IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ENVIRONMENTAL WORKING GROUP 1436 U Street, NW Suite 100 Washington, DC 20009 and WOMEN'S VOICES FOR THE EARTH 114 West Pine Street Missoula, Montana 59807, Plaintiffs, - against - UNITED STATES FOOD AND DRUG ADMINISTRATION and ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of the United States Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, Maryland 20993, Defendants.	:	Case No. 16-cv-02435 Complaint

Plaintiffs Environmental Working Group ("EWG") and Women's Voices for the Earth ("WVE"), by their attorneys Cohen & Gresser LLP, for their complaint against defendants the United States Food and Drug Administration ("FDA") and Robert M. Califf, M.D., in his official capacity as Commissioner of FDA, allege as follows:

Nature of the Action

1. This action arises from defendant FDA's failure, in violation of its statutory mandate under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq*. (the "FDCA"), as well as its own regulations, to act on a citizen petition filed *over five years ago*, on or about April 12, 2011 (the "Petition") calling on the FDA to investigate and regulate keratin hair straighteners -- cosmetic products routinely used in beauty salons across the nation to

smooth, protect, soften and relax hair -- that contain formaldehyde and formaldehyde-releasing chemicals.

2. Ample scientific evidence, described in the Petition and in scientific literature, demonstrates that use of formaldehyde-containing keratin hair straighteners poses health risks both to beauty salon workers who apply them and to the customers on whom the products are used. And anecdotal evidence, including in adverse event reports submitted to the FDA, confirms the existence of those hazards. For example, beauty salon workers have reported suffering burning eyes, breathing problems, headaches, dizziness and blurred vision after applying keratin hair straightener treatments to customers.

3. In light of the real and serious health hazards that formaldehyde-containing keratin hair straighteners pose, the Petition asks that the FDA exercise its authority under the FDCA to (a) investigate and respond appropriately to deceptive labeling of keratin hair straighteners that conceal the fact that their use will expose salon workers and customers to formaldehyde; (b) require manufacturers of keratin hair straighteners to label their products in a manner that discloses the extent to which they contain formaldehyde or formaldehyde-releasing chemicals; and (c) review whether to ban the use of formaldehyde and formaldehyde-releasing chemicals in the manufacture of keratin hair straighteners.

4. Regrettably, the FDA -- despite its repeated acknowledgement of the link between use of keratin hair straighteners by consumers and serious health risks -- has failed to act on the Petition during the nearly five-and-a-half years since its filing. In a letter on or about September 6, 2011, the FDA attributed its inaction on the Petition to "competing priorities." Later, on July 27, 2012, in response to EWG's inquiry regarding the status of the Petition, the

FDA advised EWG that the Petition remained under review and that, consistent with agency policy concerning citizen petitions, it would not provide a detailed report on the status of the Petition. Since then, EWG has received no further substantive response to the Petition from the FDA.

5. Undisputed facts establish that the FDA has unreasonably delayed in acting on the Petition. Accordingly, to prevent further harm to the health of salon workers and other members of the public who use keratin hair straighteners, EWG and WVE (together, "Plaintiffs") now bring this action under 5 U.S.C. §§ 702 and 706(1), and the FDA's own regulations, seeking appropriate orders of this Court directing the Defendants to act promptly on the Petition.

Parties

6. Plaintiff EWG is a not-for-profit corporation duly organized and existing under the laws of the District of Columbia, with its principal place of business located at 1436 U Street, NW, Suite 100, Washington, DC 20009. As a research and advocacy organization, EWG is dedicated to empowering people to live healthier lives in a healthier environment through its educational reports, online guides, mobile apps, and related campaigns. EWG's staff includes scientists, policy experts, lawyers, journalists, communications experts, and computer programmers who work tirelessly to promote public health, engaging EWG's active online community nationwide. In keeping with its mission, EWG helps consumers make more informed decisions about potentially hazardous chemical ingredients in everyday products such as cosmetics, principally through its Skin Deep Cosmetics Database. EWG further advocates reform of the federal cosmetics law to give the public greater assurance that such products are in fact safe for use.

7. Plaintiff WVE is a not-for-profit corporation duly organized and existing under the laws of the State of Montana, with its principal place of business located at 114 West Pine Street, Missoula, Montana 59807. In 1995, WVE's founders recognized that many then-existing environmental organizations failed to include women in leadership positions and did not fully recognize the systemic connections between health, class, race, and the environment. Accordingly, they established WVE as a new environmental organization, led by women, with the mission of amplifying women's voices to eliminate toxic chemicals that harm health and communities.

8. Defendant FDA is a federal government agency. Upon information and belief, FDA has its principal offices at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993. The FDA acts under the authority delegated to it by Congress and is a component of the United States Department of Health and Human Services ("HHS"), a federal agency that, upon information and belief, has its headquarters in the District of Columbia. The FDA is responsible for implementing the FDCA, including the FDCA's provisions regarding regulation of chemical ingredients in cosmetics.

9. Defendant Robert M. Califf, M.D., is Commissioner of FDA and, upon information and belief, has ultimate responsibility for the FDA's activities, including the matters alleged in this Complaint. Plaintiffs name Dr. Califf as a defendant in this action solely in his official capacity as Commissioner of the FDA.

Jurisdiction and Venue

10. This Court has subject matter jurisdiction over this action (a) pursuant to 28 U.S.C. § 1331 because the action arises under the Constitution, laws, or treaties of the United

States; and (b) pursuant to 28 U.S.C. § 1361 because this is an action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to Plaintiffs.

11. Venue is properly laid in this District pursuant to 28 U.S.C. § 1391(e)(1) because this is an action in which the defendants are an agency of the United States and an officer or employee of that agency, acting in his official capacity, one of the plaintiffs resides in this District and no real property is involved in the action.

Factual Background

The Dangers of Formaldehyde

12. Formaldehyde is a colorless and strong smelling gas that occurs naturally, at least in small amounts, and has been manufactured commercially for over a century. Most suppliers distribute formaldehyde in an aqueous solution that, when exposed to air, releases formaldehyde gas. Manufacturers use formaldehyde in the production of paper and plywood, and formaldehyde also is an ingredient in certain cosmetic products.

13. Keratin hair straighteners temporarily straighten hair by connecting strands of hair or keratin together. This connection is accomplished by using a liquid solution of keratin and a chemical cross-linking agent that are applied to hair and then set with heat from a hot hair dryer or flat iron. Federal and state government agencies have identified numerous keratin hair straighteners that contain formaldehyde or formaldehyde-releasing compounds. Salon workers and consumers are at risk for formaldehyde exposure throughout the process of using those products. For example, workers handling these products may absorb formaldehyde directly through the skin, eyes and mucous membranes to the extent they come into direct

contact with the product. Likewise, salon workers and consumers may inhale formaldehyde gas that keratin hair straighteners release when exposed to heat through blow-drying or flat ironing after application to a customer's hair.

14. Some companies, particularly those making deceptive "formaldehyde-free" labeling claims, have argued that their products contain methylene glycol, rather than formaldehyde. But methylene glycol is merely a solution of formaldehyde in water. Formaldehyde is always present in the solution, and the solution is easily reversible, especially when methylene glycol is heated. Regulatory agencies, as well as the Cosmetic Ingredient Review and the American Chemistry Council, consider methylene glycol to be equivalent to formaldehyde.

15. Scientists have documented extensively the health risks associated with formaldehyde exposure. Formaldehyde is a sensitizing allergen and the chance of an allergic reaction increases with each additional exposure. Short-term effects of such exposure include eye, nose and throat irritation, anosmia, increased upper respiratory disease, dry and sore throats, respiratory tract irritation, cough, chest pain, shortness of breath and wheezing. In addition, contact with formaldehyde-containing solutions can cause symptoms such as skin irritation and dermatitis.

16. The United States Agency for Toxic Substances and Disease Registry, the National Institute of Environmental Health Sciences and the International Agency for Research on Cancer classify formaldehyde as a known human carcinogen. Other government agencies -- including the United States Occupational Safety and Health Administration ("OSHA") and the United States Environmental Protection Agency ("EPA") -- have noted a potential link between

formaldehyde and human cancers (such as nasal and lung cancer, brain cancer and leukemia). And the National Institute for Occupational Safety and Health ("NIOSH"), which (like FDA) is a component of HHS, considers formaldehyde to be a known carcinogen. Likewise, the American Conference of Governmental Industrial Hygienists ("ACGIH") has recognized formaldehyde as a suspected human carcinogen.

17. Likewise, the National Research Council ("NRC") of the National Academy of Sciences has issued a report entitled "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde," concerning the EPA's assessment of the harm resulting from use of formaldehyde as an ingredient in products. Among other things, NRC's report concluded that formaldehyde causes cancer in humans. The report also concluded that the EPA's assessment supported NRC's conclusions that formaldehyde can cause irritation to the eyes, nose, and throat; lesions in the respiratory tract; and, at high concentrations, genetic mutations. Finally, the report concluded that the evidence was sufficient for EPA to conclude that formaldehyde exposures are a cause of cancers of the nose, nasal cavity, and upper throat.

18. In light of the hazards that formaldehyde poses to human health, OSHA regulations strictly limit workplace exposure of employees to formaldehyde. Among other things, those regulations provide that:

- Employers must assure that no employee is exposed to an airborne concentration which exceeds 0.75 parts formaldehyde per million parts of air ("ppm") as an eight-hour time weighted average , or exceeds 2 ppm as a 15-minute short-term exposure limit;
- In workplaces where employees may be exposed to airborne formaldehyde in concentrations of at least 0.5 ppm, employers must regularly monitor employee formaldehyde exposure; and
- Employers must ensure that airborne formaldehyde concentrations exceeding the TWA or the STEL occur only in regulated areas with

> signage stating, among other things, "DANGER," "MAY CAUSE CANCER" and "CAUSES SKIN, EYE AND RESPIRATORY IRRITATION."

Moreover, OSHA regulations generally require manufacturers, importers and distributors to provide extensive, written health and safety disclosures with respect to solutions that are (a) composed of 0.1 percent or more formaldehyde, or (b) capable of releasing formaldehyde into the air at concentrations exceeding 0.1 ppm. As to solutions capable of releasing formaldehyde into the air at concentrations exceeding 0.5 ppm, those warnings must include the statement "May Cause Cancer."

19. Notably, other government and industry organizations urge even tighter restrictions on formaldehyde exposure than the ones that OSHA regulations mandate. For example, NIOSH has established a recommended exposure level to formaldehyde gas of 0.016 ppm as an eight-hour time weighted average, and 0.1 ppm as a 15-minute short-term exposure limit. And ACGIH has recommended capping all employee exposure to formaldehyde gas, whether long or short-term, at 0.3 ppm.

20. Similarly, the Cosmetic Ingredient Review ("CIR") -- a body funded by the cosmetics industry -- has recommended extremely tight restrictions on the formaldehyde content of cosmetic products. In a report entitled "Amended Safety Assessment of Formaldehyde and Methylene Glycol as Used in Cosmetics," CIR's Expert Panel concluded that formaldehyde and formaldehyde equivalents "are safe for use in cosmetics when formulated to ensure use at the minimal effective concentration, but in no case should the formalin . . . concentration exceed 0.2% (w/w) which would be 0.074% (w/w) calculated as formaldehyde or 0.118% calculated as methylene glycol." The CIR report concludes, in relevant part, that

"formaldehyde and methylene glycol are unsafe for use in the present practices of use and concentration in hair smoothing products."

Oregon OSHA Investigates Formaldehyde Containing Keratin Hair Straighteners

21. During 2010, a hair stylist in the Portland, Oregon area contacted the Center for Research in Occupational and Environmental Toxicology ("CROET") at the Oregon Health Sciences University, reporting difficulty breathing, nose bleeds and eye irritation when using a popular keratin hair straightener. Initial testing of the product revealed that it contained formaldehyde, and CROET noted that the hair stylist's symptoms were consistent with formaldehyde exposure. Upon information and belief, in light of these initial results, CROET posted a notice concerning the product to its "emerging issues and alerts" website on or about September 16, 2010. Subsequently, upon further information and belief, CROET received numerous telephone calls and e-mails from hair stylists around the United States, many of whom reported health symptoms -- including burning of the eyes and throat, watering of eyes, dry mouth, anosmia, headache, "grogginess," malaise, shortness of breath and breathing difficulty -- associated with use at work of the product CROET had tested.

22. During the fall of 2010, CROET and the Oregon Occupational Safety and Health Division ("Oregon OSHA") conducted a study of keratin hair straighteners. The study included chemical analysis of various keratin hair straightener products, and testing airborne formaldehyde gas levels in hair salons associated with the use of those products. In all, CROET and Oregon OSHA tested over 100 samples of numerous keratin hair straightener products, and analyzed air samples from at least seven different hair salons.

23. CROET and Oregon OSHA published the results of their analyses in a report dated October 29, 2010 (the "2010 Report").

24. According to the 2010 Report, samples of the keratin hair straightener that was the subject of the initial hair stylist report to CROET, although labeled "formaldehyde free," in fact contained from 6.8 percent and 11.8 percent formaldehyde -- between *34 and 59 times* the CIR-recommended limit. CROET and Oregon OSHA also identified a number of other keratin hair straightener products that likewise contained formaldehyde. According to the 2010 Report, the average formaldehyde content that CROET and Oregon OSHA found in samples of those products ranged from 1.5 percent to 7.3 percent, again a significant multiple of the CIR-recommended limit.

25. The 2010 Report also noted the results of air monitoring in which CROET and Oregon OSHA checked the levels of formaldehyde gas to which a hair stylist was exposed during a single keratin hair straightener treatment. The highest short-term and long-term exposures that CROET and Oregon OSHA observed were 1.88 ppm (for 26 minutes) and 0.331 ppm, respectively. Although these levels were below the mandatory short-term exposure limit and time-weighted average limit under OSHA regulations, they were significantly higher than the formaldehyde gas exposure limits that ACGIH and NIOSH had recommended.

26. Moreover, in the 2010 Report, Oregon OSHA noted: "[I]f the same stylist had performed one more comparable two-hour [keratin hair straightener] procedure in the course of the same day, the time-weighted-average would likely have been twice as high, putting it well over the [OSHA] action level and at more than 85 percent of the [OSHA permitted exposure

limit]. A third comparable procedure would have been likely to result in exposures above the [OSHA permitted exposure limit]."

27. In the 2010 Report, based on the tests they conducted on keratin hair straighteners, CROET and Oregon OSHA concluded "that there are meaningful risks to salon workers when they are confronted with these hair smoothing products."

28. During October 2010, in connection with the release of the 2010 Report, Oregon OSHA also issued a Hazard Alert regarding its investigation. The Hazard Alert discussed Oregon OSHA's extensive testing of hair straightening products, and its finding that many popular products, despite being labeled "formaldehyde free," in fact contained significant levels of formaldehyde. The alert detailed the exposure limits for formaldehyde in the use of the products and provided information regarding how to educate and train salon workers, and reduce their exposure to the formaldehyde in keratin based hair smoothing products.

Other Actions By Governmental Agencies and Advocacy Groups Relating to Keratin Hair Straighteners

29. During the period when Oregon OSHA was conducting its tests of keratin hair straighteners, and after Oregon OSHA issued its report, authorities in a number of other states (and countries) took action regarding these products.

30. In or about October 2010, upon information and belief, the government of Ireland began recalling certain keratin hair straighteners.

31. On or about October 26, 2010, Health Canada, an agency of the government of Canada, issued a public health advisory concerning its own testing of hair straightening products. Health Canada reported that its validated tests showed that the keratin

hair straightener originally reported to CROET contained 8.4% percent formaldehyde -- *42 times* the maximum formaldehyde concentration for cosmetics in that country, and well above the concentration known to cause injury. Health Canada also reported that it was working to stop the product's distribution in Canada.

32. In November 2010, upon information and belief, authorities in France removed eight keratin hair straighteners from the market, including one of the hair smoothing products that, according to the 2010 Report, contained formaldehyde.

33. Subsequently, upon further information and belief, the government of Italy recalled four keratin hair straighteners from the market in that country.

34. On or about November 10, 2010, the California Attorney General brought suit against GIB, LLC ("GIB"), a manufacturer of keratin hair straightener products under the brand name "Brazilian Blowout," alleging that GIB unlawfully failed to inform customers or workers that formaldehyde gas was being released during the use of certain of these products. In January 2012, GIB and the California Attorney General entered into a settlement of this action. Under the terms of the settlement, GIB agreed to pay $600,000 in fees, penalties and costs, stop deceptive advertising of the products in question as "formaldehyde free" and make changes to its website.

35. Also during November 2010, the Connecticut Department of Health issued a press release cautioning Connecticut hair salon workers about the possible health effects of certain "Brazilian Blowout" products. The press release advised individuals experiencing health effects that they felt to be the result of using those products to seek the help of a medical professional, and urged salon workers, stylists or consumers interested in learning more about

the "Brazilian Blowout" products and potential formaldehyde-related health effects to contact the Occupational Health Unit of the Connecticut Department of Public Health.

36. On or about November 2010, the Campaign for Safe Cosmetics -- a group of public health and safety nonprofits that included WVE and EWG -- urged the FDA to recall specific keratin-based smoothing products.

37. On or about November 18, 2010, the California Division of Occupational Safety and Health posted a safety update to its website, explaining that use of keratin hair straighteners could involve exposure to formaldehyde, and identifying workplace precautions that should be taken to reduce the adverse effects of keratin hair straighteners containing formaldehyde.

EWG Files Its Citizen Petition

38. As concerns over keratin hair straightening products continued to mount, EWG filed its Petition, on or about April 12, 2011, requesting that the FDA take immediate action to protect the public from formaldehyde-containing keratin hair straighteners. (A true copy of the Petition is annexed to this Complaint as Exhibit A.)

39. In the Petition, EWG requested that the FDA take regulatory action to respond to the mounting health concerns surrounding the manufacturing, labeling, and marketing of keratin hair straighteners that release formaldehyde during the treatment process. The Petition also apprised the FDA of EWG's concern that at least a dozen manufacturers -- many of whom had been identified in the 2010 Report -- appeared to be concealing the formaldehyde content of the keratin hair straighteners they sell, giving rise to a significant public health risk.

40. The Petition requested that the FDA take action to investigate the marketing and labeling practices of these companies and confirm whether their products release the chemical at levels reported by various health agencies; require warning labels for hair-straighteners with formaldehyde, including formaldehyde in solution, and/or formaldehyde-releasing chemicals; and review whether to ban the use of formaldehyde and formaldehyde-releasing chemicals in keratin hair straighteners, given the significant health hazard that formaldehyde poses to consumers.

41. The FDA filed the Petition and assigned it a docket number on or about April 14, 2011.

State and Federal Officials Urge the FDA to Take Action as to Keratin Hair Straighteners

42. Around the time of the EWG petition, on or about May 6, 2011, six members of Congress sent a letter to the FDA (the "May 2011 Letter"), expressing their concern regarding the continued use of formaldehyde-containing keratin hair straighteners in the United States, and requesting that the FDA take immediate action to protect workers and consumers based on OSHA's and Oregon OSHA's testing of these products. The May 2011 Letter informed the FDA that as a result of the risks posed by formaldehyde-containing keratin hair straighteners, six countries had banned these products from their markets. The May 2011 Letter went on to express concern that, despite the risks associated with formaldehyde-containing keratin hair straighteners, those products were available and used on a daily basis in beauty salons across the United States.

43. Accordingly, the May 2011 Letter requested that the FDA issue a voluntary recall of keratin hair straighteners that, based on already-conducted testing, were known to have high levels of formaldehyde; continue testing keratin hair straighteners available

on the market to determine their formaldehyde content; require warning labels for hair straighteners that contain formaldehyde; investigate the labeling practices of companies marketing keratin hair straightener products as "formaldehyde-free"; and review whether to ban formaldehyde and formaldehyde-releasing chemicals from these products given the significant health hazard they pose.

44. Shortly after the May 2011 Letter, on or about August 30, 2011, the Commissioner of the New York State Department of Health wrote to the Commissioner of the FDA to express concern regarding the use of keratin based hair smoothing products sold in New York as well as elsewhere in the United States. The letter highlighted the serious health risk associated with the use of these products when they contain formaldehyde, and referenced new scientific information regarding the safety of formaldehyde -- including the NTP report that classified formaldehyde as a known human carcinogen, and the CIR report recommending tight limits on formaldehyde content in cosmetics generally and the particular hazards posed by formaldehyde in keratin hair straighteners. The New York State health commissioner also pointed to the product tests done by the Oregon Department of Consumer and Business Services and the European Directorate-General of Health and Consumer Affairs, showing formaldehyde content in some keratin-based hair smoothing products as high as 11.8 percent. Accordingly, the New York State health commissioner requested that "the FDA prohibit the interstate commerce of all hair smoothing products that contain formaldehyde or formaldehyde equivalents," based on her conclusion that such products are "adulterated" within the meaning of the FDCA.

45. On or about December 11, 2012, in light of continued inaction by the FDA, members of Congress again wrote to the FDA, expressing concern regarding the FDA's lack of progress investigating and taking action to protect workers and consumers from the

serious health impact that results from the use of keratin hair smoothing products that contain or release formaldehyde. That letter also discussed OSHA's hazard alert; a warning letter that the FDA had sent in August 2011 to a manufacturer of keratin hair straighteners, stating that its product was adulterated and misbranded because it contained formaldehyde but nevertheless was labeled "formaldehyde-free"; and other actions that, in the legislators' view, had not gone far enough to protect the public.

Action By Federal Regulators Subsequent to the Filing of the Petition

46. Subsequent to the filing of the Petition, federal regulators (apart from the FDA) continued to take actions demonstrating the hazards that salon workers and customers face as a result of the use of keratin hair straighteners that contain formaldehyde or formaldehyde-releasing compounds.

47. On or about May 16, 2011, NIOSH wrote to a salon owner concerning the results of a health hazard evaluation it had conducted the previous December, at the salon owner's request, to determine the extent to which salon workers were exposed to formaldehyde gas when they performed keratin hair smoothing treatments. Based on the air sample test results, NIOSH recommended that the salon discontinue use of the hair keratin straightener product in the salon. NIOSH also recommended that the salon -- if it continued using the product at all -- follow the requirements in the OSHA formaldehyde standard by providing for employees, among other things, personal protective equipment, training, eye and skin washing equipment, gloves, and medical surveillance. NIOSH further recommended that the salon conduct further air sampling and, if sampling showed formaldehyde concentrations above the NIOSH ceiling limit (or the occupational exposure limits established by other organizations and government

agencies), provide its employees with NIOSH-approved respirators until the salon implemented engineering or administrative controls to reduce formaldehyde exposures below those limits.

48. On or about September 22, 2011, OSHA issued a "hazard alert" warning stylists against the use of keratin hair straighteners containing formaldehyde. The alert discussed the results of OSHA's investigations, including air tests showing formaldehyde at levels above OSHA's permissible limits in salons using certain keratin hair straighteners.

49. According to the alert, OSHA had conducted air sampling at multiple beauty salons and found formaldehyde in the air when stylists were using hair smoothing products. Like its Oregon counterpart, OSHA found that some of these products -- although they released formaldehyde gas in normal use -- were labeled "formaldehyde free" or did not list formaldehyde on their labels or safety data sheets.

50. OSHA's alert also stated the agency's finding that beauty salon owners were not aware that the hair smoothing products could expose workers to formaldehyde where manufacturers, importers, and distributors did not include on labels of these products that they contained formaldehyde.

51. A few months later, on December 8, 2011, the U.S. Department of Labor issued a news release regarding OSHA's actions in connection with the issuance of citations and fines to beauty salons for failure to protect workers from formaldehyde exposure as a result of using hair smoothing products. The news release stated that, for calendar year 2011, OSHA had issued citations to *twenty three* salon owners and beauty schools in several different states, with fines of up to $17,500, for failure to protect workers from overexposure and potential exposure to formaldehyde. OSHA also launched new webpages designed to provide the public with

accurate information about the potential hazards related to formaldehyde contained in keratin hair straighteners.

The FDA and WVE Continue to Receive Reports of Adverse Health Effects Associated with Keratin Hair Straighteners

52. Subsequent to the filing of the Petition, the FDA has, upon information and belief, received numerous written reports of adverse health consequences that beauty salon workers have suffered following their use in the workplace of formaldehyde-containing keratin hair straighteners.

53. Upon information and belief, in or about April 2012, a hair stylist named Jennifer Arce delivered forty letters from fellow stylists to the FDA, requesting an immediate recall of hair straightening products that contain formaldehyde. In her cover letter to the FDA, Ms. Arce stated that it was her hope that, after reading the letters, the agency would realize the severity of the situation and how harmful the formaldehyde in hair smoothing products is to stylists, and take action to remove those products from the market.

54. The letters that Ms. Arce delivered to the FDA provided detailed accounts of health effects that hair stylists suffered as a result of exposure to the harmful hair straightening products. For example, the author of one of the letters -- a hair stylist in New York City -- reported that she had started performing keratin hair straightening treatments in 2011, as a faster way to get on the floor of her salon as a new stylist, often performing three or four keratin hair straightening treatments a day over a nine-month period. The stylist further reported that, during the period when she frequently used keratin hair straighteners, her health declined. She developed chronic sinus and respiratory infections that were so bad that she couldn't sleep, and

gasped for air -- she went to bed with what felt like an "elephant on her chest." Painful blisters showed up in her nose, and she required inhaled steroids due to shortness of breath.

55. Upon information and belief, a number of the stylists who wrote letters that Ms. Arce submitted to the FDA traveled to Washington, D.C. to tell their stories directly to members of Congress and, after doing so, attended meetings with the FDA, OSHA, NIOSH and the White House Cabinet Secretary.

56. In addition, the FDA has received as many as 188 adverse event reports since 2008 documenting ill effects attributed to the use of hair straightening products. These reports include the exact date of the adverse event, the age of the person that reported the adverse event, the person's gender, the outcome of the adverse event (i.e., a doctor's visit or a serious illness), identification of the hair keratin product, and a specific description of the adverse event the person experienced related to the use of the product. These adverse inference reports describe symptoms including: burning throat, nose, scalp and face; extreme hair loss; anxiety, stress and fear; severe pain; chest discomfort; change in heart rate; palpitations; fibrillation; shortness of breath in exertion and asthma attacks; nose drainage; nose bleeds; blisters in the nose, watery eyes; blurred vision; loss of smell; migraines; nausea; insomnia; flu symptoms; shaking; and even hearing loss.

57. WVE has also received reports from beauty salon workers demonstrating a correlation between the use of the keratin hair straightening treatments and problematic health issues. Stylists describe being unable to breathe due to the fumes from the hair straightening products, becoming nauseous and dizzy, experiencing heavy fatigue, burning eyes, frequent coughing, and sore and dry throats. The stylists reported experiencing these symptoms not only

when they performed the keratin hair straightener treatment on their own clients but also when the treatments were being applied to clients by other stylists in the salon.

58. A number of the stylists reported instances in which they had reported these health issues to salon owners and requested that appropriate OSHA-mandated safety measures be implemented due to the formaldehyde exposure associated with use of keratin hair straighteners, but the salon owners did not comply with their requests. Many of these individuals advised WVE that they are forced to decide whether to continue working in beauty salons that use keratin hair straighteners or forgo the ability to earn a living as a hair stylist. These are just a few examples of the personal stories contained in the letters submitted to the FDA by Ms. Arce and in reports to plaintiff WVE.

The FDA's Continuing Failure to Act on the Petition

59. Despite overwhelming evidence of the health hazards that formaldehyde-containing or releasing keratin hair straighteners pose -- and although over a thousand people have, to date, contacted the FDA to ask that the agency issue a voluntary recall of keratin hair straightening products that contain or release formaldehyde -- the FDA has not acted on the requests made in the Petition, and harmful keratin hair straightening products remain on the market. Nearly 20,000 people have signed a petition asking the FDA to recall these products.

60. In compliance with regulations requiring that the FDA respond to citizen petitions within 180 days of receipt, the FDA sent EWG a tentative response to the Petition on or about September 6, 2011. However, the FDA's response merely stated that due to "competing priorities" the agency was unable to reach a decision on the Petition. The FDA further advised EWG that it was still evaluating the Petition.

61. On or about March 7, 2012, EWG responded in writing to the FDA's September 6, 2011 letter concerning the Petition. In the letter EWG requested an update on the status of the Petition and urged the FDA to exercise greater leadership in dealing with the important matters of cosmetic safety that the Petition raised.

62. On July 27, 2012, the FDA responded to EWG's letter dated March 7, 2012. In its response the FDA advised EWG that the Petition remained under review and that "as a matter of policy" the FDA does not provide detailed status reports concerning its evaluation of citizen petitions under review.

63. The July 2012 communication from the FDA was the last substantive communication that EWG received from the FDA concerning the Petition, apart from responses to Plaintiffs' request pursuant to the Freedom of Information Act ("FOIA") for documents related to the Petition and keratin hair straighteners.

64. In November 2014, WVE published a report entitled "Beauty and Its Beast -- Unmasking the Impacts of Toxic Chemicals on Salon Workers." Among other things, WVE noted in its report that beauty salon workers who were exposed to formaldehyde gas experienced severe irritation to the eyes, nose and throat, and that long-term exposure to formaldehyde in the workplace has been associated with an increased risk of cancer. And in October 2015, WVE wrote the FDA to ask whether the agency had been taken any action with respect to keratin hair straightening products, noting its concern at the fact that the formaldehyde content of one keratin hair straightening product currently on the market -- as confirmed by the material safety data sheet for that product -- is 3 to 7 percent.

65. The FDA replied to WVE that it is currently looking at all of the data on formaldehyde and hair straighteners as a category, and would provide more specific responses to WVE's questions in the future.

66. WVE has never received the "more specific responses" that the FDA promised. Nor, to Plaintiffs' knowledge, has the FDA taken any action at all on the Petition (other than sending non-substantive correspondence to EWG). Indeed, apart from a posting on the FDA website and two warning letters that the FDA issued to manufacturers of keratin hair straightening products in 2011 and 2015 -- in which the FDA took the position that those products are "adulterated" as the FDCA, defines that term, by reason of their formaldehyde content -- Plaintiffs are unaware of any action that the FDA has taken to protect the public from the dangers that these products pose.

67. Unfortunately, upon information and belief, at least thirty three different keratin hair straighteners that have been recalled in other countries due to their potentially dangerous levels of formaldehyde remain on the market in the United States. And several companies in the United States continue to manufacture and distribute keratin hair straightening products that, according to their material safety data sheets, contain formaldehyde at levels exceeding recommended safety limits.

Cause of Action
(Unreasonable Delay)

68. Plaintiffs repeat the allegations contained in paragraphs 1 through 67.

69. The FDA is charged with enforcing the FDCA. Its statutory mission, as set forth in 21 U.S.C. § 393(b)(2)(d), includes protecting public health by ensuring that "cosmetics are safe and properly labeled."

70. The FDCA prohibits "[t]he receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise." 21 U.S.C. § 331(c).

71. The FDA has "[t]he authority to promulgate regulations for the efficient enforcement of [the FDCA]." 21 U.S.C. § 371(a).

72. Regulations promulgated pursuant to the FDCA provide that citizens may petition FDA to "issue . . . a regulation or order." 21 C.F.R. § 10.25(a)(2). The requirements for filing a citizen petition with the agency are set forth in 21 C.F.R. 10.30(b). These regulations provide explicitly that "[t]he Commissioner shall . . . rule upon each petition filed under [21 C.F.R. 10.30(c)], taking into consideration (i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute." *Id.* § 10.30(e)(1).

73. The FDA has recognized that keratin hair straighteners containing formaldehyde or formaldehyde-releasing compounds are adulterated and -- to the extent their formaldehyde content is not disclosed -- misbranded under the FDCA. The FDA should act on EWG's petition to properly regulate these cosmetic products under the FDCA.

74. The FDA's own regulations require that it act on a citizen petition within 180 days. 21 C.F.R. § 10.30(e)(2). The FDA advised EWG that it could not rule on the Petition due to "competing priorities" within the 180 days. However, upon information and belief, FDA has taken no further action on the Petition during the more than five years since it cited "competing priorities" as a reason for its failure to act on the Petition within the initial 180 day period set out in agency regulations.

75. The APA also directs each federal agency to "within a reasonable time . . . conclude a matter presented to it[,]" 5 U.S.C. § 555(b), and mandates that the Court "shall . . . compel agency action unlawfully withheld or unreasonably delayed[,]" *id*. § 706(1).

76. The FDA has unreasonably delayed agency action, for over five and a half years, by failing to issue a final response to the April 2011 Petition, in violation of the FDCA, the FDA's own implementing regulations and the APA.

77. As a result of the FDA's inaction, and given that the FDA has not effectively regulated the harmful keratin hair straighteners on the market, citizens and residents of the United States are continuing to suffer the health effects from these products.

78. Due to the FDA's delay in ruling on the Petition, citizens and residents of the United States, including the beauty salon hair stylists and consumers, remain at risk to formaldehyde exposure from keratin hair straighteners.

79. As a result of the FDA's ongoing delay, a court-ordered deadline is necessary to ensure that the FDA responds to the Petition within a specified time frame.

80. The FDA's unreasonable delay in acting on the Petition, and its failure to comply with its statutory and regulatory obligations, prevents EWG and WVE from exhausting administrative remedies by obtaining a final decision.

WHEREFORE, Plaintiffs respectfully request judgment against the Defendants as follows:

(a) Declaring that Defendants have unreasonably delayed acting on the Petition, in violation of the Administrative Procedure Act, the FDCA, and the FDA's own regulations;

(b) Directing Defendants to act on the Petition by a date certain, to be determined by the Court;

(c) Retaining jurisdiction of this matter, to ensure that Defendants comply with their legal obligations, and the Court's directives, to act on the Petition;

(d) Awarding Plaintiffs their costs and disbursements incurred in connection with this action, including reasonable attorneys' fees; and

(e) Awarding Plaintiffs such other and further relief as the Court deems just and proper.

Dated: Washington, D.C.
December 13, 2016

Respectfully submitted,

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