

Dear (Specific Cosmetic Ingredient Supplier):

It has recently come to our attention that some foreign market talc-containing products, including baby powder, are contaminated with asbestos. As such, we are concerned about the sources of talc being used in products that are manufactured and marketed in the United States. Thus, in order to assess the potential threat to domestic health and safety, we are evaluating this issue.

As you know, it is the responsibility of cosmetics manufacturers and suppliers to introduce only safe cosmetic products and ingredients into the marketplace. The Food and Drug Administration is responsible for providing guidance and regulatory oversight of industry's efforts. In the interests of protecting the public health and providing effective guidance and regulation, we seek your cooperation in providing the following information concerning talc used in cosmetic products (i.e. "cosmetic-grade talc"):

1. If you own or operate talc mines--
 - a. Please provide the location(s) of your mines.
 - b. How much raw talc do you mine annually, by weight?
 - c. Please indicate what tests you use to characterize your mine, e.g., site characterization, other characterizations/specifications.
 - d. With regard to raw cosmetic-grade talc you produce, what specifications do you use...
 - i. for identification?
 - ii. for asbestos content?
 - iii. for heavy metals content?
 - iv. for other attributes? (Please be specific.)
 - e. Have you found asbestos in raw talc from your mines? (If so, please provide more information.)
2. If you purchase cosmetic-grade talc for resale--
 - a. From whom do you purchase your talc?
 - b. How much cosmetic-grade talc do you purchase annually, by weight?
 - c. Please indicate what tests you use to characterize the talc you purchase. With regard to talc that you purchase, what specifications do you use...
 - i. for identification?
 - ii. for asbestos content?
 - iii. for heavy metals content?
 - iv. for other attributes? (Please be specific.)
 - d. Have you found asbestos in talc that you purchased from a supplier? (If so, please provide more information.)
 - e. How do you determine whether or not to accept a lot of talc from a supplier?
 - f. Do you rely on a certificate of analysis from your supplier? If so, does the certificate of analysis specifically address asbestos content?

3. How much talc for use in cosmetic products do you sell annually, by weight?
4. To whom have you sold this talc in the past year, and for what type of products?
5. Do you provide a certificate of analysis to those who purchase this talc? If so, does the certificate of analysis specifically address asbestos content?
6. Please describe the process by which you process/purify talc into a grade that would be used in cosmetic products.
7. Please indicate what tests you use to characterize the processed/purified talc? What specifications do you use...
 - a. for identification?
 - b. for asbestos content?
 - c. for heavy metals content?
 - d. for other attributes? (Please be specific.)
8. Do you have a specification or tolerance limit on an acceptable level of asbestos for this talc and, if so, what is it?
9. How do you handle product that does not meet your specifications?
10. Please provide the results of any tests performed in the past year for all tests discussed in your responses to the previous questions.

FDA does not disclose or release trade secret and confidential commercial information to third parties except as may be permitted or required by governing laws and regulations. Please provide us with information responsive to this request within 45 days of receipt.

Sincerely,

(Signatory to be decided)
(title)
Food and Drug Administration

Drafted: JGasper: OCAC: 7/24/09
Comments: LKatz: OCAC: 7/29/09
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