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CHICAGO
DENVER
JACKSONVILLE
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MADISON
MILWAUKEE
ORLANDO

ONE MARITIME PLAZA, SIXTH FLOOR
SAN FRANCISCO, CALIFORNIA 94111-3404
TELEPHONE: (415) 434-4484
FACSIMILE: (415) 434-4507

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SACRAMENTO
SAN DIEGO
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TAMPA
WASHINGTON, D.C.
WEST PALM BEACH

WRITER'S DIRECT LINE
(415) 984-9840

EMAIL ADDRESS
cbrophy@foleylaw.com

CLIENT/MATTER NUMBER
027951-0101

August 8, 2000

VIA FACSIMILE AND U.S. MAIL

Jennifer Butler
Docket Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: FDA Docket 00P-1210/CP1: Comments concerning Gottesfeld Petition for formal review of the conditions of sale, use and distribution of FDA-regulated products containing Coal Tar USP.

Dear Ms. Butler:

As suggested by FDA in its August 7, 2000 letter, Bergen Brunswig Drug Company ("Bergen Brunswig") provides these comments to the U.S. Food and Drug Administration ("FDA") regarding the above-referenced Citizen Petition submitted by Perry Gottesfeld on March 14, 2000 (FDA docket 00P-1210/CP1). Bergen Brunswig is pleased that FDA currently has the Gottesfeld petition under active consideration and welcomes this opportunity to comment.¹ In these comments, we: (1) provide background information regarding the Gottesfeld Petition, specifically, the lawsuits he and his co-plaintiff, the Attorney

¹ We note that Mr. Gottesfeld has recognized the authority of FDA to regulate the safety and effectiveness of pharmaceuticals and their labeling, and has availed himself of the appropriate mechanism, submission of a Citizen's Petition, to raise his concerns. Petitions to amend the Monograph, 21 CFR § 330.10, require careful scrutiny by the FDA in light of the new data offered. Here the petitioner attempts to utilize both to the petition process and also civil lawsuits demanding additional label statements beyond those in the Monograph.

00P-1210

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General of the State of California, have filed against nearly twenty manufacturers, distributors and retailers of shampoos, soaps, ointments and other FDA-regulated products containing Coal Tar, USP; and (2) pose questions relating to FDA's Monograph recognizing the safety and efficacy of the labeling requirements for Coal Tar USP, 21 CFR Part 358, Subpart H (hereinafter "Coal Tar Monograph") and Bergen Brunswig's duties and responsibilities as a manufacturer and distributor of Coal Tar Monograph products under FDA law in light of the court challenge mounted by Gottesfeld and the State of California.

1. **Background of the Gottesfeld Petition.**

Gottesfeld-California lawsuit against pharmaceutical manufacturers, distributors and retailers. FDA should not consider the Gottesfeld Petition in isolation, but should take notice of Mr. Gottesfeld's pending lawsuit against manufacturers, distributors, and retailers of FDA-regulated products containing pharmaceutical grade coal tar that is pending in San Francisco County Superior Court.² In this suit, which is brought jointly with the California Attorney General, plaintiffs allege two counts. The first count contends that defendant manufacturers, distributors and retailers have violated the warning provision of California's Safe Drinking Water and Toxic Enforcement Act of 1986, commonly called "Proposition 65" after the ballot measure under which it was adopted. The gravamen of this charge is (notwithstanding defendants' compliance with FDA regulations concerning sale, labeling and distribution of the products at issue) by dint of a generic listing of "soots, tars and mineral oils" on Proposition 65's list of carcinogens, that additional Proposition 65 warnings informing consumers that coal tar "is known to the state of California to cause cancer" are required when pharmaceutical products containing Coal Tar USP are sold in California. The second count contends that defendants' sale and distribution of subject pharmaceuticals without the California-mandated warnings constitute an unfair trade practice in violation of California Business and Professions Code § 17200.

Although brought under state law, the predicate factual and technical issues the Court will decide are clearly issues that Congress has delegated to FDA under the Federal Food Drug and Cosmetic Act ("FFDCA"). Principal among the determinations that FDA must necessarily make in its review of the Gottesfeld Petition are (1) whether pharmaceuticals containing Coal Tar USP are safe when used in concentrations authorized under the Coal Tar

² *Perry Gottesfeld v. Alva-Amco Pharmacal Cos, Inc., et. al.*, San Francisco Co. Super. Ct., case no. 300643, consolidated with *The People of the State of California ex rel. Bill Lockyer v. Alva-Amco Pharmacal Cos. Inc., et. al.*, San Francisco Co. Super. Ct., case no. 3000827. The consolidated cases are scheduled for trial September 11, 2000. For information, a copy of the Complaints filed by Gottesfeld and the Attorney General and the Answer filed by Bergen Brunswig are enclosed.

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Monograph, or if limitations to the sale, use and distribution of such products are warranted; and (2) what cautions or instructions should be included in the labeling to advise consumers. These questions will also be the focus of the upcoming Proposition 65 litigation, and will be decided by the "finder of fact" - judge or jury - as the case may be.

Unlike the FDA process, the Proposition 65 inquiry will be a "battle of the experts" with the final decision made by the "finder of fact" - who will certainly have little or no medical or scientific expertise.³ Briefly, defendants must prove that when used by the "average consumer" over a "lifetime," that pharmaceutical preparations containing Coal Tar USP will not increase the risk of cancer by more than 1 additional case in 100,000 consumers. This "proof" has two major prongs: (1) the calculation of an so-called "No Significant Risk Level" ("NSRL"); and (2) an exposure assessment to determine if "average consumer" using the product in question over a "lifetime" will be exposed to an amount in excess of the NSRL.

Interest of Bergen Brunswig Drug Company. Bergen Brunswig distributes pharmaceutical products to the continental United States and its territories, including many of the Coal Tar Monograph products at issue in the Gottesfeld-California action. Bergen Brunswig also markets two dandruff shampoos under its trade names, "Brite-Life" and "Good Neighbor Pharmacy," that are formulated and labeled by a toll manufacturer in compliance with the Coal Tar Monograph.

Bergen Brunswig is a defendant in the California lawsuit. Although it has received an offer from the Attorney General, the offer was limited to the two products that Bergen Brunswig markets under its trademarks "Brite-Life" and "Good Neighbor Pharmacy," and expressly excluded the toll manufacturer of the products. The proffered terms of settlement require Bergen Brunswig to pay a small penalty and either stop selling Brite-Life and Good Neighbor Pharmacy shampoos or to place a Proposition 65 warning on the label. The text of the state mandated warning is:

WARNING: This product contains coal tar, a chemical known to the state of California to cause cancer.

This "warning" would misbrand the shampoos and does not comply with the labeling forms of the Monograph.

³ Perhaps the principal reason that Proposition 65 defendants feel obligated to settle rather than litigate the merits of their case, is that the courts are ill-prepared (indeed were never intended) to decide complex scientific and toxicological issues of first impression, such as establishing a no significant risk level for chemicals.

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The proffered settlement would not cover Bergen Brunswig's distribution of products under other defendants' trademarks.⁴ Further, the Attorney General reserved its right to investigate and prosecute Bergen Brunswig in regards to the products it distributes, suggesting that it would not undertake additional investigation until after trial, now scheduled to begin September 11, 2000. If the current defendants (which include many, but not all, of Bergen Brunswig's vendors) settle with the State, then the Attorney General would extend "downstream protection" for past acts to cover Bergen Brunswig. Where Bergen Brunswig's vendors are not defendants in the present case or may be exempt from prosecution under Proposition 65 (because they have fewer than 10 employees), the Attorney General reserved its right to prosecute Bergen Brunswig for the vendor's products. To avoid additional liability as a distributor of pharmaceutical products, the Attorney General advised Bergen Brunswig either to stop distributing pharmaceuticals containing Coal Tar USP in California or to label them with the above Proposition 65 warning. Finally, the settlement offer was tendered by the Attorney General and did not guarantee that co-plaintiff Perry Gottesfeld would concur in all respects.

Bergen Brunswig was willing to withdraw Brite-Life and Good Neighbor Pharmacy dandruff shampoos from the California market to avoid the high cost and uncertainty of a trial.⁵ The "requirement" to withdraw or label its vendors' products raised significant legal and contractual issues, especially where two of its vendors, Johnson & Johnson and Whitehall Laboratories, have been diligently preparing to defend their determinations that California cancer warnings are not required on the labels of their pharmaceuticals containing Coal Tar USP.

Moreover, Bergen Brunswig believes that the California Proposition 65 warning is alarmist in tone and misleading in substance, impart, because such warning provides neither an explanation of the risk nor instructions to mitigate the hazard. Bergen Brunswig is concerned that the Gottesfeld/Attorney General-mandated warning, in its starkness may

⁴ As an accommodation to Bergen Brunswig to avoid the expense of trial, the Attorney General did offer to dismiss such claims without prejudice or "construe" the complaint to cover only the two products sold under Bergen Brunswig's trademark. Bergen Brunswig is concerned that if it agrees to less than a full dismissal of the claims against it, that it will be subjected to a stream of prosecutions in the future. Central to Bergen Brunswig's decision not to take advantage of the Attorney General's offer of a limited settlement, is that the products at issue are regulated by FDA, and the Attorney General's determinations about OTC pharmaceuticals containing Coal Tar USP appear to conflict irreconcilably with the Coal Tar Monograph and requirements imposed under the FFDCa.

⁵ Bergen Brunswig's California sales of the two products at issue are fewer than 1000 units.

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constitute "misbranding." Without FDA approval, Bergen Brunswig would not want to label its products with the warning, let alone apply such warnings to pharmaceuticals manufactured by others. For these reasons, Bergen Brunswig finds itself caught - between the demands of Proposition 65, (as interpreted by Gottesfeld and the Attorney General) and the clear requirements of FDA regulations and the Coal Tar Monograph.

2. **Specific Questions for FDA concerning sale use and distribution of Coal Tar USP products.**

Does FDA consider Coal Tar USP to be the same chemical substance as crude coal tar? The Proposition 65 listing under which plaintiffs Gottesfeld and the Attorney General are challenging the legality of coal tar USP products is "soots, tars and mineral oils." (21 CCR § 12000.) The basis of the listing is the 1984 IARC Monograph (Volume 35), issued by the International Agency for Research on Cancer.⁶ Although pharmaceutical use of coal tar is mentioned in the IARC Monograph, the coal tar is "crude" coal tar, not Coal Tar USP. In promulgating the Coal Tar Monograph, FDA set strict parameters for the manufacture and use of Coal Tar USP in pharmaceuticals, and in fact established a unique CAS number for the chemical. If FDA has prescribed the chemical parameters of Coal Tar USP and purposefully set it apart from generic or crude coal tar by issuing it under a unique CAS number, Coal Tar USP may not be subject to Proposition 65, because its carcinogenicity was not considered in the IARC Monograph and Coal Tar USP has not been listed by California in its own right.

Does the OTC Monograph docket for Coal Tar Shampoos show that the composition of the formulations upon which the Monograph was written are identical to the Fraunhofer study's "coal tar oils" in the attachment to the Gottesfeld petition? If not, the new Fraunhofer study is not a sufficient basis for amending the Monograph's findings since these data do not involve the same active ingredient, 21 CFR § 330.10 (A)(12).

What is the average consumers' use of dandruff shampoos, soaps and ointments? How does FDA determine consumer use? Is the human dose properly extrapolated in the petitioner's study?

Proposition 65 warnings. Does FDA consider the provision of the Proposition 65 warning on Coal Tar products to constitute "misbranding," within the meaning of the

⁶ World Health Organization, *IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans*, Polynuclear Aromatic Compounds, Part 4, Bitumens, Coal-tars and Derived Products, Shale-oils and Soots, 21-28 February 1984.

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FFDCA. If not, does FDA approve of the addition to the Monograph of the Proposition 65 safe-harbor warning for inclusion on OTC pharmaceuticals containing Coal Tar USP?

Cancer warnings. After review of the Gottesfeld petition, if FDA finds that Coal Tar USP poses a risk of cancer when shampoos, soaps, ointments and other OTC pharmaceuticals, are used according to labeled directions, what cautionary text or instruction would FDA recommend to be used to inform consumers?

3. Additional Information Will Be Submitted to FDA.

To inform interested parties that FDA has the Gottesfeld Petition under active consideration, we circulated a copy of Dr. Charles Ganley's letter of August 7, 2000 to co-defendants in the Gottesfeld lawsuit. Within the next few days, Whitehall Laboratories will submit a copy of a comprehensive exposure assessment that we believe is responsive to FDA's request for additional pertinent information. The assessment is entitled, *Estimation of Lifetime Skin Cancer Risk from the Use of Coal Tar Containing Shampoos*, K.S. Crump Group Inc., ICF Consulting (July, 2000).

* * *

Bergen Brunswig thanks FDA for the opportunity to submit comments for consideration during the Gottesfeld Petition proceedings. If you have any questions or require additional information regarding the above, please contact me.

Sincerely,



Carol René Brophy
Counsel for
Bergen Brunswig Drug Company

CRB/hs
Enclosure

1 Mark S. Pollock (SBN 80539)
1207 Coombs Street
2 Napa, Ca 94559
(707) 257-8935
(707) 257-8937 (fax)

3 Melvin B. Pearlston (SBN 54291)
4 PACIFIC JUSTICE CENTER
424 First Street
5 Eureka, California 95501
(707) 443-4000
6 (707) 443-4096 (fax)

7 Attorneys for Plaintiff
Perry Gottesfeld

ENDORSED
FILED
San Francisco County Superior Court

FEB 25 1999

ALAN CARLSON, Clerk
BY: CRISTINA E. BAUTISTA
Deputy Clerk

9 SUPERIOR COURT OF THE STATE OF CALIFORNIA
10 COUNTY OF SAN FRANCISCO

11
12 Perry Gottesfeld,

CASE NO. 300643

13 Plaintiff,

14 vs.

**FIRST AMENDED
COMPLAINT FOR CIVIL PENALTIES
AND INJUNCTIVE RELIEF**

15 Alva-Amco Pharmacal Cos., Inc., Baker
16 Cummins Dermatologicals/Baker Norton
Pharmaceuticals, c/o IVAX Corp., Benjamin
17 Ansehl, Inc., Bergen Brunswig Drug Co.,
Dayton Hudson Corp., Dermik Labs, Inc., Doak
18 Dermatologics, Subsidiary of Bradley
Pharmaceutical, Inc., Drug Barn, Galderma,
19 Gen Derm Corporation, Guy & O'Neill,
Healthpoint, J.K. Pharmaceutical, Inc., Long's
20 Drug Stores, Neutrogena, Person & Covey, Inc.,
Pierre Fabre, Inc., Reedco, Inc., Stiefel
21 Laboratories, Inc., Westwood-Squibb
Pharmaceutical, Inc., and Whitehall
22 Laboratories, and DOES 1 through 400
inclusive,

23 Defendants.

24 _____ /
25 Plaintiff Perry Gottesfeld alleges as follows:

26 ///

27 ///

28 ///

INTRODUCTION

1
2 1. This Complaint seeks civil penalties and an injunction to remedy the continuing
3 failure of defendants, Alva-Amco Pharmacal Cos., Inc., Baker Cummins Dermatologicals/Baker
4 Norton Pharmaceuticals, c/o IVAX Corp., Benjamin Ansehl, Inc., Bergen Brunswig Drug Co.,
5 Dayton Hudson Corp., Dermik Labs, Inc., Doak Dermatologics, Subsidiary of Bradley
6 Pharmaceutical, Inc., Drug Barn, Galderma, Gen Derm Corporation, Guy & O’Niel,
7 Healthpoint, J.K. Pharmaceutical, Inc., Long’s Drug Stores, Neutrogena, Person & Covey, Inc.,
8 Pierre Fabre, Inc., Reedco, Inc., Stiefel Laboratories, Inc., Westwood-Squibb Pharmaceutical,
9 Inc., and Whitehall Laboratories., and DOES 1 through 400 inclusive, to give clear and
10 reasonable warnings to those residents of California, who use their hair care products and skin
11 care products that contain coal tar. The use of these hair care products and skin care products is
12 causing these people to be exposed to coal tar. Coal tar and its constituents (as set forth in
13 Exhibit “A”, attached hereto and incorporated herein by reference), are chemicals known to the
14 State of California to cause cancer.

15 2. Defendants are all businesses that manufacture, market, and/or distribute hair
16 care products and skin care products that contain coal tar and its constituents (as set forth in
17 Exhibit “A”, attached hereto and incorporated herein by reference). Defendants intend that
18 residents of California use the hair care products and skin care products that defendants
19 manufacture, market, and/or distribute. When these hair care products and skin care products
20 are used in their normally intended manner, they expose people to coal tar and its constituents.
21 In spite of knowing that residents of California were being exposed to these chemicals when
22 they use the hair care products and skin care products that they market, defendants did not
23 provide clear and reasonable warning that these hair care products and skin care products cause
24 exposure to chemicals known to cause cancer.

25 3. Plaintiff seeks injunctive relief pursuant to Health & Safety Code Section
26 25249.7 to compel defendants to bring their business practices into compliance with section
27 25249.5 et seq. by providing a clear and reasonable warning to each individual who in the future
28 may be exposed to the above mentioned toxic chemicals. Plaintiff also seeks injunctive relief

1 pursuant to Business & Professions Code Sections 17203 and 17204, which grant the Court the
2 authority to enjoin any unlawful business practice constituting an act of unfair competition.

3 PARTIES

4 4. Plaintiff PERRY GOTTFELD is an individual concerned with enforcement of
5 California and federal environmental law and a "person" pursuant to Health & Safety Code
6 Section 25118.

7 5. Defendants are all businesses that market hair care products and skin care
8 products containing coal tar and its constituents in California, including the City and County of
9 San Francisco.

10 6. Plaintiff is ignorant of the true names or capacities of the defendants sued herein
11 under the fictitious names DOES 1 through 400, inclusive. Defendants DOES 1 through 400
12 inclusive are therefore sued herein pursuant to Cal. Code Civ. Proc. §474.

13 7. Plaintiff brings this enforcement action against defendants pursuant to Health &
14 Safety Code Section 25249.7(d). Attached hereto and incorporated by reference is a copy of a
15 60-day Notice letter dated March 20, 1998, (Exhibit "A"), which plaintiff sent to California's
16 Attorney General. Substantially similar letters were sent to every District Attorney in the state,
17 and to the City Attorneys of every California city with a population greater than 750,000. On
18 the same date, plaintiff sent a similar 60-Day Notice letter to defendants, Alva-Amco Pharmacal
19 Cos., Inc., Baker Cummins Dermatologicals/Baker Norton Pharmaceuticals, c/o IVAX Corp.,
20 Bergen Brunswig Drug Co., Dayton Hudson Corp., Dermik Labs, Inc., Doak Dermatologics,
21 Subsidiary of Bradley Pharmaceutical, Inc., Galderma, Gen Derm Corporation, Guy & O'Neill,
22 Healthpoint, J.K. Pharmaceutical, Inc., Long's Drug Stores, Neutrogena, Person & Covey, Inc.,
23 Reedco, Inc., Stiefel Laboratories, Inc., Westwood-Squibb Pharmaceutical, Inc., and Whitehall
24 Laboratories. Attached to the 60-Day Notice Letters sent to said defendants was a summary of
25 Proposition 65 that was prepared by California's Office of Environmental Health Hazard
26 Assessment. In addition, each 60-Day Notice Letter plaintiff sent was accompanied by a
27 Certificate of Service attesting to the service of the 60-Day Notice Letter on each entity which
28 received it.

1 8. Plaintiff brings this enforcement action against defendants pursuant to Health &
2 Safety Code Section 25249.7(d). Attached hereto and incorporated by reference is a copy of a
3 60-day Notice letter dated April 6, 1998, (Exhibit "B"), which plaintiff sent to California's
4 Attorney General. Substantially similar letters were sent to every District Attorney in the state,
5 and to the City Attorneys of every California city with a population greater than 750,000. On
6 the same date, plaintiff sent a similar 60-Day Notice letter to defendant, Drug Barn. Attached to
7 the 60-Day Notice Letter sent to said defendant was a summary of Proposition 65 that was
8 prepared by California's Office of Environmental Health Hazard Assessment. In addition, each
9 60-Day Notice Letter plaintiff sent was accompanied by a Certificate of Service attesting to the
10 service of the 60-Day Notice Letter on each entity which received it.

11 9. Plaintiff brings this enforcement action against defendants pursuant to Health &
12 Safety Code Section 25249.7(d). Attached hereto and incorporated by reference is a copy of a
13 60-day Notice letter dated June 12, 1998, (Exhibit "C"), which plaintiff sent to California's
14 Attorney General. Substantially similar letters were sent to every District Attorney in the state,
15 and to the City Attorneys of every California city with a population greater than 750,000. On
16 the same date, plaintiff sent a similar 60-Day Notice letter to defendant, Alva-Amco Pharmacial
17 Cos., Inc. Attached to the 60-Day Notice Letters sent to said defendants was a summary of
18 Proposition 65 that was prepared by California's Office of Environmental Health Hazard
19 Assessment. In addition, each 60-Day Notice Letter plaintiff sent was accompanied by a
20 Certificate of Service attesting to the service of the 60-Day Notice Letter on each entity which
21 received it.

22 10. Plaintiff brings this enforcement action against defendants pursuant to Health &
23 Safety Code Section 25249.7(d). Attached hereto and incorporated by reference is a copy of a
24 60-day Notice letter dated June 15, 1998, (Exhibit "D"), which plaintiff sent to California's
25 Attorney General. Substantially similar letters were sent to every District Attorney in the state,
26 and to the City Attorneys of every California city with a population greater than 750,000. On
27 the same date, plaintiff sent a similar 60-Day Notice letter to defendants, Pierre Fabre, Inc.,
28 Reedco, Inc., and Stiefel Laboratories, Inc. Attached to the 60-Day Notice Letters sent to said

1 defendants was a summary of Proposition 65 that was prepared by California's Office of
2 Environmental Health Hazard Assessment. In addition, each 60-Day Notice Letter plaintiff sent
3 was accompanied by a Certificate of Service attesting to the service of the 60-Day Notice Letter
4 on each entity which received it.

5 11. Plaintiff brings this enforcement action against defendants pursuant to Health
6 & Safety Code Section 25249.7(d). Attached hereto and incorporated by reference are copies of
7 a 60-day Notice letters dated March 20, 1998, and April 6, 1998 (Exhibit "E"), which plaintiff
8 sent to California's Attorney General. Substantially similar letters were sent to every District
9 Attorney in the state, and to the City Attorneys of every California city with a population greater
10 than 750,000. On the same date, plaintiff sent similar 60-Day Notice letters to Sav-On
11 American Drug Stores, American Procurement & Logistics Private Label Division (Sav-On),
12 Walgreen Co., and Rite Aid Corporation. By way of these letters, defendant Benjamin Ansehl,
13 Inc. was put on notice of this action. Attached to the 60-Day Notice Letters sent to said
14 defendants was a summary of Proposition 65 that was prepared by California's Office of
15 Environmental Health Hazard Assessment. In addition, each 60-Day Notice Letter plaintiff sent
16 was accompanied by a Certificate of Service attesting to the service of the 60-Day Notice Letter
17 on each entity which received it.

18 12. Defendants are all businesses that employ more than ten people.

19 JURISDICTION

20 13. The Court has jurisdiction over this action pursuant to California Health & Safety
21 Code Section 25249.7, and Business & Professions Code Sections 17203 and 17204, which
22 allow enforcement in any court of competent jurisdiction. California Constitution Article VI,
23 Section 10 grants the Superior Court "original jurisdiction in all causes except those given by
24 statute to other trial courts." Chapter 6.6 of the Health & Safety Code, and Division 7, part 2
25 (Sections 17200 et seq.) of the Business & Professions Code, which contain the statutes under
26 which this action is brought, do not grant jurisdiction to any other trial court.

27 14. This Court also has jurisdiction over the defendants because they are businesses
28 that have sufficient minimum contacts in California and within the City and County of San

1 Francisco. Defendants intentionally availed themselves of the California and San Francisco
2 County markets for hair care products. It is thus consistent with traditional notions of fair play
3 and substantial justice for the San Francisco Superior Court to exercise jurisdiction over them.

4 15. Venue is proper in this Court because acts of which plaintiff complains occurred
5 within the County of San Francisco during the times relevant to this Complaint.

6 FIRST CLAIM FOR RELIEF
7 (Violation of Proposition 65)

8 16. Plaintiff realleges and incorporates by reference into this First Claim for Relief,
9 as if specifically set forth herein, paragraphs 1 through 11, inclusive.

10 17. The People of the State of California have declared by referendum under
11 Proposition 65 (California Health & Safety Code § 25249.5 et seq.) their right "[t]o be informed
12 about exposures to chemicals that cause cancer."

13 18. To effectuate this goal, Section 25249.6 of the Health and Safety Code mandates
14 that persons who, in the course of doing business, knowingly and intentionally expose any
15 individual to a chemical known to the State of California to cause cancer or birth defects must
16 provide a clear and reasonable warning to such individual prior to the exposure.

17 19. Since before four (4) years prior to the notices set forth herein, and the date of the
18 filing of this Complaint, defendants have engaged in conduct which violates Health and Safety
19 Code Section 25249.6 et seq. This conduct includes knowingly and intentionally exposing to the
20 above mentioned toxic chemicals, California residents who use hair care products and skin care
21 products that contain coal tar and its constituents. The normally intended use of defendants' hair
22 care products and skin care products cause exposure to coal tar and its constituents, chemicals
23 known to the State of California to cause cancer. Defendants have not provided clear and
24 reasonable warnings, within the meaning of Health & Safety Code Sections 25249.6 and
25 25249.11.

26 20. At all times relevant to this action, defendants knew that the hair care products
27 and skin care products they marketed were causing exposures to coal tar and its constituents.
28 Defendants intended that residents of California use their hair care products and skin care
products in such ways as would lead to significant exposures to coal tar and its constituents.

PRAYER FOR RELIEF

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2
3 Wherefore, plaintiff prays for judgment against defendants, Alva-Amco Pharmacal Cos.,
4 Inc., Baker Cummins Dermatologicals/Baker Norton Pharmaceuticals, c/o IVAX Corp.,
5 Benjamin Anshel, Bergen Brunswig Drug Co., Dayton Hudson Corp., Dermik Labs, Inc., Doak
6 Dermatologicals, Subsidiary of Bradley Pharmaceutical, Inc., Drug Barn, Galderma, Gen Derm
7 Corporation, Guy & O'Neill, Healthpoint, J.K. Pharmaceutical, Inc., Long's Drug Stores,
8 Neutrogena, Person & Covey, Inc., Pierre Fabre, Inc., Reedco, Inc., Stiefel Laboratories, Inc.,
9 Westwood-Squibb Pharmaceutical, Inc., and Whitehall Laboratories, and DOES 1 through 400
10 inclusive, as follows:

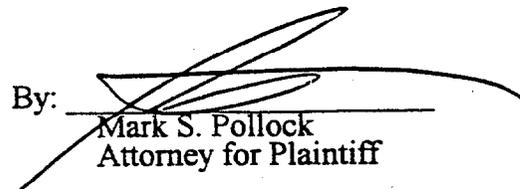
11 1. Pursuant to the First Claim for Relief, that defendants., Alva-Amco Pharmacal
12 Cos., Inc., Baker Cummins Dermatologicals/Baker Norton Pharmaceuticals, c/o IVAX Corp.,
13 Benjamin Anshel, Inc., Bergen Brunswig Drug Co., Dayton Hudson Corp., Dermik Labs, Inc.,
14 Doak Dermatologicals, Subsidiary of Bradley Pharmaceutical, Inc., Drug Barn, Galderma, Gen
15 Derm Corporation, Guy & O'Neill, Healthpoint, J.K. Pharmaceutical, Inc., Long's Drug Stores,
16 Neutrogena, Person & Covey, Inc., Pierre Fabre, Inc., Reedco, Inc., Stiefel Laboratories, Inc.,
17 Westwood-Squibb Pharmaceutical, Inc., and Whitehall Laboratories, and DOES 1 through 400
18 inclusive, be assessed a civil penalty in an amount equal to \$2,500.00 per day per individual
19 exposed, in violation of Section 25249.6 of the California Health & Safety Code, to coal tar and
20 its constituents as the result of defendants' marketing of hair care products and skin care
21 products;

22 2. That pursuant to the Second Claim for Relief, all defendants be enjoined,
23 restrained, and ordered to comply with the provisions of Section 25249.5, et seq. of the
24 California Health & Safety Code, and not commit any further unlawful or unfair business
25 practices;

26 3. That pursuant to the Second Claim for Relief, all defendants be assessed
27 reasonable attorney's fees according to the usual hourly rate of plaintiff's counsel herein, and for
28 costs of suit actually incurred by plaintiff for the preparation and pursuit of this action, and

4. For such other relief as this Court deems just and proper.

Dated: February 24, 1999

By: 

Mark S. Pollock
Attorney for Plaintiff

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TEL: (707) 257-8935
E-MAIL: hanshan@community.net
FAX: (707) 257-8937

1207 COOMBS STREET
NAPA, CA 94559-1289

MARK S. POLLOCK
LITIGATION COUNSEL
ENVIRONMENTAL COMPLIANCE

March 20, 1998

Don Roden, President
Bergen Brunswig Drug Co.
4000 Metropolitan Drive
Orange, CA 92868

RE: AMENDED 60-DAY NOTICE
California Health & Safety Code Section 25249.6 (Proposition 65)
Carcinogenic Coal Tar Product - Good Neighbor Shampoo

Dear Mr. Roden:

In accordance with Section 25249.7(d), Chapter 6.6, of the California Health and Safety Code, Perry Gottesfeld hereby gives an amended notice of his intention to file a lawsuit sixty days hence in which he will allege that Bergen Brunswig Drug Co. knowingly or intentionally exposed individuals "to chemicals known to the State of California as causing cancer or reproductive toxicity without first giving clear and reasonable warning," in violation of Section 25249.6 of Proposition 65.

The noticing party is Perry Gottesfeld, 1255 Post Street, Suite 904, San Francisco, California 94109, telephone 415-441-5199. Perry Gottesfeld is a private individual. The attorney representing Perry Gottesfeld is Mark S. Pollock, 1207 Coombs Street, Napa, California 94559-1289, telephone 707-257-8935.

STATEMENT OF PARTICULARS

Identity of Violator(s)

Bergen Brunswig Drug Company is a "person" within the meaning of Section 25249.11, Chapter 6.6., of the California Health and Safety Code (Proposition 65).

Consumer Products or Services

Good Neighbor Pharmacy Therapeutic Gel Shampoo is distributed by Bergen Brunswig Drug Company. The aforementioned product is directed for use for the control of symptoms of dandruff, psoriasis, and seborrheic dermatitis. According to its ingredient list, the aforementioned products is comprised of 2.5% coal tar solution.

Identity of Chemicals

Coal tar and the following constituent chemicals, present in coal tar have been determined by the State of California to cause cancer and/or reproductive toxicity:

<u>Chemical Compound</u>	<u>Date Listed</u>
Coal tar	February 27, 1987
Benzo[a]pyrene	July 1, 1987
Benzo[b]fluoranthene	July 1, 1987
Benzo[j]fluoranthene	July 1, 1987
Benzo[k]fluoranthene	July 1, 1987
Benz[a]anthracene	July 1, 1987
Carbazole	May 1, 1996
Crysene	January 1, 1990
Dibenz[a,h]anthracene	January 1, 1988
Dibenz[a,j]acridine	January 1, 1988
Indeno[1,2,3-cd]pyrene	January 1, 1988

Description of Illegal Activity

The alleged violators are knowingly distributing, advertising, and selling chemicals known to the state of California to cause cancer and/or reproductive harm without providing the clear and reasonable warning required by Proposition 65.

Exposure Without a Clear and Reasonable Warning

The aforementioned product contains no warnings on its label, or anywhere in or on its container, or the fact that it is known to cause cancer or reproductive toxicity.

Individuals Exposed

Persons using the aforementioned product.

Route of Exposure

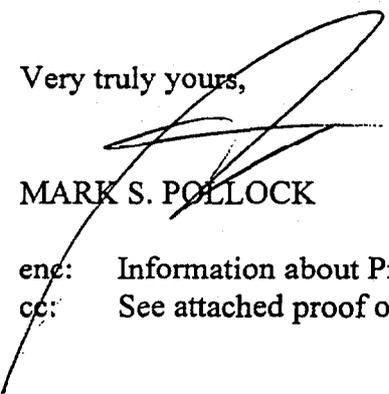
Persons using the aforementioned product were exposed by dermal exposure and/or inhalation of the product.

Duration of Violations

Violations for failure to warn commenced one year after the chemicals were listed by the Governor as a chemical known to the State of California to cause cancer and/or reproductive toxicity, and continue to the present. Under Proposition 65, each failure to warn, release,

discharge and exposure constitutes a separate violation. Health & Safety Code Section 25249.7(b).
The maximum civil penalty for each such violation is \$2,500.00 per day.

Very truly yours,



MARK S. POLLOCK

enc: Information about Proposition 65

cc: See attached proof of service list

TEL: (707) 257-8935
E-MAIL: hanshan@community.net
FAX: (707) 257-8937

1207 COOMBS STREET
NAPA, CA 94559-1289

MARK S. POLLOCK
LITIGATION COUNSEL
ENVIRONMENTAL COMPLIANCE

March 20, 1998

Don Roden, President
Bergen Brunswig Drug Co.
4000 Metropolitan Drive
Orange, CA 92868

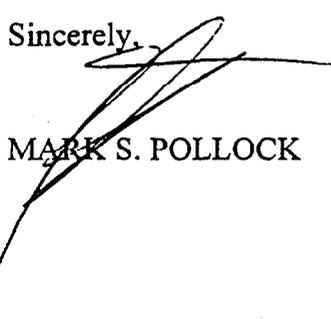
RE: Notification of New Attorney
Proposition 65 Claim of Perry Gottesfeld

Dear Mr. Roden:

This letter is to inform you that I will be the attorney of record for Perry Gottesfeld's Proposition 65 claim which Judith C. Wolff was previously handling. Any future correspondence should be with my office.

I am interested in setting up a meeting between members of the industry and also the Attorney General to discuss this matter. Please contact my office if your company is interested in participating in this meeting.

Sincerely,



MARK S. POLLOCK

PROOF OF SERVICE

I declare that I am employed in the City and County of Napa, California. My business address is 1207 Coombs Street, Napa, California 94559-1289. I am over the age of eighteen (18) years and am not a party to the within action.

On 3/20/98, I served the following documents:

**AMENDED 60-DAY NOTICE LETTER; NOTIFICATION OF NEW
ATTORNEY FOR PROPOSITION 65 CLAIM BY PERRY GOTTESFELD**

on the parties listed below, by placing a true and correct copy thereof addressed as follows:

District Attorney Alameda County 1225 Fallon Street, Rm. 900 Oakland, CA 94612	District Attorney Alpine County Box 248 Markleeville, CA 96120	District Attorney Amador County 708 Court Street # 202 Jackson, CA 95642
District Attorney Butte County 25 County Center Drive Oroville, CA 95965	District Attorney Calaveras County Government Center San Andreas, CA 95249	District Attorney Colusa County 547 Mark Street Colusa, CA 95932
District Attorney Contra Costa County Box 670 Martinez, CA 94553	District Attorney Del Norte County 450 H Street Crescent City, CA 95531	District Attorney El Dorado County 515 Main Street Placerville, CA 95667
District Attorney Fresno County 2220 Tulare Street # 1000 Fresno, CA 93721	District Attorney Glenn County Box 430 Willows, CA 95988	District Attorney Humboldt County 825 5th Street Eureka, CA 95501
District Attorney Imperial County 939 West Main Street El Centro, CA 92243	District Attorney Inyo County PO Drawer D Independence, CA 93526	District Attorney Kern County 1215 Truxtun Avenue Bakersfield, CA 93301
District Attorney Kings County 1400 West Laey Blvd. Hanford, CA 93230	District Attorney Lake County 255 N. Forbes Street Lakeport, CA 95453	District Attorney Lassen County 220 S. Lassen St. Susanville, CA 96130
District Attorney Los Angeles County 210 W. Temple Street, Suite 18000 L.A., CA 90012	District Attorney Madera County 209 West Yosemite St. Madera, CA 93637	District Attorney Marin County 3501 Civic Ctre. Dr., Rm. 183 San Rafael, CA 94903

District Attorney Mariposa County Box 748 Mariposa, CA 95338	District Attorney Mendocino County Box 1000 Ukiah, CA 95482	District Attorney Merced County 222 M Street Merced, CA 95340
District Attorney Modoc County Box 1171 Alturas, CA 96101	District Attorney Mono County Box 617 Bridgeport, CA 93517	District Attorney Monterey County 240 Church St. Salinas, CA 93901
District Attorney Napa County 931 Parkway Mall Napa, CA 94559	District Attorney Nevada County 201 Church St., Suite 8 Nevada City, CA 95959	District Attorney Orange County 700 Civic Ctr. Drive West, 2nd Floor Santa Ana, CA 92701
District Attorney Placer County 11562 B. Avenue, Dewitt Center Auburn, CA 95603	District Attorney Plumas County Box 10716 Quincy, CA 95971	District Attorney Riverside County 4075 Main St., 1st Floor Riverside, CA 92501
District Attorney Sacramento County Box 749 Sacramento, CA 95814	District Attorney San Benito County 375 6th St. Hollister, CA 95023	District Attorney San Bernadino County 316 N. Mountain View Avenue San Bernadino, CA 92415
District Attorney San Diego County 330 W. Broadway, Suite 1320 San Diego, CA 92112	District Attorney San Joaquin County Box 990 Stockton, CA 95201	District Attorney Barry La Barbera San Luis Obispo County 1050 Monterey St., Rm. 450 San Luis Obispo, CA 93408
District Attorney San Mateo County 401 Marshall St. Redwood City, CA 94063	District Attorney Santa Barbara County 1105 Santa Barbara St. Santa Barbara, CA 93101	District Attorney Santa Clara County 70 W. Hedding St., West Wing San Jose, CA 95110
District Attorney Santa Cruz County 701 Ocean St. Santa Cruz, CA 95061	District Attorney Shasta County 1525 Court St., 3rd floor Redding, CA 96001-1632	District Attorney Sierra County Box 457 Downieville, CA 95936
District Attorney Siskiyou County Box 986 Yreka, CA 96097	District Attorney Solano County 600 Union Avenue Fairfield, CA 94533	District Attorney Sonoma County 600 Administration Dr., Rm. 212 Santa Rosa, CA 95403
District Attorney Stanislaus County 1100 I Street, Rm. 200 Box 442 Modesto, CA 95353	District Attorney Sutter County 446 Second St. Yuba City, CA 95991	District Attorney Tehama County Box 519 Red Bluff, CA 96080
District Attorney Trinity County Box 310 Weaverville, CA 96093	District Attorney Tulare County 2350 Burrel Ave., Suite 224 Visalia, CA 93291	District Attorney Tuolumne County 2 South Green Sonora, CA 95370

District Attorney Ventura County 800 South Victoria Avenue Ventura, CA 93009	District Attorney Yolo County 204 4th Street Woodland, CA 95695	District Attorney Yuba County 215 5th St. Marysville, CA 95901
City Attorney's Office City of San Jose 151 West Mission Street San Jose, CA 95110	City Attorney's Office City of San Diego 1200 3rd Avenue, Suite 700 San Diego, CA 92101	San Francisco City Attorney Louise Renne, Esq. 1390 Market Street, 5th floor San Francisco, CA 94102
State of California Office of the Attorney General Dan Lungren, Esq. Attn: Sue Firing Consumer Complaints Public Inquiry Department P.O. Box 944255 Sacramento, CA 94244	Tony Alperin City Attorney City of Los Angeles 200 North Main Street 17th Floor City Hall East Los Angeles, CA 90012	District Attorney Terrence Hallinan, Esq. City and County of San Francisco Hall of Justice 850 Bryant Street San Francisco, CA 94103
Don Roden, President Bergen Brunswick Drug. Co. 4000 Metropolitan Drive Orange, CA 92868		

[X] BY MAIL - I placed each such sealed envelope, with postage thereon fully prepaid for first-class mail, for collection and mailing at Napa, California, following ordinary business practices, being familiar with the practice of THE LAW OFFICES OF MARK S. POLLOCK for processing correspondence. I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Dated: 3/20/98

Sue Purewal
Sue Purewal

COPY

1 BILL LOCKYER Attorney General
of the State of California
2 RODERICK E. WALSTON
Chief Assistant Attorney General
3 THEODORA BERGER
Assistant Attorney General
4 CRAIG C. THOMPSON
Supervising Deputy Attorney General
5 EDWARD G. WEIL
SUSAN S. FIERING (State Bar No. 121621)
6 Deputy Attorneys General
1515 Clay St., 15th Floor
7 Oakland, CA 94612
Telephone: (510) 622-2142

ENDORSED
FILED
San Francisco County Superior Court

FEB 2 1999

8 Attorneys for the People of the State of California
9 ex rel. Bill Lockyer, Attorney General of the
State of California

10 SUPERIOR COURT OF THE STATE OF CALIFORNIA
11 CITY AND COUNTY OF SAN FRANCISCO
12

13 PEOPLE OF THE STATE OF CALIFORNIA ex)
rel. BILL LOCKYER, Attorney General of the)
14 State of California,)

15 Plaintiffs,)

16 v.)

17 ALVA-AMCO PHARMACAL COS., INC.;)
BAKER NORTON PHARMACEUTICALS;)
18 BENJAMIN ANSEHL, INC.; BERGEN)
BRUNSWIG DRUG CO.; DAYTON HUDSON,)
CORP.; DERMIK LABS, INC.; DOAK)
19 DERMATOLOGICS; GALDERMA; GEN)
DERM CORP.; GUY & O'NEILL, INC.;)
20 HEALTHPOINT; J.K. PHARMACEUTICAL,)
INC.; LONG'S DRUG STORES, INC.;)
21 MEDICIS PHARMACEUTICAL CORP.;)
NEUTROGENA CORP.; PERSON & COVEY,)
22 INC.; REEDCO, INC.; RITE AID CORP.; SAV-)
ON/AMERICAN DRUG STORES &)
23 AMERICAN PROCUREMENT & LOGISTICS)
(private label division); STIEFEL)
24 LABORATORIES, INC.; WALGREEN CORP.;)
WESTWOOD-SQUIBB PHARMACEUTICAL,)
25 INC.; WHITEHALL LABORATORIES; and)
DOES 1-200)

26 Defendants.
27

No. 300827

FIRST AMENDED COMPLAINT
FOR CIVIL PENALTY AND
INJUNCTIVE RELIEF

(a) Anti-trust/ Unfair Competition
(q) Other (Environment)

1 5. Defendant BENJAMIN ANSEHL, INC. is a business entity that manufactures,
2 distributes and/or sells Coal Tar Products to consumers within the state of California.

3 6. Defendant BERGEN BRUNSWIG DRUG CO. is a business entity that
4 manufactures, distributes and/or sells Coal Tar Products to consumers within the state of
5 California.

6 7. Defendant DAYTON HUDSON, CORP. is a business entity that
7 manufactures, distributes and/or sells Coal Tar Products to consumers within the state of
8 California.

9 8. Defendant DERMIK LABS, INC. is a business entity that manufactures,
10 distributes and/or sells Coal Tar Products to consumers within the state of California.

11 9. Defendant DOAK DERMATOLOGICS is a business entity that manufactures,
12 distributes and/or sells Coal Tar Products to consumers within the state of California.

13 10. Defendant GALDERMA is a business entity that manufactures, distributes
14 and/or sells Coal Tar Products to consumers within the state of California.

15 11. Defendant GEN DERM CORP. is a business entity that manufactures,
16 distributes and/or sells Coal Tar Products to consumers within the state of California.

17 12. Defendant GUY & O'NEILL, INC. is a business entity that manufactures,
18 distributes and/or sells Coal Tar Products to consumers within the state of California.

19 13. Defendant HEALTHPOINT is a business entity that manufacturers and/or
20 distributes Coal Tar Products to consumers within the state of California.

21 14. Defendant J.K. PHARMACEUTICAL, INC. is a business entity that
22 manufactures, distributes and/or sells Coal Tar Products to consumers within the state of
23 California.

24 15. Defendant LONG'S DRUG STORES, INC. is a business entity that
25 manufactures, distributes and/or sells Coal Tar Products to consumers within the state of
26 California.

27 16. Defendant MEDICIS PHARMACEUTICAL CORP. is a business entity that

1 manufactures, distributes and/or sells Coal Tar Products to consumers within the state of
2 California.

3 17. Defendant NEUTROGENA CORP. is a business entity that manufactures,
4 distributes and/or sells Coal Tar Products to consumers within the state of California.

5 18. Defendant PERSON & COVEY, INC. is a business entity that manufactures,
6 distributes and/or sells Coal Tar Products to consumers within the state of California.

7 19. Defendant REEDCO, INC. is a business entity that manufactures, distributes
8 and/or sells Coal Tar Products to consumers within the state of California.

9 20. Defendant RITE AID CORP. is a business entity that manufactures, distributes
10 and/or sells Coal Tar Products to consumers within the state of California.

11 21. Defendant SAV-ON/AMERICAN DRUG STORES & AMERICAN
12 PROCUREMENT & LOGISTICS is a business entity that manufactures, distributes and/or
13 sells Coal Tar Products to consumers within the state of California.

14 22. Defendant STIEFEL LABORATORIES, INC. is a business entity that
15 manufactures, distributes and/or sells Coal Tar Products to consumers within the state of
16 California.

17 23. Defendant WALGREEN CORP. is a business entity that manufactures,
18 distributes and/or sells Coal Tar Products to consumers within the state of California.

19 24. Defendant WESTWOOD-SQUIBB PHARMACEUTICAL, INC. is a business
20 entity that manufactures, distributes and/or sells Coal Tar Products to consumers within the
21 state of California.

22 25. Defendant WHITEHALL LABORATORIES is a business entity that
23 manufactures, distributes and/or sells Coal Tar Products to consumers within the state of
24 California.

25 26. The true names and capacities of the defendants sued herein as Does 1 through
26 200 are unknown to plaintiff, who therefore sues them by such fictitious names. Plaintiff
27 will amend this complaint to allege the true names and capacities of these defendants when

1 they have been determined. Each of the fictitiously named defendants is responsible in some
2 manner for the conduct alleged herein.

3 III. JURISDICTION AND VENUE

4 27. This Court has jurisdiction pursuant to California Constitution Article VI,
5 section 10, because this case is a cause not given by statute to other trial courts.

6 28. This Court has jurisdiction over the defendants named above because they do
7 sufficient business in California, or otherwise have sufficient minimum contacts in California
8 to render the exercise of jurisdiction over them by the California courts consistent with
9 traditional notions of fair play and substantial justice.

10 29. Venue is proper in this Court because the cause arises in the City and County
11 of San Francisco where some of the violations of law have occurred.

12 IV. STATUTORY BACKGROUND

13 A. Proposition 65

14 30. The Safe Drinking Water and Toxic Enforcement Act of 1986 is an initiative
15 statute passed as "Proposition 65" by a vote of the People in November of 1986.

16 31. The warning requirement of Proposition 65 is contained in Health and Safety
17 Code section 25249.6, which provides:

18 No person in the course of doing business shall knowingly and
19 intentionally expose any individual to a chemical known to the state to
20 cause cancer or reproductive toxicity without first giving clear and
reasonable warning to such individual, except as provided in Section
25249.10

21 32. Implementing regulations promulgated by the Health and Welfare Agency
22 provide that the warning method "must be reasonably calculated, considering the alternative
23 methods available under the circumstances, to make the warning message available to the
24 individual prior to exposure." 22 CCR § 12601(a).

25 33. The regulations prescribe certain types of warnings that are considered valid,
26 including: (A) warnings on labels, (B) identification at the retail outlet through "shelf
27 labeling, signs, menus, or a combination thereof," and (C) " a system of signs, public

1 advertising identifying the system and toll-free information services, that provides clear and
2 reasonable warnings." 22 CCR §§ 12601(b)(1)(A)-(C).

3 34. Proposition 65 also establishes a procedure by which the state is to develop a
4 list of chemicals "known to the State to cause cancer or reproductive toxicity." Health &
5 Safety Code section 25249.8. No warning need be given concerning a listed chemical until
6 one year after the chemical first appears on the list. Id., § 25249.10(b).

7 35. Proposition 65 provides that any person "violating or threatening to violate"
8 the statute may be enjoined in any court of competent jurisdiction. Health & Safety Code, §
9 25249.7. To "threaten to violate" is defined to mean "to create a condition in which there is
10 a substantial probability that a violation will occur." Id., § 25249.11(e). In addition,
11 violators are liable for civil penalties of up to \$2,500 per day for each violation, recoverable
12 in a civil action. Id., § 25249.7(b). Actions to enforce the law "may be brought by the
13 Attorney General in the name of the People of the State of California or by any district
14 attorney". Id., § 25249.7(c).

15 **B. The Unfair Competition Act**

16 36. California Business and Professions Code section 17200 provides that "unfair
17 competition shall mean and include unlawful, unfair or fraudulent business practice."
18 Section 17203 of the Business and Professions Code provides that "(a)ny person performing
19 or proposing to perform an act of unfair competition within this state may be enjoined in any
20 court of competent jurisdiction."

21 37. Section 17206(a) provides that any person violating Section 17200 "shall be
22 liable for a civil penalty not to exceed two thousand five hundred dollars (\$2,500) for each
23 violation, which shall be assessed and recovered in a civil action brought in the name of the
24 people of the State of California by the Attorney General or by any district attorney." Under
25 section 17205, these penalties are "cumulative to each other and to the remedies or penalties
26 available under all other laws of this state."
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V. FACTS

38. Soots, tars and mineral oils were listed under Proposition 65 as chemicals known to the State of California to cause cancer on February 27, 1987. 22 CCR § 12000. Coal tar is a form of tar, listed as "soots, tars and mineral oils."

39. Benzo[a]pyrene is a constituent of coal tar and was listed under Proposition 65 as a chemical known to the State of California to cause cancer on July 1, 1987.

40. Benzo[b]fluoranthene is a constituent of coal tar and was listed under Proposition 65 as a chemical known to the State of California to cause cancer on July 1, 1987.

41. Benzo[j]fluoranthene is a constituent of coal tar and was listed under Proposition 65 as a chemical known to the State of California to cause cancer on July 1, 1987.

42. Benzo[k]fluoranthene is a constituent of coal tar and was listed under Proposition 65 as a chemical known to the State of California to cause cancer on July 1, 1987.

43. Benz[a]anthracene is a constituent of coal tar and was listed under Proposition 65 as a chemical known to the State of California to cause cancer on July 1, 1987.

44. Carbazole is a constituent of coal tar and was listed under Proposition 65 as a chemical known to the State of California to cause cancer on May 1, 1996.

45. Chrysene is a constituent of coal tar and was listed under Proposition 65 as a chemical known to the State of California to cause cancer on January 1, 1990.

46. Dibenz[a,h]anthracene is a constituent of coal tar and was listed under Proposition 65 as a chemical known to the State of California to cause cancer on January 1, 1988.

47. Dibenz[a,j]acridine is a constituent of coal tar and was listed under Proposition 65 as a chemical known to the State of California to cause cancer on January 1, 1988.

48. Indeno[1,2,3-cd]pyrene is a constituent of coal tar and was listed under

1 Proposition 65 as a chemical known to the State of California to cause cancer on January 1,
2 1988.

3 49. Defendants manufacture, distribute and sell Coal Tar Products. The Coal Tar
4 Products contain coal tar and its constituents, including but not limited to, Benzo[a]pyrene,
5 Benzo[b]fluoranthene, Benzo[j]fluranthene, Benzo[k]fluoranthene, Benz[a]anthracene,
6 Carbazole, Chrysene, Dibenz[a,h]anthracene, Dibenz[a,j]acridine, Indeno[1,2,3-cd]pyrene
7 which are absorbed by persons using the Coal Tar Products. Each defendant knows or has
8 known since at least February 27, 1987 that the Coal Tar Products contain coal tar and its
9 constituents and that persons using these products are exposed to coal tar and its constituents.

10 50. From at least February 27, 1988 to the present, Defendants have failed to
11 provide consumers of the Coal Tar Products with a clear and reasonable warning that they
12 are being exposed to chemicals known to the State of California to cause cancer.

13 VI. FIRST CAUSE OF ACTION

14 (For Violation of Proposition 65)

15 51. Paragraphs 1 through 50 are realleged as if fully set forth herein.

16 52. Plaintiffs are informed and believe, and based on such information and belief
17 allege, that each defendant employs ten or more persons.

18 53. By committing the acts alleged above, each defendant has, in the course of
19 doing business, knowingly and intentionally exposed individuals to coal tar, a chemical
20 known to the state of California to cause cancer without first giving clear and reasonable
21 warning to such individuals, within the meaning of Health and Safety Code section 25249.6.

22 54. Said violations render each defendant liable to plaintiff for civil penalties of up
23 to \$2,500 per day for each violation.

24 VII. SECOND CAUSE OF ACTION

25 (For Unlawful Business Practices)

26 55. Paragraphs 1 through 54 are realleged as if fully set forth herein.

27 56. By committing the acts alleged above, each defendant has engaged in unlawful

1 business practices which constitute unfair competition within the meaning of Business and
2 Professions Code section 17200.

3 57. Said violations render each defendant liable to plaintiff for civil penalties of
4 up to \$2,500 per day for each violation.

5

6

PRAYER FOR RELIEF

7

WHEREFORE, plaintiffs pray that the Court:

8

1. Pursuant to the First and Second Causes of Action, grant civil penalties
9 according to proof;

10

2. Pursuant to Health and Safety Code section 25249.7, and Business and
11 Professions Code sections 17203, enter such preliminary injunctions, permanent injunctions,
12 or other orders prohibiting defendant from exposing persons within the State of California to
13 coal tar and its constituents without providing clear and reasonable warnings, as plaintiffs
14 shall specify in further application to the court;

15

3. Award plaintiffs their costs of suit;

16

4. Grant such other and further relief as the court deems just and proper.

17

Respectfully submitted,

18

Dated: 2/2/99

19

BILL LOCKYER, Attorney General
of the State of California
RODERICK E. WALSTON

20

Chief Assistant Attorney General
THEODORA BERGER

21

Assistant Attorney General
CRAIG C. THOMPSON

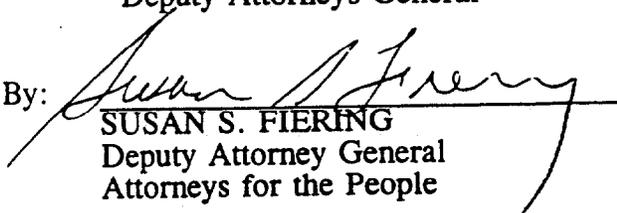
22

Supervising Deputy Attorney General
EDWARD G. WEIL

23

SUSAN S. FIERING
Deputy Attorneys General

24

By: 

SUSAN S. FIERING
Deputy Attorney General
Attorneys for the People

25

26

27

COPY

1 CHRISTIAN VOLZ (SBN 139352)
2 CAROL RENÉ BROPHY (SBN 155767)
3 P. JOSEPH SANDOVAL (SBN 193979)
4 McKENNA & CUNEO, L.L.P.
5 Steuart Street Tower, 27th Floor
6 One Market Plaza
7 San Francisco, California 94105
8 Telephone: (415) 267-4000
9 Facsimile: (415) 267-4198

ENDORSED
FILED
San Francisco County Superior Court

MAY - 7 1999

ALAN CARLSON, Clerk
BY: KEVIN R. DOUGHERTY
Deputy Clerk

7 Attorneys for Defendants
8 BERGEN BRUNSWIG DRUG COMPANY

9 SUPERIOR COURT OF THE STATE OF CALIFORNIA
10 FOR THE COUNTY OF SAN FRANCISCO

12 PEOPLE OF THE STATE OF CALIFORNIA ex
13 rel. BILL LOCKYER, Attorney General of the
14 State of California,

15 Plaintiffs,

16 vs.

17 ALVA-AMCO PHARMACAL COS., INC.;
18 BAKER NORTON PHARMACEUTICALS;
19 BENJAMIN ANSEHL, INC.; BERGEN
20 BRUNSWIG DRUG COMPANY; DAYTON
21 HUDSON, CORP.; DERMIK LABS, INC.;
22 DOAK DERMATOLOGICS; GALDERMA;
23 GEN DERM CORP.; GUY & O'NIELL, INC.;
24 HEALTHPOINT; J.K. PHARMACEUTICAL
25 INC.; LONG'S DRUG STORES, INC.; MEDICS
26 PHARMACEUTICAL CORP.; NEUTROGENA
27 CORP.; PERSON & COVEY, INC.; REEDCO,
28 INC.; RITE AID CORP.; SAV-ON/AMERICAN
DRUG STORES AND AMERICAN
PROCUREMENT AND LOGISTICS (private
label division); STIEFEL LABORATORIES,
INC.; WALGREEN CORP.; WESTWOOD-
SQUIBB PHARMACEUTICAL, INC.;
WHITEHALL LABORATORIES; and DOES 1-
200

Defendants.

CASE NO. 300827

VERIFIED ANSWER TO FIRST
AMENDED COMPLAINT FOR CIVIL
PENALTIES AND INJUNCTIVE
RELIEF

1
2 Defendant Bergen Brunswick Drug Company ("Bergen Brunswick") answers Plaintiffs'
3 First Amended Complaint ("Complaint") as follows:

4 **SPECIFIC ANSWERS**

5 1. Bergen Brunswick admits that the Complaint purports to seek an injunction and
6 civil penalties and avers that the language of Proposition 65 speaks for itself. To the extent that
7 the allegations of Paragraph 1 assert legal conclusions, Bergen Brunswick denies the same. To
8 the extent any further response is required, Bergen Brunswick denies the allegations of Paragraph
9 1.

10 2. Bergen Brunswick admits that the Plaintiff is the State of California. Bergen
11 Brunswick avers that the language of the Health and Safety Code section 25249.7(c),
12 Government Code section 12607, and Business and Professions Code section 17200 speak for
13 themselves.

14 3. The allegations of Paragraph 3 are not directed to Bergen Brunswick, and
15 therefore no response is required. To the extent a response is required, Bergen Brunswick states
16 that it is without knowledge or information sufficient to form a belief as to the truth of the
17 allegations of Paragraph 3, and therefore denies the same.

18 4. The allegations of Paragraph 4 are not directed to Bergen Brunswick, and
19 therefore no response is required. To the extent a response is required, Bergen Brunswick states
20 that it is without knowledge or information sufficient to form a belief as to the truth of the
21 allegations of Paragraph 4, and therefore denies the same.

22 5. The allegations of Paragraph 5 are not directed to Bergen Brunswick, and
23 therefore no response is required. To the extent a response is required, Bergen Brunswick states
24 that it is without knowledge or information sufficient to form a belief as to the truth of the
25 allegations of Paragraph 5, and therefore denies the same.

1 6. Bergen Brunswick admits that it is a "business entity." To the extent that
2 Paragraph 6 contains other allegations of fact, Bergen Brunswick denies each and every
3 allegation.

4 7. The allegations of Paragraph 7 are not directed to Bergen Brunswick, and
5 therefore no response is required. To the extent a response is required, Bergen Brunswick states
6 that it is without knowledge or information sufficient to form a belief as to the truth of the
7 allegations of Paragraph 7, and therefore denies the same.

8 8. The allegations of Paragraph 8 are not directed to Bergen Brunswick, and
9 therefore no response is required. To the extent a response is required, Bergen Brunswick states
10 that it is without knowledge or information sufficient to form a belief as to the truth of the
11 allegations of Paragraph 8, and therefore denies the same.

12 9. The allegations of Paragraph 9 are not directed to Bergen Brunswick, and
13 therefore no response is required. To the extent a response is required, Bergen Brunswick states
14 that it is without knowledge or information sufficient to form a belief as to the truth of the
15 allegations of Paragraph 9, and therefore denies the same.

16 10. The allegations of Paragraph 10 are not directed to Bergen Brunswick, and
17 therefore no response is required. To the extent a response is required, Bergen Brunswick states
18 that it is without knowledge or information sufficient to form a belief as to the truth of the
19 allegations of Paragraph 10 and therefore denies the same.

20 11. The allegations of Paragraph 11 are not directed to Bergen Brunswick, and
21 therefore no response is required. To the extent a response is required, Bergen Brunswick states
22 that it is without knowledge or information sufficient to form a belief as to the truth of the
23 allegations of Paragraph 11 and therefore denies the same.

24 12. The allegations of Paragraph 12 are not directed to Bergen Brunswick, and
25 therefore no response is required. To the extent a response is required, Bergen Brunswick states
26 that it is without knowledge or information sufficient to form a belief as to the truth of the
27 allegations of Paragraph 12 and therefore denies the same.

1 13. The allegations of Paragraph 13 are not directed to Bergen Brunswig, and
2 therefore no response is required. To the extent a response is required, Bergen Brunswig states
3 that it is without knowledge or information sufficient to form a belief as to the truth of the
4 allegations of Paragraph 13 and therefore denies the same.

5 14. The allegations of Paragraph 14 are not directed to Bergen Brunswig, and
6 therefore no response is required. To the extent a response is required, Bergen Brunswig states
7 that it is without knowledge or information sufficient to form a belief as to the truth of the
8 allegations of Paragraph 14 and therefore denies the same.

9 15. The allegations of Paragraph 15 are not directed to Bergen Brunswig, and
10 therefore no response is required. To the extent a response is required, Bergen Brunswig states
11 that it is without knowledge or information sufficient to form a belief as to the truth of the
12 allegations of Paragraph 15 and therefore denies the same.

13 16. The allegations of Paragraph 16 are not directed to Bergen Brunswig, and
14 therefore no response is required. To the extent a response is required, Bergen Brunswig states
15 that it is without knowledge or information sufficient to form a belief as to the truth of the
16 allegations of Paragraph 16 and therefore denies the same.

17 17. The allegations of Paragraph 17 are not directed to Bergen Brunswig, and
18 therefore no response is required. To the extent a response is required, Bergen Brunswig states
19 that it is without knowledge or information sufficient to form a belief as to the truth of the
20 allegations of Paragraph 17, and therefore denies the same.

21 18. The allegations of Paragraph 18 are not directed to Bergen Brunswig, and
22 therefore no response is required. To the extent a response is required, Bergen Brunswig states
23 that it is without knowledge or information sufficient to form a belief as to the truth of the
24 allegations of Paragraph 18, and therefore denies the same.

25 19. The allegations of Paragraph 19 are not directed to Bergen Brunswig, and
26 therefore no response is required. To the extent a response is required, Bergen Brunswig states
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1 that it is without knowledge or information sufficient to form a belief as to the truth of the
2 allegations of Paragraph 19, and therefore denies the same.

3 20. The allegations of Paragraph 20 are not directed to Bergen Brunswig, and
4 therefore no response is required. To the extent a response is required, Bergen Brunswig states
5 that it is without knowledge or information sufficient to form a belief as to the truth of the
6 allegations of Paragraph 20, and therefore denies the same.

7 21. The allegations of Paragraph 21 are not directed to Bergen Brunswig, and
8 therefore no response is required. To the extent a response is required, Bergen Brunswig states
9 that it is without knowledge or information sufficient to form a belief as to the truth of the
10 allegations of Paragraph 21, and therefore denies the same.

11 22. The allegations of Paragraph 22 are not directed to Bergen Brunswig, and
12 therefore no response is required. To the extent a response is required, Bergen Brunswig states
13 that it is without knowledge or information sufficient to form a belief as to the truth of the
14 allegations of Paragraph 22, and therefore denies the same.

15 23. The allegations of Paragraph 23 are not directed to Bergen Brunswig, and
16 therefore no response is required. To the extent a response is required, Bergen Brunswig states
17 that it is without knowledge or information sufficient to form a belief as to the truth of the
18 allegations of Paragraph 23, and therefore denies the same.

19 24. The allegations of Paragraph 24 are not directed to Bergen Brunswig, and
20 therefore no response is required. To the extent a response is required, Bergen Brunswig states
21 that it is without knowledge or information sufficient to form a belief as to the truth of the
22 allegations of Paragraph 24, and therefore denies the same.

23 25. The allegations of Paragraph 25 are not directed to Bergen Brunswig, and
24 therefore no response is required. To the extent a response is required, Bergen Brunswig states
25 that it is without knowledge or information sufficient to form a belief as to the truth of the
26 allegations of Paragraph 25, and therefore denies the same.

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1 26. Bergen Brunswig states that it is without knowledge or information sufficient to
2 form a belief as to the truth of the allegations of the first two sentences of Paragraph 26, and
3 therefore denies the same. To the extent that the allegations of the last sentence of Paragraph 26
4 are directed toward Bergen Brunswig, Bergen Brunswig denies the same. To the extent the
5 allegations of the last sentence of Paragraph 26 are directed to defendants other than Bergen
6 Brunswig, Bergen Brunswig states that it is without knowledge or information sufficient to form
7 a belief as to the truth of the allegations of the last sentence of Paragraph 26, and therefore
8 denies the same.

9 27. The allegations of Paragraph 27 assert legal conclusions of law to which no
10 response is required. To the extent a response is required, Bergen Brunswig denies the
11 allegations of paragraph 27.

12 28. The allegations of Paragraph 28 asserts legal conclusion to which no response is
13 required. To the extent response is required and to the extent the allegations of Paragraph 28 are
14 directed to Bergen Brunswig, Bergen Brunswig admits that it has sufficient contacts with
15 California for jurisdiction. To the extent that the allegations of Paragraph 28 are directed toward
16 defendants other than Bergen Brunswig, Bergen Brunswig states that it is without knowledge or
17 information sufficient to form a belief as to the truth of the allegations of Paragraph 28, and
18 therefore denies the same.

19 29. Paragraph 29 asserts legal conclusion to which no response is required. To the
20 extent a response is required and to the extent that the allegations of Paragraph 29 are directed at
21 Bergen Brunswig, Bergen Brunswig denies each and every allegation. To the extent that the
22 allegations of Paragraph 29 are directed toward defendants other than Bergen Brunswig, Bergen
23 Brunswig states that it is without knowledge or information sufficient to form a belief as to the
24 truth of the allegations of Paragraph 29, and therefore denies the same.

25 30. Bergen Brunswig admits that the Safe Drinking Water and Toxic Enforcement
26 Act of 1986, codified at Health and Safety Code sections 25249 *et seq.*, is an initiative measure
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1 known as "Proposition 65" which was approved by a majority of California voters in November
2 of 1986.

3 31. The allegations of Paragraph 31 assert legal conclusions to which no response is
4 required. To the extent that any response is required, Bergen Brunswig states that the quoted
5 and cited statute speaks for itself, and denies the remaining allegations of Paragraph 31.

6 32. The allegations of Paragraph 32 assert legal conclusions to which no response is
7 required. To the extent that any response is required, Bergen Brunswig admits that Paragraph
8 32 purports to quote from the cited regulation, but denies that it is quoted in its entirety and
9 states that the regulation speaks for itself.

10 33. The allegations of Paragraph 33 assert legal conclusions to which no response is
11 required. To the extent that any response is required, Bergen Brunswig admits that Paragraph
12 33 purports to quote from the cited regulation, but denies that it is quoted in its entirety and
13 states that the regulation speaks for itself.

14 34. The allegations of Paragraph 34 assert legal conclusions to which no response is
15 required. To the extent that any response is required, Bergen Brunswig states that the quoted
16 and cited statutes speak for themselves, and denies the remaining allegations of Paragraph 34.

17 35. The allegations of Paragraph 35 assert legal conclusions to which no response is
18 required. To the extent that any response is required, Bergen Brunswig admits that Paragraph
19 35 purports to quote from the cited statutes, but denies that the cited statutes are quoted in their
20 entirety. Bergen Brunswig states that the cited statutes speak for themselves. To the extent that
21 any response is required, Bergen Brunswig denies the remaining allegations of Paragraph 35.

22 36. The allegations of Paragraph 36 asserts legal conclusions to which no response is
23 required. To the extent that a response is required, Bergen Brunswig admits that Paragraph 36
24 purports to quote from the cited statutes, but denies that the cited statutes are quoted in their
25 entirety. Bergen Brunswig states that the cited statutes speak for themselves. Bergen Brunswig
26 denies the remaining allegations of Paragraph 36.

1 37. The allegations of Paragraph 37 asserts legal conclusions to which no response is
2 required. To the extent that a response is required, Bergen Brunswig admits that Paragraph 37
3 purports to quote from the cited statutes, but denies that the cited statutes are quoted in their
4 entirety. Bergen Brunswig states that the cited statutes speak for themselves. Bergen Brunswig
5 denies the remaining allegations of Paragraph 37.

6 38. Bergen Brunswig admits that on February 27, 1987, the State of California listed
7 "soots, tars, and mineral oils" on the list of "[c]hemicals known to the state to cause cancer"
8 contained in Title 22, California Code of Regulations, section 12000(b). Bergen Brunswig
9 denies the remaining allegations of Paragraph 38.

10 39. Bergen Brunswig admits that Benzo[a]pyrene is included in the list of
11 "[c]hemicals known to the state to cause cancer" contained in Title 22, California Code of
12 Regulations, section 12000(b). Bergen Brunswig denies the remaining allegations of Paragraph
13 39.

14 40. Bergen Brunswig admits that Benzo[b]fluoranthene is included in the list of
15 "[c]hemicals known to the state to cause cancer" contained in Title 22, California Code of
16 Regulations, section 12000(b). Bergen Brunswig denies the remaining allegations of Paragraph
17 40.

18 41. Bergen Brunswig admits that Benzo[j]fluoranthene is included in the list of
19 "[c]hemicals known to the state to cause cancer" contained in Title 22, California Code of
20 Regulations, section 12000(b). Bergen Brunswig denies the remaining allegations of Paragraph
21 41.

22 42. Bergen Brunswig admits that Benzo[k]fluoranthene is included in the list of
23 "[c]hemicals known to the state to cause cancer" contained in Title 22, California Code of
24 Regulations, section 12000(b). Bergen Brunswig denies the remaining allegations of Paragraph
25 42.

26 43. Bergen Brunswig admits that Benz[a]anthracene is included in the list of
27 "[c]hemicals known to the state to cause cancer" contained in Title 22, California Code of
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1 Regulations, section 12000(b). Bergen Brunswig denies the remaining allegations of Paragraph
2 43.

3 44. Bergen Brunswig admits that Carbazole is included in the list of “[c]hemicals
4 known to the state to cause cancer” contained in Title 22, California Code of Regulations,
5 section 12000(b). Bergen Brunswig denies the remaining allegations of Paragraph 44.

6 45. Bergen Brunswig admits that Chrysene is included in the list of “[c]hemicals
7 known to the state to cause cancer” contained in Title 22, California Code of Regulations,
8 section 12000(b). Bergen Brunswig denies the remaining allegations of Paragraph 45.

9 46. Bergen Brunswig admits that Dibenz[a,h]anthracene is included in the list of
10 “[c]hemicals known to the state to cause cancer” contained in Title 22, California Code of
11 Regulations, section 12000(b). Bergen Brunswig denies the remaining allegations of Paragraph
12 46.

13 47. Bergen Brunswig admits that Dibenz[a,j]acridine is included in the list of
14 “[c]hemicals known to the state to cause cancer” contained in Title 22, California Code of
15 Regulations, section 12000(b). Bergen Brunswig denies the remaining allegations of Paragraph
16 47.

17 48. Bergen Brunswig admits that Indeno[1,2,3-cd]pyrene is included in the list of
18 “[c]hemicals known to the state to cause cancer” contained in Title 22, California Code of
19 Regulations, section 12000(b). Bergen Brunswig denies the remaining allegations of Paragraph
20 48.

21 49. Bergen Brunswig denies each and every allegation set forth in Paragraph 49 and
22 restates, realleges and incorporates its responses to Paragraphs 39 through 48 as fully set forth
23 therein. To the extent that the allegations of Paragraph 49 are directed toward defendants other
24 than Bergen Brunswig, Bergen Brunswig states that it is without knowledge or information
25 sufficient to form a belief as to the truth of the allegations of Paragraph 49, and therefore denies
26 the same.

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SECOND AFFIRMATIVE DEFENSE

2. As a second, separate affirmative defense to the Complaint, and to each cause of action alleged therein, Bergen Brunswig alleges that its has provided clear and reasonable warnings within the meaning of Health & Safety Code §§ 25249.6, 25249.11 and Title 22 of the California Code of Regulations § 12601(b)(2) when required to do so.

THIRD AFFIRMATIVE DEFENSE

3. As a third, separate affirmative defense to the Complaint, and to each cause of action alleged therein, Bergen Brunswig alleges that the "no significant risk level" for one or more chemicals listed in the Complaint, as determined by OEHHA and published at Title 22 of the California Code of Regulations § 12705, is invalid and cannot be enforced against Bergen Brunswig.

FOURTH AFFIRMATIVE DEFENSE

4. As a fourth, separate affirmative defense to the Complaint, and to each cause of action alleged therein, Bergen Brunswig alleges that any exposure to a chemical known to the State of California to be a carcinogen or reproductive toxin that occurs as a result of the reasonably anticipated uses of the products that are the subject of this action poses "no significant risk" of causing cancer or reproductive toxicity to users of those products, within the meaning of Health & Safety Code § 25249.10(c).

FIFTH AFFIRMATIVE DEFENSE

5. As a fifth, separate affirmative defense to the Complaint, and to each cause of action alleged therein, Bergen Brunswig alleges that, in the course of doing business it has not intentionally exposed any individual to a chemical known to the State of California to cause cancer or reproductive toxicity in humans.

SIXTH AFFIRMATIVE DEFENSE

6. As a sixth, separate affirmative defense to the Complaint, and to each cause of action alleged therein, Bergen Brunswig alleges that, in the course of doing business it has not

1 knowingly exposed any individual to a chemical known to the State of California to cause
2 cancer or reproductive toxicity in humans.

3 **SEVENTH AFFIRMATIVE DEFENSE**

4 7. As an seventh, separate affirmative defense to the Complaint, and to each cause
5 of action alleged therein, Bergen Brunswig alleges that any conduct of Bergen Brunswig was
6 fully justified and in good faith.

7 **EIGHTH AFFIRMATIVE DEFENSE**

8 8. As a eighth, separate affirmative defense to the Complaint, and to each cause of
9 action alleged therein, Bergen Brunswig alleges that Plaintiffs are estopped from maintaining
10 this action.

11 **NINTH AFFIRMATIVE DEFENSE**

12 9. As a ninth, separate affirmative defense to the Complaint, and to each cause of
13 action alleged therein, Bergen Brunswig alleges that to the extent the people of the State of
14 California have been injured by its conduct, which Eergen Brunswig denies, any damages for
15 those injuries should be offset by any damages caused Bergen Brunswig by the State of
16 California, including, but not limited to, the cost of labeling its products in the manner
17 demanded by the official representative(s) of the State of California.

18 **TENTH AFFIRMATIVE DEFENSE**

19 10. As a tenth, separate affirmative defense to the Complaint, Bergen Brunswig
20 alleges that, to the extent that the causes of action in the Complaint are based upon Health and
21 Safety Code Section 25249.5 *et seq.*, any violation occurring before the one-year period
22 provided by the applicable statute of limitations, Code of Civil Procedure Section 340(2), are
23 barred.

24 **ELEVENTH AFFIRMATIVE DEFENSE**

25 11. As a eleventh, separate affirmative defense to the Complaint, Bergen Brunswig
26 alleges that, to the extent that the causes of action in the Complaint are governed by the statute
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1 of limitations set forth in Business & Professions Code Section 17208, which provides a four
2 year statute of limitations, any alleged violations before that period are barred.

3 **TWELFTH AFFIRMATIVE DEFENSE**

4 12. As a twelfth, separate affirmative defense to the Complaint, and to each cause of
5 action alleged therein, Bergen Brunswig alleges that Plaintiffs' inexcusable and unreasonable
6 delay in filing and serving this action has operated to the detriment and prejudice of Bergen
7 Brunswig and, as a consequence, Plaintiffs are barred from seeking the relief sought, or any
8 relief whatsoever.

9 **THIRTEENTH AFFIRMATIVE DEFENSE**

10 13. As an thirteenth, separate affirmative defense to the Complaint, and to each cause
11 of action alleged therein, Bergen Brunswig alleges that any recovery by Plaintiffs should be
12 offset and diminished by the value to consumers of the use of Bergen Brunswig's products.

13 **FOURTEENTH AFFIRMATIVE DEFENSE**

14 14. As a fourteenth, separate affirmative defense to the Complaint, and to each cause
15 of action alleged therein, Bergen Brunswig alleges that recovery of the fines and penalties
16 sought by Plaintiffs is unconstitutional because such fines or penalties are excessive and violate
17 the Excessive Fines Clause of the Eighth Amendment to the U.S. Constitution, Section 1 of the
18 Fourteenth Amendment to the United States Constitution, and other provisions of the United
19 States Constitution, the Excessive Fines Clause of Article 1, Section 17 of the California
20 Constitution, and other provisions of the California Constitution.

21 **FIFTEENTH AFFIRMATIVE DEFENSE**

22 15. As a fifteenth, separate affirmative defense to the Complaint, and to each cause
23 of action alleged therein, Bergen Brunswig alleges that private enforcement provisions of Health
24 & Safety Code Section 25249.7(d) and Business & Professions Code Section 17200 are
25 unconstitutional because each one encroaches upon the constitutional duty of the Attorney
26 General to ensure that the laws of the State are uniformly and adequately enforced and thus
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1 infringe upon the executive power in violation of the separation of powers doctrine of Article
2 III, Section 3 of the California Constitution.

3 **SIXTEENTH AFFIRMATIVE DEFENSE**

4 16. As a sixteenth, separate affirmative defense to the Complaint, and to each cause
5 of action alleged therein, Bergen Brunswig alleges that Plaintiffs fails to state sufficient basis for
6 injunctive relief, in that there is no threat of immediate or irreparable harm, and/or in that any
7 such injunctive relief would be inconsistent with requirements of, or orders issued by, state
8 and/or local agencies.

9 **SEVENTEENTH AFFIRMATIVE DEFENSE**

10 17. As a seventeenth, separate affirmative defense to the Complaint, and to each
11 cause of action alleged therein, Bergen Brunswig alleges that it has undertaken all reasonable
12 efforts within its power to prevent harm to Plaintiffs, the public, or any other entity, and that no
13 such harm has occurred to such persons or entities as a result of Bergen Brunswig's actions or
14 omissions.

15 **EIGHTEENTH AFFIRMATIVE DEFENSE**

16 18. As a eighteenth, separate affirmative defense to the Complaint, and to each cause
17 of action alleged therein, Bergen Brunswig alleges that Plaintiffs' right to recovery, if any, is
18 barred because Proposition 65 is preempted by provisions of federal law, including but not
19 limited to, provisions of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 360k(a).

20 **NINETEENTH AFFIRMATIVE DEFENSE**

21 19. As a nineteenth, separate affirmative defense to the Complaint, Bergen Brunswig
22 alleges that, to the extent that the cause of action set forth in the Complaint is preempted by
23 federal law, this Court has no subject matter jurisdiction of the Complaint.

24 **TWENTIETH AFFIRMATIVE DEFENSE**

25 20. As a twentieth, separate affirmative defense to the Complaint, and to each cause
26 of action alleged therein, Bergen Brunswig alleges that it has complied with all statutes,
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1 regulations and other laws in effect at the time of the conduct allegedly giving rise to Plaintiffs'
2 claims.

3 **TWENTY-FIRST AFFIRMATIVE DEFENSE**

4 21. As a twenty-first, separate affirmative defense to the Complaint, and to each
5 cause of action alleged therein, Bergen Brunswig alleges that Plaintiffs' right to recovery, if any,
6 is barred because Proposition 65 violates Bergen Brunswig's Due Process rights under the
7 United States Constitution Amendment V, applied to the states by the Fourteenth Amendment,
8 as the Act and its implementing regulations fail to provide fair notice regarding when or how
9 Bergen Brunswig is required to provide Proposition 65 warnings to consumers who use its
10 products.

11 **TWENTY-SECOND AFFIRMATIVE DEFENSE**

12 22. As an twenty-second, separate affirmative defense to the Complaint, and to each
13 cause of action alleged therein, Bergen Brunswig alleges that Plaintiffs' right to recovery, if any,
14 is barred because Proposition 65 impermissibly burdens interstate commerce in violation of the
15 Commerce of the U.S. Constitution (Art. I, Sec. 8, Cl. 3).

16 **TWENTY-THIRD AFFIRMATIVE DEFENSE**

17 23. As a twenty-third, separate affirmative defense to the Complaint, and to each
18 cause of action alleged therein, Bergen Brunswig alleges that pharmaceutical grade coal tar
19 ("coal tar U.S.P.") used in Bergen Brunswig's products is not a known carcinogen and has not
20 been listed by the State of California as such pursuant to Proposition 65, but to the extent that
21 such a claim may be made, coal tar U.S.P. was designated by the State of California in error
22 because the scientific data relied upon to effect a finding of reproductive toxicity was flawed,
23 out-of-date, inaccurate, not scientifically valid, incorrectly interpreted by the State, or did not
24 meet the minimum criteria necessary for use by the scientific community in general, or by the
25 State of California when listing a chemical on the list pursuant to Proposition 65.

1 the scientific community in general, or by the State of California when listing a chemical or
2 maintaining a chemical on the list pursuant to Proposition 65.

3 **TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

4 27. As a twenty-seventh, separate affirmative defense to the Complaint, and to each
5 cause of action alleged therein, Bergen Brunswig alleges that coal tar, and tar are not known
6 reproductive toxins and have not been listed by the State of California as such pursuant to
7 Proposition 65, but to the extent that such a claim may be made, Coal Tar (as that term is used in
8 the Complaint) and tar were designated by the State of California in error because the scientific
9 data relied upon to effect a finding of reproductive toxicity was flawed, out-of-date, inaccurate,
10 not scientifically valid, incorrectly interpreted by the State, or did not meet the minimum criteria
11 necessary for use by the scientific community in general, or by the State of California when
12 listing or maintaining a chemical on the list pursuant to Proposition 65.

13 **TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

14 28. As a twenty-eighth, separate affirmative defense to the Complaint, and to each
15 cause of action alleged therein, Bergen Brunswig alleges that there is no duty to provide a
16 Proposition 65 warning with respect to the individual constituents of a chemical mixture and/or
17 compound that has been listed under Proposition 65. Therefore, there is no duty to provide a
18 Proposition 65 warning as to carcinogenicity with respect to the purported constituents of
19 "soots, tars, and mineral oils" as listed in Title 22, California Code of Regulations, section
20 12000(b).

21 **TWENTY-NINTH AFFIRMATIVE DEFENSE**

22 29. As a twenty-ninth, separate affirmative defense to the Complaint, and to each
23 cause of action alleged therein, Bergen Brunswig alleges that no individual has suffered any
24 injury through exposure to coal tar U.S.P. contained in Bergen Brunswig's products.
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DATED: May 7, 1999

Respectfully submitted,

McKENNA & CUNEO, L.L.P

By Carol Rene Brophy
Carol Rene Brophy

Attorneys for Defendant
BERGEN BRUNSWIG DRUG COMPANY

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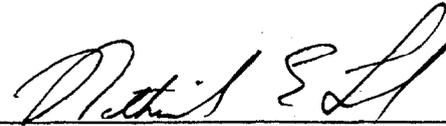
VERIFICATION

I, Nathaniel Lord, declare:

I am Vice President of Risk Management of Bergen Brunswig Drug Company, a party to this action, and am authorized to make this verification for and on its behalf, and I make this verification for that reason. I have read the foregoing Answer to Complaint for Civil Penalty and Injunctive Relief and know its contents. I am informed and believe that the matters stated in it are true, and on that ground allege that the matters stated in it are true.

Executed in San Francisco County, State of California

Dated: May 6, 1999



Nathaniel Lord
Vice President, Risk Management
Bergen Brunswig Drug Company

1 **PROOF OF SERVICE BY MAIL**

2 **STATE OF CALIFORNIA, COUNTY OF SAN FRANCISCO**

3 I am employed in the aforesaid county, State of California; I am over the age of 18 years
4 and not a party to the within action; my business address is **One Market Tower, 27th Floor,**
5 **San Francisco, California 94105.**

6 On May 7, 1999 I caused a copy of **DEFENDANT BERGEN BRUNSWIG DRUG**
7 **COMPANY'S ANSWER TO FIRST AMENDED COMPLAINT FOR CIVIL**
8 **PENALTIES AND INJUNCTIVE RELIEF** to be transmitted by facsimile transmission in
9 accordance with the standard practice of McKenna & Cuneo, L.L.P. to Susan S. Fiering, Esq.
10 Deputy Attorney General, State of California, Department of Justice, **Facsimile Number (510)**
11 **622-2270.** I am familiar with McKenna & Cuneo's practice for processing documents for
12 faxing in the ordinary course of business.

13 On May 7, 1999 I also served the above-referenced document on the interested parties in
14 this action by placing **true copies** thereof, enclosed in sealed envelopes, postage prepaid,
15 addressed as follows:

16 **SEE ATTACHED MAILING LIST.**

17 I am readily familiar with the business practice of my place of employment in respect to the
18 collection and processing of correspondence, pleadings and notices for mailing with United
19 States Postal Service.

20 The foregoing sealed envelopes were placed for collection and mailing this date
21 consistent with the ordinary business practice of my place of employment, so that it will be
22 picked up this date with postage thereon fully prepaid at San Francisco, California, in the
23 ordinary course of such business.

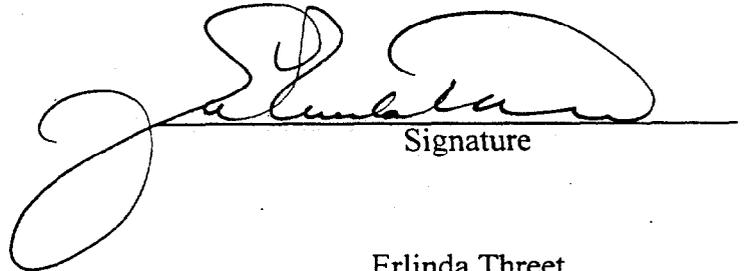
24 (STATE)

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

25 (FEDERAL)

I declare under penalty of perjury that the foregoing is true and correct, and that I am employed at the office of a member of the bar of this Court at whose direction the service was made.

26 Executed on May 7, 1999 at San Francisco, California.

27 
Signature

28 Erlinda Threet
Print Name

SERVICE LIST

People v. Alva-Amco, et al.

San Francisco Superior Court Case No. BC 300827

Perry Gottesfeld v. Alva-Amco, et al.

San Francisco Superior Court Case No. 300643

Counsel

Representing

Susan S. Fiering, Esq.
Deputy Attorney General
State of California
Department of Justice
1515 Clay Street, 20th Floor
Oakland, CA 94612-1413
Facsimile: (510) 622-2270
Telephone: (510) 622-2142

Counsel for Plaintiff
PEOPLE OF THE STATE OF CALIFORNIA

Leslie Krasny, Esq.
MORIN & KRASNY
201 Spear Street, Suite #1600
San Francisco, CA 94105
Facsimile: (415) 957-5905
Telephone: (415) 957-0101

Co-Counsel for Defendants
ALVA-AMCO PHARMACAL COS., INC.
and PERSON & COVEY, INC.

Richard O. Wood., Esq.
BELL, BOYD & LLOYD
Three First National Plaza
70 West Madison Street,
Suite 3300
Chicago, IL 60602-4207
Facsimile: (312) 372-2098
Telephone: (312) 372-1121

Co-Counsel for Defendants
ALVA-AMCO PHARMACAL COS., INC.
and PERSON & COVEY, INC.

Betty-Jane Kirwan, Esq.
LATHAM & WATKINS
633 W. Fifth Street, Suite 4000
Los Angeles, CA 90071-2007
Facsimile: (213) 891-8763
Telephone: (213) 485-1234

Counsel for Defendant
BAKER NORTON PHARMACEUTICALS

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Counsel

Trenton H. Norris, Esq.
McCutchen, Doyle, Brown & Enersen
3 Embarcadero Center, #1800
San Francisco, CA 94111
Facsimile: (415) 393-2062
Telephone: (415) 393-2286

Gene Livingston, Esq.
Matt Goldman, Esq.
LIVINGSTON & MATTESICH
1201 K Street, Suite #1100
Sacramento, CA 95814
Facsimile: (916) 448-1709
Telephone: (916) 442-1111

Alan J. Pope, Esq.
LONGS DRUG STORES, INC.
OFFICE OF GENERAL COUNSEL
141 North Civic Drive
Walnut Creek, CA 94596
Facsimile: (925) 210-6887
Telephone: (925) 210-6999

Roger Lane Carrick, Esq.
David B. Sadwick, Esq.
Brian K. Brookey, Esq.
PRESTON GATES & ELLIS LLP
725 South Figueroa Street, Suite 2100
Los Angeles, CA 90017-5524
Facsimile: (213) 624-5924
Telephone: (213) 624-2395

Noah Graff, Esq.
Jack Zebrowski, Esq.
Hughes Hubbard & Reed LLP
350 South Grand Avenue,
36th Floor
Los Angeles, CA 90071-3442
Facsimile: (213) 613-2950
Telephone: (213) 613-2800

Representing

Co-Counsel for Defendant
GUY & O'NEILL, INC.

Counsel for Defendant
J.K. PHARMACEUTICALS

Counsel For Defendant
LONGS DRUG STORES, INC.

Counsel for Defendants
NEUTROGENA CORP. and
LONGS DRUG STORES, INC.

Counsel for Defendant
PIERRE FABRE, INC.

Counsel

1 Charlotte Lowell, Esq.
2 SKADDEN ARPS SLATE MEAGHER &
3 FLOM LLP

4 525 University Avenue, Suite 220
5 Palo Alto, CA 94301

6 **Facsimile: (650) 470-4675**

7 **Telephone: (650) 470-4640**

8 Martin Grass, CEO
9 Rite Aid Corp.
10 30 Hunter Lane
11 Camp Hill, PA 17011

12 Rebecca Delgado
13 c/o CT Corporation Systems
14 818 West Seventh Street, Second Floor
15 Los Angeles, CA 90017

16 **Facsimile:**

17 **Telephone:**

18 Brian J. Donato, Esq.
19 HYMAN, PHELPS & MCNAMARA, P.C.
20 2603 Main Street, Suite 650
21 Irvine, CA 92614

22 **Facsimile: (949) 553-7433**

23 **Telephone: (949) 553-7400**

24 Renee D. Wasserman
25 Rogers, Joseph, O'Donnell
26 & Quinn

27 311 California St., 10th Floor
28 San Francisco, CA 94104

Facsimile: (415) 956-6457

Telephone: (415) 956-2828

David Gabor, Esq.
Mary Ellen Hogan, Esq.
McDERMOTT, WILL & EMERY
2049 Century Park East, #3400
Los Angeles, CA 90067-3208

Facsimile: (310) 277-4730

Telephone: (310) 277-4110

Representing

Counsel for Defendant
REEDCO, INC.

Agent for Service on Behalf of Defendant
RITE AID CORP.

Registered Agent for Service of Process On
behalf of Defendants
SAV-ON/AMERICAN DRUG STORES &
AMERICAN PROCUREMENT &
LOGISTICS

Counsel for Defendant
STIEFEL LABORATORIES, INC.

Counsel for Defendant
WALGREEN CO.

Counsel for Defendant
WESTWOOD-SQUIBB
PHARMACEUTICAL, INC.

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Counsel

Bruce S. Klafter, Esq.
ORRICK, HERRINGTON &
SUTCLIFFE LLP
Old Federal Reserve Bank Building
400 Sansome Street
San Francisco, CA 94111-3143
Facsimile: (415) 773-5759
Telephone: (415) 392-1122

Representing

Counsel for Defendant
WHITEHALL LABORATORIES

Federal Express

Align to

Central Services
FOLEY & LARDNER
ONE MARITIME PLAZA, 6TH FLOOR
SAN FRANCISCO CA 94111
(415)434-4484

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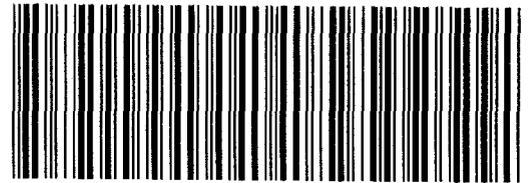
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