

**UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET**

I (a) PLAINTIFFS (Check box if you are representing yourself <input type="checkbox"/>) Valeant Pharmaceuticals International	DEFENDANTS Michael O. Leavitt, Secretary of U.S. Dep't of Health and Human Services; Andrew C. von Eschenbach, M.D., Commissioner of the Food and Drug Administration
(b) County of Residence of First Listed Plaintiff (Except in U.S. Plaintiff Cases): Orange County, California	County of Residence of First Listed Defendant (In U.S. Plaintiff Cases Only):
(c) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.) Hogan & Hartson, LLP, 1999 Avenue of the Stars, Suite 1400, Los Angeles, CA 90067 (310) 785-4600	Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an X in one box only.) Case 8:08-cv-00449-AGS Document 1 Filed 04/25/2008 Page 1 of 13

<input type="checkbox"/> 1 U.S. Government Plaintiff <input type="checkbox"/> 3 Federal Question (U.S. Government Not a Party)	(Place an X in one box for plaintiff and one for defendant.) Citizen of This State PTF DEF <input type="checkbox"/> 1 <input type="checkbox"/> 1 Incorporated or Principal Place of Business in this State <input type="checkbox"/> 4 <input type="checkbox"/> 4
<input checked="" type="checkbox"/> 2 U.S. Government Defendant <input type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III)	Citizen of Another State PTF DEF <input type="checkbox"/> 2 <input type="checkbox"/> 2 Incorporated and Principal Place of Business in Another State <input type="checkbox"/> 5 <input type="checkbox"/> 5
	Citizen or Subject of a Foreign Country PTF DEF <input type="checkbox"/> 3 <input type="checkbox"/> 3 Foreign Nation <input type="checkbox"/> 6 <input type="checkbox"/> 6

IV. ORIGIN (Place an X in one box only.)

<input checked="" type="checkbox"/> 1 Original Proceeding	<input type="checkbox"/> 2 Removed from State Court	<input type="checkbox"/> 3 Remanded from Appellate Court	<input type="checkbox"/> 4 Reinstated or Reopened	<input type="checkbox"/> 5 Transferred from another district (specify):	<input type="checkbox"/> 6 Multi-District Litigation	<input type="checkbox"/> 7 Appeal to District Judge from Magistrate Judge
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V. REQUESTED IN COMPLAINT: JURY DEMAND: Yes No (Check 'Yes' only if demanded in complaint.)

CLASS ACTION under F.R.C.P. 23: Yes No MONEY DEMANDED IN COMPLAINT: \$ _____

VI. 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.)
 Challenge to the FDA's approval of an Abbreviated New Durg Application as arbitrary and capricious under the Administrative Procedure Act, 5 U.S.C. 500, et al.

VII. NATURE OF SUIT (Place an X in one box only.)

OTHER-STATUTES <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce/ICC Rates/etc. <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities /Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input checked="" type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Act <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Info. Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes	CONTRACT <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loan (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	TORTS PERSONAL INJURY: <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Fed. Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury-Med Malpractice <input type="checkbox"/> 365 Personal Injury-Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability	TORTS PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability BANKRUPTCY <input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 American with Disabilities - Employment <input type="checkbox"/> 446 American with Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus/Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition FORFEITURE/PENALTY <input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs <input type="checkbox"/> 660 Occupational Safety /Health <input type="checkbox"/> 690 Other	LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS-Third Party 26 USC 7609
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VIII(a). IDENTICAL CASES: Has this action been previously filed and dismissed, remanded or closed? No Yes

If yes, list case number(s): _____

FOR OFFICE USE ONLY: Case Number: SACV08-00449 AG (AGRx)

**UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET**

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

VIII(b). RELATED CASES: Have any cases been previously filed that are related to the present case? No Yes

If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:

- (Check all boxes that apply) A. Arise from the same or closely related transactions, happenings, or events; or
 B. Call for determination of the same or substantially related or similar questions of law and fact; or
 C. For other reasons would entail substantial duplication of labor if heard by different judges; or
 D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: List the California County, or State if other than California, in which EACH named plaintiff resides. (Use an additional sheet if necessary.)
 Check here if the U.S. government, its agencies or employees is a named plaintiff.
 Orange County, California

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List the California County, or State if other than California, in which EACH named defendant resides. (Use an additional sheet if necessary).

- Check here if the U.S. government, its agencies or employees is a named defendant.
 Michael O. Leavitt - Washington, D.C.
 Andrew C. von Eschenbach - Maryland

List the California County, or State if other than California, in which EACH claim arose. (Use an additional sheet if necessary)
 Note: In land condemnation cases, use the location of the tract of land involved.

Maryland

X. SIGNATURE OF ATTORNEY (OR PRO PER): *Daniel D. Conroy* Date April 24, 2008

Notice to Counsel/Parties: The CV-71 (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. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

VALEANT PHARMACEUTICALS INTERNATIONAL

CASE NUMBER

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MICHAEL O. LEAVITT, in his official capacity as
Secretary of the U.S. Department of Health and
Human Services;
and
ANDREW C. VON ESCHENBACH, M.D., in his official
capacity as Commissioner of the Food and Drug Administration

SUMMONS

TO: DEFENDANT(S): MICHAEL O. LEAVITT; and ANDREW C. VON ESCHENBACH, M.D.

A lawsuit has been filed against you.

Within 60 days after service of this summons on you (not counting the day you received it), you must serve on the plaintiff an answer to the attached complaint amended complaint counterclaim cross-claim or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff's attorney, HOGAN & HARTSON, LLP, whose address is 1999 Avenue of the Stars, #1400, Los Angeles, CA 90067. If you fail to do so, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

Clerk, U.S. District Court

Dated: APR 25 2008

By: ROLLS ROYCE PASCHAL
Deputy Clerk



(Seal of the Court)

1144

[Use 60 days if the defendant is the United States or a United States agency, or is an officer or employee of the United States. Allowed 60 days by Rule 12(a)(3)].

1 Richard de Bodo (State Bar No. 128199)
2 J. Drew Diamond (State Bar No. 205028)
3 David G. Chang (State Bar No. 241923)
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U.S. DISTRICT COURT
CENTRAL DISTRICT OF CALIF.
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FILED

7 Attorneys for Plaintiff
8 VALEANT PHARMACEUTICALS INTERNATIONAL

9
10 **UNITED STATES DISTRICT COURT**
11 **CENTRAL DISTRICT OF CALIFORNIA**
12 **SOUTHERN DIVISION**

13 VALEANT PHARMACEUTICALS
14 INTERNATIONAL

Case No. SACV08-00449 AG (AGRx)

15
16 Plaintiff

**VALEANT'S VERIFIED
COMPLAINT**

17 v.

18 MICHAEL O. LEAVITT,
19 *in his official capacity as*
20 *Secretary of the U.S. Department of*
Health and Human Services,

21 and

22 ANDREW C. VON ESCHENBACH,
23 M.D., *in his official capacity as*
24 *Commissioner of the Food and*
Drug Administration,

25
26 Defendants.

COPY

27
28 Valeant's Verified Complaint

1
2 Plaintiff Valeant Pharmaceuticals (“Valeant”), by its undersigned counsel,
3 hereby brings this Verified Complaint against Defendants Michael O. Leavitt, in his
4 official capacity as Secretary of the United States Department of Health and Human
5 Services (“HHS”) and Andrew C. von Eschenbach, M.D., in his official capacity as
6 Commissioner of the United States Food and Drug Administration (“FDA”), and
7 alleges as follows:
8

9
10 **PRELIMINARY STATEMENT**

11 1. This action is brought by Valeant under the Administrative Procedure
12 Act (“APA”) to hold unlawful as arbitrary, capricious, and an abuse of discretion,
13 and to set aside, the FDA’s final approval of Spear Pharmaceutical’s (“Spear’s”)
14 generic version of Valeant’s pioneer drug product, EFUDEX® (fluorouracil) 5%
15 Cream (“Efudex Cream”).

16 2. Valeant’s Efudex Cream is the top-selling topical treatment for patients
17 with a form of skin cancer called “superficial basal cell carcinoma” (“sBCC”),
18 having achieved a 93% success rate in clinical trials for sBCC and having earned the
19 confidence of dermatologists throughout the United States. Efudex Cream is also
20 approved to treat a form of sun-damaged skin called “actinic keratosis” (“AK”).

21 3. On April 11, 2008, the FDA approved Abbreviated New Drug
22 Application No. 77-524 (“ANDA”) for a 5% fluorouracil cream sponsored by Spear
23 and sought to be promoted as a generic version of Efudex Cream (ANDA No. 77-
24 5224). As an ANDA-approved generic, Spear may now promote its cream to treat
25 **both** actinic keratoses and superficial basal cell carcinoma – this despite the fact that
26 Spear’s cream has never been studied in a single cancer patient.
27
28

JURISDICTION AND VENUE

1
2 9. Jurisdiction in this Court is based on 28 U.S.C. § 1331 in that this is a
3 civil action arising under the laws of the United States; the APA, 5 U.S.C. § 551 *et*
4 *seq.* in which Valeant is seeking judicial review of an agency action from which it
5 has suffered a legal wrong, has been adversely affected, and has been aggrieved; 28
6 U.S.C. § 1361 in that this is an action to compel an officer of the United States to
7 perform his duty; and 28 U.S.C. §§ 2201-2202 (declaratory judgment) in that there
8 exists between Valeant and the Defendants an actual, justiciable controversy as to
9 which Valeant requires a declaration of its rights by this Court, as well as temporary,
10 preliminary, and permanent injunctive relief to prohibit the Defendants from
11 violating laws and regulations.

12 10. Venue is proper in this Court under 28 U.S.C. § 1391(e), as Valeant
13 resides in this judicial district.

BACKGROUND

14
15
16 11. Valeant manufactures and markets Efudex Cream, an FDA-approved
17 “innovator” drug (sometimes referred to as a “pioneer,” “brand-name” or “branded”
18 drug). The active ingredient in Efudex is fluorouracil, a chemotherapy agent.

19 12. Efudex Cream is used to treat superficial basal cell carcinoma, among
20 the most common forms of cancer in humans. Ineffectively treated, sBCC could
21 lead to further growth into other parts of the skin, and in some instances, metastasize
22 to nearby parts of the body. Efudex Cream is also used to topically treat multiple
23 actinic keratoses, which are scalings or crustings of the skin caused primarily by
24 overexposure to the sun.

25 13. Efudex Cream was first approved by the FDA over 30 years ago for the
26 treatment of sBCC. To this day, Efudex Cream remains the only topical fluorouracil

1 product on the market that has been demonstrated to be safe and effective for the
2 treatment of this condition.

3 14. On December 22, 2004, Spear, a drug company primarily producing
4 generic dermatological products, filed its ANDA seeking approval of a generic
5 version of Valeant's Efudex Cream. Under relevant portions of the FDCA, parties
6 are permitted to file ANDAs for permission to market and distribute generic forms
7 of FDA-approved innovator drugs, such as Efudex Cream.

8 15. In order for the FDA to approve an ANDA, the applicant must prove
9 that its generic is "bioequivalent" to the innovator drug. Clinical testing on which
10 bioequivalence is established shall be conducted "using the most accurate, sensitive,
11 and reproducible approach available." 21 C.F.R. § 320.24(a).

12 16. The FDA remarkably concluded that as between AK (sun-damaged
13 skin) and sBCC (cancer), clinical testing in AK provided the "most accurate,
14 sensitive, and reproducible approach available" to determine the bioequivalence of
15 Spear's product to Valeant's Efudex cream for the treatment of sBCC.

16 17. In 2004, Valeant filed a Citizen's Petition ("Petition") urging the FDA
17 to require that any proposed Efudex generic should first be tested on cancer patients,
18 as success of the drug in treating sun-damaged skin does not provide evidence that
19 the cream delivers the requisite amount of active ingredient to cancerous skin cells.
20 Valeant submitted scientific evidence showing, among other things, that it is
21 impossible to determine the bioequivalence of such a product based simply upon its
22 effect on sun-damaged skin. In the years that followed, Valeant supplemented its
23 Petition with statements from several experts, as well as other scientific and medical
24 evidence supporting its position.

25 18. The FDA approved Spear's ANDA on April 11, 2008. On the same
26 date, the FDA denied Valeant's Petition and approved Spear's ANDA to market a
27 generic version of Efudex Cream as a treatment for sBCC and AK. In doing so, the
28

1 FDA completely ignored the statements of Valeant's three medical experts and
2 offered a decision that reflects a lack of reasoned decision-making and is filled with
3 internal contradictions.

4 19. The FDA's approval of Spear's generic product required a
5 determination that Spear's product was "bioequivalent" to Valeant's Efudex Cream.

6 20. The FDA conceded that Spear was required to prove bioequivalence
7 through, among other things, clinical trials ("in vivo" or "in the body" testing).
8 However, the FDA's own rules require that clinical testing on which bioequivalence
9 is established must be conducted "using the most accurate, sensitive, and
10 reproducible approach available."

11 21. The FDA concluded that, as between tests on cancer (sBCC) patients
12 and tests on individuals with sun-damaged skin (AK), clinical testing on individuals
13 with sun-damaged skin (AK) provided the "most accurate, sensitive, and
14 reproducible approach available" to determine the bioequivalence of Spear's
15 product to Valeant's Efudex Cream for the treating cancer.

16 22. Several statements offered by the FDA as the basis for its decision to
17 focus on AK testing, and for denying Valeant's petition, are either false or
18 contradict other statements made by the FDA.

19 23. In addition to making contradictory statements in its Response to
20 Valeant's Petition, the FDA failed to consider significant and relevant information
21 and expert statements bearing on the accuracy, sensitivity, and reproducibility of the
22 bioequivalence testing that it relied upon in connection with Spear's ANDA.

23 24. Specifically, the FDA failed to acknowledge or consider any of the
24 following important and relevant information provided by Valeant's experts:

25 25. Howard Maibach, M.D., a world renowned academic dermatologist and
26 professor at University of California San Francisco School of Medicine, showed that
27 AK clinical studies are extremely variable and subjective, depend almost entirely on
28

1 physician observation, and “appear to be unreliable.” Dr. Maibach further
2 concluded that such a comparative clinical study carried out on AK patients could
3 not support a finding of bioequivalence in another indication such as sBCC.

4 26. Khanh P. Tran, M.D., a Board-certified dermatopathologist, showed,
5 using histopathologic slides, that AK and sBCC differ significantly in the cells they
6 first affect, the manner in which they affect those cells, and the cells that they spread
7 into.

8 27. Dennis M. Fisher, M.D., an expert statistician, as well as a physician,
9 showed in statistical terms the difficulty of using information about a topical drug’s
10 performance on individuals with sun-damaged skin to predict its effectiveness in
11 treating patients with skin cancer.

12 CAUSE OF ACTION

13 (Administrative Procedure Act: 14 Violation of the FDCA and Applicable Regulations) 15

16 28. Valeant realleges, reasserts, and incorporates by reference herein each
17 of the allegations contained in paragraphs 1 through 27 of the Complaint, as though
18 set forth fully herein.

19 29. The FDA’s approval of the ANDA for the generic Efudex Cream was
20 unlawful and in violation of the FDCA and the agency’s own regulations.

21 30. The FDA’s approval of the ANDA constitutes final agency action for
22 which Valeant has no other adequate remedy within the meaning of 5 U.S.C. § 704.

23 31. The FDA’s approval of the ANDA was not in accordance with federal
24 law and therefore violates 5 U.S.C. § 706(2)(A).

25 32. The FDA’s approval of the ANDA constitutes agency action in excess
26 of statutory jurisdiction, authority, or limitations, or short of statutory right, in
27 violation of 5 U.S.C. § 706(2)(C).

1 33. Valeant will be irreparably harmed if the Defendants are not required to
2 suspend the FDA's approval of the ANDA because the purported generic was
3 approved in violation of federal law.

4 34. There is no mechanism by which Valeant can be made whole for the
5 injury that would result from the FDA's approval of the ANDA if the approval is
6 not suspended. Valeant is without an adequate remedy at law because of the unique
7 nature of the harm.

8 35. The intent of Congress will be served by an Order directing the FDA to
9 suspend its approval of the ANDA. In addition, the public interest will be served by
10 such an Order.

11
12 **PRAYER FOR RELIEF**

13 WHEREFORE, Valeant requests that this Court enter the following:

14 A. A declaratory judgment pursuant to 28 U.S.C. § 2201(a) in Valeant's
15 favor and against the Defendants, by:


- 16 (i) Declaring that the FDA's action, findings, and conclusion to
17 approve ANDA No. 77-524 were unlawful and in violation of
18 the FDCA;
- 19 (ii) Declaring that the FDA's action, findings, and conclusion to
20 approve ANDA No. 77-524 were arbitrary, capricious, and an
21 abuse of the FDA's discretion;
- 22 (iii) Declaring that the FDA's approval of ANDA No. 77-524 is
23 invalid;
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- 1 B. An Order granting Valeant a temporary, preliminary, and permanent
2 injunction that requires the FDA to suspend its approval of ANDA No. 77-524;
3 C. An award to Valeant of its costs, fees, and expenses; and
4 D. An award of such other and further relief as justice and its cause require.

5 Dated: April 23, 2008

6 Case 8:08-cv-00449-AG-AGR Document 1 Filed 04/25/2008 Page 12 of 13

7 Respectfully submitted,

8
9 By 
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11 J. Drew Diamond (State Bar No. 205028)
12 David G. Chang (State Bar No. 241923)
13 **HOGAN & HARTSON LLP**
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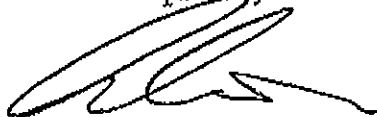
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28 Attorneys for Plaintiff
VALEANT PHARMACEUTICALS
INTERNATIONAL

1 VERIFICATION OF COMPLAINT

2
3 I, Alexandra Coles, citizen of Canada, resident of Orange County, California,
4 and General Manager of Global Dermatology at Valeant Pharmaceuticals
5 International ("Valeant"), verify (i) that I am authorized to make and sign the
6 Verified Complaint as set forth on behalf of Valeant in Valeant's Verified
7 Complaint; (ii) that the facts and matters set forth therein have been generated and
8 assembled by authorized employees, counsel, and experts of Valeant; and (iii) that I
9 am informed and believe that the facts and matters set forth therein are true.

10 I verify under penalty of perjury that the foregoing statement is true and
11 correct.

12 Executed on April 23, 2008 in Milan, Italy.

13
14 By: 
15 Alexandra Coles
16 General Manager of Global Dermatology
17 Valeant Pharmaceuticals International
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