

May 11, 2015

Sarah Kotler  
Director, Division of Freedom of Information  
Office of the Executive Secretariat  
Office of the Commissioner  
U.S. Food and Drug Administration  
Room 1033  
5630 Fishers Lane  
Rockville, MD 20857

**Re: Freedom of Information Act Request**

Dear Ms. Kotler:

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and corresponding U.S. Food and Drug Administration (FDA) regulations, 21 C.F.R. Part 20, the EWG Action Fund hereby requests copies of the following records<sup>1</sup> located within FDA:

- (1) All records since 2000 relating to asbestos or asbestos-like fibrous silicate contamination or potential contamination of consumer products—such as cosmetics, drugs and food—that contain talc, including, but not limited to, asbestos testing and results, studies conducted or received by FDA relating to asbestos contamination, and risk assessments relating to potential contamination;
- (2) All records since 2000 relating to the sourcing of talc for consumer products;
- (3) All records since 2000 relating to FDA's 2009-2010 testing survey of talc and talc products and reasons for FDA's decision to conduct the survey;
- (4) All records since completion of FDA's 2009-2010 talc survey relating to FDA's inaction on regulating asbestos in consumer products; and
- (5) All records since 2000 of FDA's communications with the U.S. Consumer Products Safety Commission; U.S. Customs and Border Protection; other federal agencies and/or lawmakers; state agencies, port authorities, and/or lawmakers; and/or companies that manufacture, process, and/or distribute consumer products and/or chemicals, including their respective trade associations (e.g., Personal Care Products Council and American Chemistry Council) relating to the actual or potential presence of asbestos or asbestos-like fibrous silicates in talc and talc-containing products.

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<sup>1</sup> For purposes of this FOIA request, "records" means information of any kind, including writings; written summaries of oral discussions; memoranda; emails, including subject lines, the names of recipients, their e-mail addresses, and any attachments; text messages; letters; notes; meeting requests; calendar entries, including the names of invitees, their e-mail addresses, and any attachments; meeting minutes; documents; drawings; graphs; charts; photographs; electronic and magnetic meeting recordings; records of telephone conversations, including cell-phone records; and any other compilation of data from which information can be obtained.

EWG Action Fund respectfully requests that the FDA respond to this request within twenty (20) business days of receipt, as required by FDA regulations, 21 C.F.R. § 20.41.

Copies of all records provided should be mailed to:

Reade Wilson  
Staff Attorney  
EWG Action Fund  
1436 U Street NW, Suite 101  
Washington, DC 20009

Should you determine that portions of the requested records are exempt from disclosure, please segregate those portions and mail the remaining records. For any records or portions of records that you determine to be exempt, please provide a specific description of the record or portion of the record exempted along with a particularized description of the exemption and applicable citation.

EWG Action Fund is a 501(c)(4) nonprofit organization whose mission is to protect public health and the environment by educating the public and advocating on a wide range of policy issues. EWG Action Fund and its supporters are especially concerned about protecting users from toxic chemicals and substances in consumer products. In furtherance of this mission, EWG Action Fund is engaged in public education, advocacy, and the review of the government's implementation of its statutory mandates. EWG Action Fund is interested in (i) furthering the public's understanding of the health risks posed by asbestos-contaminated talc and (ii) reviewing what action FDA has taken to ensure the safety of talc-containing consumer products. Thus, EWG Action Fund seeks the requested records consistent with the purposes of FOIA, namely "the citizens' right to be informed about 'what their government is up to.'"<sup>2</sup>

Given the widespread use of talc among American consumers and the health concerns that asbestos contamination of talc raises, EWG Action Fund seeks this information in the interest of public information and consumer safety. Talc is present in a wide range of consumer products, including not only cosmetics, but also pharmaceutical products and food. It is used in more than 4,200 cosmetic products in North America<sup>3</sup> and in every category of cosmetic product including baby powder, body powder, and powder makeup.<sup>4</sup> One study found that a full forty percent of American women have used talcum powder for feminine hygiene, with a large proportion applying the powder on a daily basis.<sup>5</sup> Talc is also present in more than 40,000 prescription and over-the-counter drugs, where it may serve as a colorant or an inactive ingredient.<sup>6</sup> Furthermore, although there are no specifications for the purification of food-grade talc, talc is used in food

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<sup>2</sup> U.S. Dep't of Justice v. Reporters Comm. for Freedom of Press, 489 U.S. 749, 773 (1989).

<sup>3</sup> Andrew Schneider, FDA: Weak Laws, Sparse Resources Handcuff Agency, Seattle Post-Intelligencer, at 2 (October 31, 2014), <http://www.seattlepi.com/national/article/FDA-Weak-laws-sparse-resources-handcuff-agency-5861903.php>.

<sup>4</sup> Cosmetic Ingredient Review, Safety Assessment Of Talc As Used In Cosmetics, at 4 (2013), *available at* <http://www.cir-safety.org/sites/default/files/talc032013rep.pdf>.

<sup>5</sup> Int'l Agency For Research On Cancer, Vol. 93 Carbon Black, Titanium Dioxide, And Talc, IARC Monographs On The Evaluation Of Carcinogenic Risks To Humans, at 305-308 (WHO Press 2010).

<sup>6</sup> Schneider, *supra* note 3.

such as rice and gum, in food processing, and in insecticides and fungicides; in fact, its use in these areas is on the rise.<sup>7</sup> Thus Americans are exposed to, and even consume, talc from many everyday sources.

In addition to the hundreds of thousands of tons of talc produced domestically every year, the U.S. relies on uninspected foreign imports for a significant portion of its talc supply. In 2014, for instance, the U.S. produced 535,000 tons of talc and imported an additional 260,000 tons.<sup>8</sup> In the eighteen months between April 2013 and October 2014, the U.S. accepted more than 1,400 shipments of raw talc and talc-containing consumer items from thirty-four countries,<sup>9</sup> but shipments like these have not been inspected routinely to ensure their safety.<sup>10</sup>

This widely used material poses serious safety concerns because of its potential contamination with asbestos, a known human carcinogen.<sup>11</sup> Talc and asbestos “are naturally occurring minerals that may be found in close proximity in the earth.”<sup>12</sup> FDA recommends that to avoid asbestos contamination in talc products, producers should first choose mining sites carefully and then adequately purify the talc,<sup>13</sup> but it is unclear the extent to which the agency actively ensures that producers follow these precautions. A 1976 investigation of talc-based cosmetics and pharmaceutical talc on the market revealed that many of these products were contaminated with asbestos and asbestos-like impurities.<sup>14</sup> Although the industry-led and -funded Cosmetic Ingredient Review (CIR) responded by developing specifications for talc requiring that it be free from detectable asbestos,<sup>15</sup> these specifications are merely voluntary: manufacturers are not required to file data on ingredients with the FDA, nor can the FDA require premarket review of cosmetic products or their ingredients.<sup>16</sup>

Talc that is contaminated with asbestos poses a serious health concern. Consumers are exposed to talc and any possible impurities not only on their skin, but also through respiration of talc dust during application.<sup>17</sup> The International Agency for Research on Cancer, a unit of the World

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<sup>7</sup> Id.; FDA, Talc, <http://www.fda.gov/cosmetics/productsingredients/ingredients/ucm293184.htm> (last updated Mar. 19, 2014); Talc: The Softest Mineral, Geology.com, *available at* <http://geology.com/minerals/talc.shtml> (talc is used as a carrier for insecticides and fungicides and readily sticks to plants).

<sup>8</sup> U.S. Geological Survey, Talc and Pyrophyllite, in Mineral Commodity Summaries 158, 158 (U.S. Geological Survey 2015).

<sup>9</sup> Schneider, supra note 3.

<sup>10</sup> Id.; FDA, Information for Cosmetics Importers (last updated Nov. 19, 2014),

<http://www.fda.gov/Cosmetics/InternationalActivities/Importers/default.htm#Imports1> (FDA does not inspect all imports and focuses its inspections on imported consumer goods, not raw materials, and on certain categories of goods with identified “trends in violations”).

<sup>11</sup> FDA, supra note 7.

<sup>12</sup> Id.

<sup>13</sup> Id.

<sup>14</sup> Int’l Agency For Research On Cancer, supra note 5, at 303-304, 309.

<sup>15</sup> Cosmetic Ingredient Review, supra note 4, at 1-2.

<sup>16</sup> Amalia K. Corby-Edwards, Cong. Research Serv., R42594, FDA Regulation of Cosmetics and Personal Care Products 6, 11 (2012); see FDA, FDA Authority Over Cosmetics (last updated Mar. 20, 2014), [http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm#Does\\_FDA\\_approve](http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm#Does_FDA_approve) (“Neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients. The law also does not require cosmetic companies to share their safety information with FDA”).

<sup>17</sup> E.g., Int’l Agency For Research On Cancer, supra note 5, at 309; see also Andrew Schneider, Study: Cosmetic Talc Products Carry Asbestos Peril, Seattle Post-Intelligencer (Oct. 31, 2014),

Health Organization, classifies talc that contains asbestos as carcinogenic to humans and classifies the perineal use of talc body powders as “possibly carcinogenic to humans.”<sup>18</sup> A series of studies published in 2014 investigated the death of a woman who died of mesothelioma, an illness caused exclusively by asbestos exposure. Investigators found asbestos fibers in the woman’s lungs and lymph nodes and in the popular body powder brand the woman used, concluding that her use of the powder was her only exposure to asbestos and was the cause of her fatal mesothelioma.<sup>19</sup> Since the publication of these findings, other mesothelioma victims have come forward with claims that talcum powder was their only source of asbestos exposure, and several legal claims are now pending alleging that the product’s manufacturer failed to warn consumers of this danger.<sup>20</sup> In light of the proven connection between mesothelioma and at least one brand of talc powder, and the possibility that other talc products contain carcinogenic contaminants, EWG Action Fund seeks to learn what FDA knows about this serious health concern and what actions FDA has taken, or plans to take, to protect consumers from asbestos-contaminated talc.

### **Fee Waiver**

EWG Action Fund seeks a fee waiver due to the fact that “disclosure of the information is in the public interest because it is likely to contribute significantly to the public understanding of the operations of government” and because disclosure is not in the commercial interest of EWG Action Fund.<sup>21</sup> This request meets the factors outlined in FDA regulations and DOJ’s FOIA Guide.<sup>22</sup>

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<http://www.seattlepi.com/national/article/Study-Cosmetic-talc-products-carry-asbestos-peril-5861858.php>. (Simulations of personal use of talc powder established that application of contaminated talc released inhalable asbestos into the air, these fibers lingered in the air even longer than talc fibers, and applying the powder in a closed space such as a bathroom increased the likelihood of inhaling the asbestos fibers).

<sup>18</sup> American Cancer Society, Talcum Powder and Cancer (last updated Nov. 21, 2014),

<http://www.cancer.org/cancer/cancercauses/othercarcinogens/athome/talcum-powder-and-cancer>.

<sup>19</sup> Robert E. Gordon, et al., Asbestos in Commercial Talcum Powder as a Cause of Mesothelioma in Women, 20 *Int’l J. Of Occupational Health* 318 (Oct. 2014); see also Amanda Frank, Perilous Powder: Asbestos in Cosmetics Causes Lung Cancer, Center For Effective Government, Nov. 6, 2014,

<http://www.foreffectivegov.org/blog/perilous-powder-asbestos-cosmetics-causes-lung-cancer>; Schneider, *supra* note 17 (reporting that the product in question was Cashmere Bouquet body powder, formerly manufactured by Colgate-Palmolive).

<sup>20</sup> See, e.g., Barlow v. Colgate-Palmolive, 772 F.3d. 1001 (4th Cir. 2014); In re N.Y.C. Asbestos Litigation, No. 107211/08, 2013 WL 6985407 (N.Y. Cnty. Sup. Ct. Nov. 26, 2013); Feinberg v. Colgate-Palmolive Co., No. 190070/11, 2012 WL 954271 (N.Y. Cnty. Sup. Ct. Mar. 22, 2012).

<sup>21</sup> See 5 U.S.C. § 552(a)(4)(A)(iii); see also 21 C.F.R. § 20.46.

<sup>22</sup> 21 C.F.R. § 20.46; U.S. Dep’t Of Justice, Freedom of Information Act Guide (May 2004) (Approval of a fee waiver requires that (1) the subject matter of the requested records must concern “operations or activities of the government,” (2) disclosure must be “likely to contribute” to an understanding of government operations or activities, (3) disclosure must contribute to the understanding of the “public at large,” and (4) disclosure must contribute “significantly” to public understanding of the subject matter. If the requester has a commercial interest in the disclosure (factor 5), then this commercial interest must not be “primary” (factor 6) in comparison to the public interest in disclosure).

1. The request's subject matter concerns operations or activities of the government.

The subject matter of this request concerns the operations or activities of the federal government. Although FDA has publicized the results of one study investigating the possible presence of asbestos in talc, more action is needed to learn how common asbestos contamination is and to protect the public from asbestos-contaminated goods. Even the study FDA did conduct on this matter, its 2009-2010 talc survey, was seriously limited, as FDA itself acknowledges.<sup>23</sup> Of nine talc suppliers FDA asked for samples, only four complied with the request, and the absence of asbestos in the products tested does not prove that all or even most products on the market are asbestos-free.<sup>24</sup> Moreover, FDA has repeatedly denied requests that it act to address this area of concern, such as a 2008 petition from the Cancer Prevention Coalition seeking a warning-label requirement.<sup>25</sup> EWG seeks the requested records to understand why FDA's actions have been so limited and what more, if anything, FDA is doing to protect consumers from products containing carcinogenic asbestos.

2. The requested records are likely to contribute to an understanding of the subject matter.

The records are likely to inform an understanding of FDA's activities concerning asbestos-contaminated talc, in a manner that is not already public knowledge. The disclosure of these records will make public any information FDA has as to the possible presence of asbestos in talc products, including what prompted FDA to conduct its 2009-2010 product survey. Since previous, direct requests for FDA action on talc have gone unheeded,<sup>26</sup> the records are likely to "reveal meaningfully information" as to FDA's reasons for its inaction and as to any other steps FDA has taken to protect the public health in this area.<sup>27</sup>

3. The disclosure will contribute to the understanding of the public at large.

Disclosure of the requested information will contribute to the understanding of the public at large since EWG Action Fund will disseminate information gleaned from the records for purposes of informing the public. EWG Action Fund conducts educational and investigative analyses and disseminates information through a variety of channels, including press releases, online and social media posts, communications to lawmakers and administrative agencies, and e-mails to supporters and like-minded third parties. EWG Action Fund's established interest in chemical safety and environmental health gives it the specialized knowledge and ability and intention to disseminate the information requested in a manner that will contribute to public understanding.

4. The disclosure contributes "significantly" to public understanding.

Disclosure of the requested records will contribute "significantly" to public understanding of FDA's actions to protect consumers from contaminated talc.<sup>28</sup> Although FDA has publicized its

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<sup>23</sup> FDA, *supra* note 7.

<sup>24</sup> *Id.*

<sup>25</sup> Cosmetic Ingredient Review, *supra* note 4, at 1-2.

<sup>26</sup> *Id.*

<sup>27</sup> 21 C.F.R. § 20.46(b)(2).

<sup>28</sup> 21 C.F.R. § 20.46(b)(4).



2009-2010 study of talc products, the disclosure of records pertaining to additional FDA activities, if any, will help paint a more comprehensive picture of FDA's work in this area. The records will allow consumers to understand whether FDA has responded adequately to this important health concern.

5. There is no commercial interest in the disclosure.

Finally, this request is not in the commercial interest of the requester. EWG Action Fund has no intention of using this information in a manner that relates to "business, trade, or profit."<sup>29</sup> Any publication of EWG Action Fund's analysis of the requested information would be for the sole purpose of dissemination to the public to educate consumers and to advocate on behalf of American consumers.

For the foregoing reasons, it is clear that the disclosure of the information requested is in the public interest because it is likely to contribute significantly to the public's understanding of FDA's activities and investigation of asbestos in consumer products. Therefore, please waive all processing and copying fees pursuant to 5 U.S.C. § 552(a)(4) and 21 C.F.R. § 20.46. The request for a fee waiver should not be construed as an extension of time in which to reply to this FOIA request.

Thank you for your consideration. If you have any questions, please do not hesitate to contact me at (202) 667-6982.

Sincerely,



Reade Wilson  
Staff Attorney  
EWG Action Fund

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<sup>29</sup> 21 C.F.R. § 20.46(c)(1).