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13 CENTER FOR ENVIRONMENTAL HEALTH

14 SUPERIOR COURT OF THE STATE OF CALIFORNIA  
15 COUNTY OF SAN FRANCISCO

16 CENTER FOR ENVIRONMENTAL HEALTH, a  
17 non-profit corporation,

18 Plaintiff,

19 v.

20 INSIGHT PHARMACEUTICALS LLC;  
21 PRESTIGE CONSUMER HEALTHCARE, INC.;  
22 and DOES 1-100,

23 Defendants.

ELECTRONICALLY  
**FILED**

Superior Court of California,  
County of San Francisco

**05/07/2026**  
Clerk of the Court

BY: BOWMAN LIU  
Deputy Clerk

Civil Case No.: CGC-25-630369

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

Health & Safety Code §25249.6 *et seq.*

1 Plaintiff Center for Environmental Health, in the public interest, based on information and belief  
2 and investigation of counsel, except for information based on knowledge, hereby makes the following  
3 allegations:

4 **INTRODUCTION**

5 1. This First Amended Complaint seeks to remedy Defendants’ ongoing violations of  
6 California’s Proposition 65, Health & Safety Code §25249.5, *et seq.* Defendants violate Proposition 65  
7 by knowingly and intentionally exposing individuals in California to phenazopyridine hydrochloride  
8 (“Phenazopyridine Hydrochloride”), a chemical known to the State of California to cause cancer. Such  
9 exposures have occurred, and continue to occur, when individuals ingest the Uristat and Monistat  
10 Products containing Phenazopyridine Hydrochloride such as those sold under the Uristat brand (the  
11 “Uristat Products”) and Monistat brand (“Monistat Products”). The Uristat and Monistat Products are  
12 manufactured, distributed, purchased for use, sold, offered for sale, provided, or offered to be provided  
13 by Defendants. Individuals are exposed to Phenazopyridine Hydrochloride when they ingest the Uristat  
14 and Monistat Products.

15 2. Under Proposition 65, it is unlawful for businesses to knowingly and intentionally expose  
16 individuals in California to chemicals known to the State to cause cancer without first providing clear  
17 and reasonable warnings to exposed individuals. Defendants manufacture, distribute, purchase for use,  
18 sell, offer to sell, provide, or offer to provide the Uristat and Monistat Products containing significant  
19 quantities of Phenazopyridine Hydrochloride to individuals in California, thereby exposing these  
20 individuals to Phenazopyridine Hydrochloride.

21 3. Despite the fact that Defendants expose individuals to Phenazopyridine Hydrochloride,  
22 Defendants provided no clear and reasonable warnings about the carcinogenic effects associated with  
23 Phenazopyridine Hydrochloride exposure prior to CEH’s initiation of this action. Since that time,  
24 Defendants have begun providing adequate warnings on the Monistat Products, but not the Uristat  
25 Products. However, Defendants continue to sell Monistat Products without warnings in California.  
26 Defendants’ conduct with regard to both the Monistat and Uristat Products thus violates the warning  
27 provision of Proposition 65. Health & Safety Code §25249.6.

28 /

**PARTIES**

1  
2 4. Plaintiff CENTER FOR ENVIRONMENTAL HEALTH (“CEH”) is a non-profit  
3 corporation dedicated to protecting the public from environmental health hazards and toxic exposures.  
4 CEH is based in Oakland, California and incorporated under the laws of the State of California. CEH is  
5 a “person” within the meaning of Health & Safety Code §25249.11(a) and brings this enforcement  
6 action in the public interest pursuant to Health & Safety Code §25249.7(d). CEH is a nationally  
7 recognized not-for-profit environmental advocacy group that has prosecuted numerous Proposition 65  
8 cases in the public interest. Through its work, CEH has created substantial public benefit, including the  
9 reformulation or removal from the market of millions of products harming consumers and the  
10 environment. CEH also provides information to Californians about the health risks associated with  
11 exposure to hazardous substances when manufacturers and other responsible parties fail to do so.

12 5. Defendant INSIGHT PHARMACEUTICALS LLC is a person in the course of doing  
13 business within the meaning of Health & Safety Code §25249.11. INSIGHT PHARMACEUTICALS  
14 LLC manufactures, distributes, purchases for use, sells, offers to sell, provides, or offers to provide the  
15 Uristat and Monistat Products containing Phenazopyridine Hydrochloride to individuals in California.

16 6. Defendant PRESTIGE CONSUMER HEALTHCARE, INC. is a person in the course of  
17 doing business within the meaning of Health & Safety Code §25249.11. PRESTIGE CONSUMER  
18 HEALTHCARE, INC. manufactures, distributes, purchases for use, sells, offers to sell, provides, or  
19 offers to provide the Uristat and Monistat Products containing Phenazopyridine Hydrochloride to  
20 individuals in California.

21 7. The true names of DOES 1 through 100 are either unknown to CEH at this time or the  
22 applicable time period before which CEH may file a Proposition 65 action has not run. When CEH  
23 ascertains the identifies of the DOE Defendants or the applicable time period before which CEH may  
24 file a Proposition 65 action has run, CEH will amend the Complaint to reflect the true names and  
25 identities of the DOE Defendants.

26 8. The defendants identified in the paragraphs 5 through 6 and DOES 1 through 100 are  
27 collectively referred to herein as “Defendants.”

28 /

1 **JURISDICTION AND VENUE**

2 9. The Court has jurisdiction over this action pursuant to Health & Safety Code §25249.7,  
3 which allows enforcement in any court of competent jurisdiction, and pursuant to California  
4 Constitution Article VI, Section 10, because this case is a cause not given by statute to other trial courts.

5 10. This Court has jurisdiction over Defendants because each is a business entity that either  
6 (i) has its principal place of business in California or is headquartered in California; or (ii) does  
7 sufficient business, has sufficient minimum contacts in California, or otherwise avails itself of the  
8 California market through its manufacture, distribution, purchasing for use, selling, offering to sell,  
9 providing, or offering to provide the Uristat and Monistat Products in California and such business and  
10 contacts gave rise to the claims at issue. Such contacts with California also render the exercise of  
11 jurisdiction over Defendants by California courts consistent with traditional notions of fair play and  
12 substantial justice.

13 11. Venue is proper in San Francisco County Superior Court because one or more of the  
14 violations arise in the County of San Francisco.

15 **BACKGROUND FACTS**

16 12. The People of the State of California have declared by initiative under Proposition 65  
17 their right “[t]o be informed about exposures to chemicals that cause cancer, birth defects, or other  
18 reproductive harm.” Proposition 65, §1(b).

19 13. To effectuate this goal, Proposition 65 prohibits exposing people to chemicals listed by  
20 the State of California as known to cause cancer, birth defects, or other reproductive harm above certain  
21 levels without a “clear and reasonable warning” unless the business responsible for the exposure can  
22 prove that it fits within a statutory exemption. Health & Safety Code §25249.6 states, in pertinent part:

23 No person in the course of doing business shall knowingly and intentionally  
24 expose any individual to a chemical known to the state to cause cancer or  
25 reproductive toxicity without first giving clear and reasonable warning to such  
individual ...

26 14. On January 1, 1988, the State of California officially listed Phenazopyridine  
27 Hydrochloride as causing cancer. 27 California Code of Regulations (“C.C.R.”) §27001(b). On January  
28 1, 1989, Phenazopyridine Hydrochloride became subject to the clear and reasonable warning

1 requirement regarding the carcinogenic effects of Phenazopyridine Hydrochloride under Proposition 65.  
2 Health & Safety Code §25249.10(b).

3 15. Phenazopyridine Hydrochloride is intentionally added to the Uristat and Monistat  
4 Products, and is listed as the active ingredient on such Products' labels. People who consume the Uristat  
5 and Monistat Products are exposed to Phenazopyridine Hydrochloride.

6 16. Defendants' Uristat and Monistat Products contain sufficient quantities of  
7 Phenazopyridine Hydrochloride such that individuals who ingest the Uristat and Monistat Products are  
8 exposed to significant amounts of Phenazopyridine Hydrochloride. The primary route of exposure for  
9 the violations is ingestion when individuals take the Uristat and Monistat Products as recommended.  
10 These exposures occur in homes, workplaces, retail establishments, and everywhere else throughout  
11 California where the Uristat and Monistat Products are ingested.

12 17. Defendants continue to sell the Uristat and Monistat Products without any clear and  
13 reasonable warning regarding the carcinogenic effects of Phenazopyridine Hydrochloride.

14 18. Any person acting in the public interest has standing to enforce Proposition 65 provided  
15 that such person supplied the requisite public enforcers with a valid 60-Day Notice of Violation and  
16 such public enforcers are not diligently prosecuting the action within such time. Health & Safety Code  
17 §25249.7(d).

18 19. More than sixty days prior to naming each Defendant in this lawsuit, CEH provided a 60-  
19 Day "Notice of Violation" of Proposition 65 to the California Attorney General, to the District Attorneys  
20 of every county in California, to the City Attorneys of every California city with a population greater  
21 than 750,000, and to each of the named Defendants. In compliance with Health & Safety Code  
22 §25249.7(d) and 27 C.C.R. §25903(b), each Notice included the following information: (1) the name  
23 and address of each violator; (2) the statute violated; (3) the time period during which violations  
24 occurred; (4) specific descriptions of the violations, including (a) the routes of exposures to  
25 Phenazopyridine Hydrochloride from Defendants' Uristat and Monistat Products; and (b) the specific  
26 type of Uristat and Monistat Products sold or provided in violation of Proposition 65; and (5) the name  
27 of the specific Proposition 65-listed chemical that is the subject of the violations described in each  
28

1 Notice. Each Notice also included a proposal for resolution of the noticed claims and a demand that  
2 Defendants preserve all evidence relevant to the noticed claims.

3 20. CEH also sent a Certificate of Merit for each Notice to the California Attorney General,  
4 to the District Attorneys of every county in California, to the City Attorneys of every California city  
5 with a population greater than 750,000, and to each of the named Defendants. In compliance with  
6 Health & Safety Code §25249.7(d) and 11 C.C.R. §3101, each Certificate certified that CEH’s counsel:  
7 (1) has consulted with one or more persons with relevant and appropriate experience or expertise who  
8 reviewed facts, studies, or other data regarding the exposures to Phenazopyridine Hydrochloride alleged  
9 in each Notice; and (2) based on the information obtained through such consultations, believes that there  
10 is a reasonable and meritorious case for a citizen enforcement action based on the facts alleged in each  
11 Notice. In compliance with Health & Safety Code §25249.7(d) and 11 C.C.R. §3102, each Certificate  
12 served on the Attorney General included factual information – provided on a confidential basis –  
13 sufficient to establish the basis for the Certificate, including the identity of the person(s) consulted by  
14 CEH’s counsel and the facts, studies, or other data reviewed by such persons.

15 21. None of the public prosecutors with the authority to prosecute violations of Proposition  
16 65 have commenced or are diligently prosecuting a cause of action against Defendants under Health &  
17 Safety Code §25249.5, *et seq.*, based on the claims asserted in any of CEH’s Notices regarding  
18 Phenazopyridine Hydrochloride in the Uristat and Monistat Products.

19 22. Defendants both know and intend that individuals ingest the Uristat and Monistat  
20 Products, thus exposing them to Phenazopyridine Hydrochloride.

21 23. Under Proposition 65, an exposure is “knowing” where the party responsible for such  
22 exposure has:

23 knowledge of the fact that a[n] ... exposure to a chemical listed pursuant to  
24 [Health & Safety Code §25249.8(a)] is occurring. No knowledge that the ...  
25 exposure is unlawful is required.

26 27 C.C.R. §25102(n). This knowledge may be either actual or constructive. *See, e.g.*, Final Statement  
27 of Reasons Revised (November 4, 1988) (pursuant to former 22 C.C.R. Division 2, §12601).  
28

1           24. Defendants continue to expose individuals to Phenazopyridine Hydrochloride without  
2 prior clear and reasonable warnings regarding the carcinogenic toxicity of Phenazopyridine  
3 Hydrochloride.

4           25. CEH has engaged in good-faith efforts to resolve the claims alleged herein prior to filing  
5 this Complaint.

6           26. Any person “violating or threatening to violate” Proposition 65 may be enjoined in any  
7 court of competent jurisdiction. Health & Safety Code §25249.7. “Threaten to violate” is defined to  
8 mean “to create a condition in which there is a substantial probability that a violation will occur.”  
9 Health & Safety Code §25249.11(e). Proposition 65 provides for civil penalties not to exceed \$2,500  
10 per day for each violation of Proposition 65.

11           27. The Uristat and Monistat Products are over-the-counter (“OTC”) drug products. Thus, no  
12 prescription is required to buy them. Neither the Uristat nor Monistat Products have been approved by  
13 the Federal Food and Drug Administration (“FDA”). Neither the Uristat nor Monistat Products were the  
14 subject of a new drug application. Neither the Uristat nor Monistat Products are covered by a federal  
15 drug monograph.

16           28. In prior litigation concerning the Uristat Products, Defendants argued that it is impossible  
17 for them to comply both with federal drug law and Proposition 65. Yet, Defendants recently began  
18 providing Proposition 65 warnings for the Monistat Products without violating federal law. That  
19 warning states: “WARNING: This product can expose you to chemicals including phenazopyridine  
20 hydrochloride, which is known to the State of California to cause cancer. For more information go to  
21 [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).” Nevertheless, Defendants continue to both sell and offer some Monistat  
22 Products for sale in California without the Proposition 65 warning.

23           29. In prior litigation concerning the Uristat Products, Defendants misled the Court by  
24 arguing that a statement by FDA in 1983 “required that any drugs containing phenazopyridine  
25 hydrochloride” include a warning discussing “neoplasia in rats.” This argument, which was adopted by  
26 the Court, is not true. The FDA’s statement regarding precautionary language for drugs containing  
27 Phenazopyridine Hydrochloride, however, relates only to prescription drug products, not OTC ones.  
28 Accordingly, it does not and cannot apply to the Covered Products.



1           1.       That the Court, pursuant to Health & Safety Code §25249.7(a), preliminarily and  
2 permanently enjoin Defendants from either offering the Uristat Products and Monistat Products that will  
3 be sold in California or providing the Uristat Products and Monistat Products to California consumers  
4 without either reducing the Phenazopyridine Hydrochloride levels in their Uristat Products and Monistat  
5 Products such that no Proposition 65 warnings are required or providing prior clear and reasonable  
6 warnings, as CEH shall specify in further application to the Court;

7           2.       That the Court, pursuant to Health & Safety Code §25249.7(b), assess civil penalties  
8 against each Defendant in the amount of \$2,500 per day for each violation of Proposition 65 according  
9 to proof;

10          3.       That the Court, pursuant to Health & Safety Code §25249.7(a), order Defendants to take  
11 action to stop ongoing unwarned exposures to Phenazopyridine Hydrochloride resulting from the use of  
12 the Uristat Products and Monistat Products sold or provided to consumers by Defendants, as CEH shall  
13 specify in further application to the Court;

14          4.       That the Court, pursuant to Code of Civil Procedure §1021.5 or any other applicable  
15 theory, grant CEH its reasonable attorneys' fees and costs of suit; and

16          5.       That the Court grant such other and further relief as may be just and proper.

17  
18 Dated:   May 6, 2026

Respectfully submitted,

19 LEXINGTON LAW GROUP, LLP

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21 \_\_\_\_\_  
22 Mark Todzo  
23 Patrick Carey  
24 Meredyth Merrow  
25 Attorneys for Plaintiff  
26 Center for Environmental Health  
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