting the
21 true nature of Exeltis's prescription prenatal vitamins, and therefore decreasing its sales, revenue,
22 goodwill, harming its reputation, and placing it at a competitive disadvantage.

23 95. First Databank's conduct causes substantial injury women across the country as well.
24 By misrepresenting the status of all prescription prenatal vitamins, First Databank will cause state
25 Medicaid programs and private insurance plans to deny coverage for patients, causing them to pay
26 out-of-pocket for prenatal vitamins. Many patients will not be able to afford the substantially
27 increased price for these prescription vitamins or any other over-the-counter prenatal vitamins, and
28 thus, their children will be at an increased risk of being born with a neural birth defect.

1 96. These injuries are substantial and not outweighed by any countervailing benefits to
2 consumers.

3 **COUNT III**
4 **FALSE ADVERTISING LAW, Cal. Bus. & Prof. Code § 17500 et seq.**

5 97. Exeltis incorporates the allegations in Paragraphs 1 through 96 here by reference.

6 98. First Databank is threatening to publish false information about Exeltis's prenatal
7 vitamins in the drug databases that it sells to payors nationwide.

8 99. First Databank's advertising statements that Exeltis's prescription prenatal products
9 are Non-Rx and over-the-counter are false, untrue, and misleading. They are likely to deceive payors
10 and the public. First Databank also makes false and misleading statements about the accuracy and
11 completeness of its drug databases.

12 100. First Databank knows or should have known that these statements are untrue. Exeltis
13 has explained this to First Databank on numerous occasions. Moreover, all other drug files—both
14 private and government—correctly code these products as “prescription” and “Rx.”

15 101. First Databank's conduct will cause financial injury to women who need prescription
16 prenatal vitamins. It will also injure Exeltis in its business. Exeltis will suffer losses in sales,
17 revenue, goodwill, and harm to its reputation as a result of First Databank's conduct.

18 **COUNT IV**
19 **INTENTIONAL INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE**

20 102. Exeltis incorporates the allegations in Paragraphs 1 through 101 here by reference.

21 103. The common law prohibits intentional interference with prospective economic
22 advantage.

23 104. Exeltis has business relationships, including both contractual and beneficial
24 relationships, with purchasers of its prescription prenatal vitamins, including distributors, HMOs,
25 hospitals, physicians, pharmacies, PBMS, insurers, and other healthcare providers who purchase its
26 prescription prenatal vitamins. Exeltis also has business relationships with patients.

27 105. Exeltis had a reasonable business expectancy of selling additional prescription
28 prenatal vitamins to these purchasers and patients.

1 106. First Databank knows that Exeltis has such business relationships with purchasers of
2 its prescription prenatal vitamins and the economic benefits that flow from them.

3 107. First Databank will intentionally and tortuously interfere with Exeltis's business
4 relationships if it changes its coding and misrepresents to payors and patients regarding the nature of
5 Plaintiff's prescription prenatal vitamin supplements. If it makes this change, First Databank will
6 falsely characterize these products as "Non-Rx" or over-the-counter. As a result, many Medicaid
7 state plans and other payors will not reimburse for these products.

8 108. Because these products will not be reimbursed, Exeltis's business relationships and
9 contracts will be harmed. Many of its customers and patients will stop purchasing its products
10 because First Databank is causing them not to be reimbursed.

11 109. First Databank has no legitimate justification for its interference.

12 110. This interference is wrongful as it will cause Medicaid programs to violate federal
13 law and cause many commercial payors to violate their plans.

14 111. Exeltis will suffer actual financial losses as a result of First Databank's interference,
15 including lost profits from the sales of its prescription prenatal products, diversion of sales, and loss
16 of goodwill.

17 112. Plaintiff is entitled to injunctive relief, monetary damages to recoup the lost benefits
18 of their business expectancies, the consequential damages caused by First Databank's interference, all
19 lost profits, punitive damages, and attorney fees and costs.

20 **COUNT V**
21 **TRADE LIBEL**

22 113. Exeltis incorporates the allegations in Paragraphs 1 through 112 here by reference.

23 114. The common law prohibits trade libel.

24 115. When it undertakes its announced coding change, First Databank will publish false
25 and disparaging written materials that Exeltis's prescription prenatal vitamins are "Non-Rx" and
26 over-the-counter.

27 116. These false and disparaging statements will have been made in writing and will be
28 published in First Databank's various database, including to pharmacies that purchase and resell

1 Exeltis's prescription products.

2 117. First Databank knows—in part, because Exeltis has told it—that these statements will
3 be false and that these statements will decrease access to prescription prenatal products, harming both
4 women and Exeltis's business.

5 118. Exeltis will suffer special damages as a result of this conduct, in the form of lost
6 product sales and market share due to First Databank's false and defamatory statements.

7 **RELIEF SOUGHT**

8 Exeltis respectfully requests that this Court:

- 9 a. Issue a preliminary and permanent injunction enjoining First Databank from falsely
10 and misleadingly characterizing Exeltis's prescription prenatal vitamins;
- 11 b. Issue a declaration that Exeltis's prescription prenatal vitamins cannot lawfully be
12 coded as "Non-Rx";
- 13 c. Award compensatory damages for any lost sales of its prescription prenatal vitamins;
- 14 d. Award trebled and/or punitive damages for First Databank's misconduct;
- 15 e. Order disgorgement of First Databank's profits;
- 16 f. Award costs, attorney fees, and pre- and post-judgment interest;
- 17 g. Enter any other relief that is just and proper.

18
19 Dated: August 17, 2017

Respectfully Submitted,

20 By: /s/ Ryan M. Sandrock

21 Ryan M. Sandrock (SBN 251781)
22 rsandrock@sidley.com
23 Sidley Austin LLP
24 555 California Street
25 Suite 2000
26 San Francisco, CA 94104
27 Telephone: +1 415 772 1200
28 Facsimile: +1 415 772 7400

Richard D. Raskin (*pro hac motion forthcoming*)
rraskin@sidley.com
Sidley Austin LLP

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One South Dearborn
Chicago, Illinois 60603
Telephone: +1 312 853 7000
Facsimile: +1 312 853 7036

Benjamin M. Mundel (*pro hac motion forthcoming*)
bmundel@sidley.com
Sidley Austin LLP
1501 K St NW
Washington, DC 20005
Telephone: +1 202 736 8157
Facsimile: +1 202 736 8711

Attorneys for Plaintiff
EXELTIS USA, INC.