Memorandum of Meeting

Date: March 22, 2010

Place: FDA, University Station, College Park, MD

Participants:

Visitors:
Rio Tinto: Judy Brown, Raga S. Elim
Barretts Minerals: Kevin D. Porterfield

FDA:
FDA: Linda M. Katz, M.D., M.P.H., Patricia A. Hansen, Ph.D., Robert L. Bronaugh, Ph.D., John Gasper J.D., Fred Hurley, Donald Havery

Subject: Talc

The meeting was held at the request of Rio Tinto, to discuss the January 27, 2010 and February 4, 2010 letters received by Rio Tinto and other talc producers/distributors. Specific issues from the letters that were to be addressed included the use of talc in cosmetics, the information FDA requested in the letters, and what FDA intended to do with the information.

FDA representatives described a general concern about the presence of asbestos in talc. This concern intensified when asbestos was reported last year in Chinese and Korean talc products. They also noted that FDA has limited information about the talc industry's testing procedures, acceptable asbestos levels, and specifications for "cosmetic grade" talc. Further, FDA has no specific data on the Chinese and Korean talc incidents except that the findings were "false positives."

FDA's letters were sent to talc producers listed in the International Cosmetic Ingredient Dictionary as an attempt to target the largest suppliers of "cosmetic" talc. FDA needs the requested information to assure that domestically produced and imported talc products that are sold to U.S. consumers are safe. Once FDA has collected the information requested, FDA will look into the feasibility of potentially issuing guidance to industry.

Industry representatives proposed a "workshop" setting where information on the talc industry could be exchanged rather than putting it in writing. This was later clarified to mean a meeting of those persons, including scientists, who could provide FDA the scientific background and detailed information on mineralogy, processing, and analytical methodology that would address FDA's questions posed in the letter to industry.

Industry representatives indicated that they did not have specific information on the Korean incident, but they were working with the Personal Care Products Council on talc standards and procedures for testing talc for asbestos. They indicated that the findings of asbestos in Chinese

talc were false positives. They offered to provide information on the specific issues and how they were resolved, the methods used, and measures to avoid false positives in the future.

Industry representatives suggested holding a meeting where scientific information could be exchanged. FDA was not adverse to this and suggested that industry will need to arrange for the meeting in writing, provide information on who should attend, and the subject areas to be covered. Industry representatives agreed to send FDA such a letter including an agenda, meeting objectives, and participants.

The Specialty Minerals/Barretts Minerals representative said they did not receive the original FDA letter but they would like to receive one officially. FDA representatives agreed to send them a letter.

Action items:

- FDA to send letter to Specialty Minerals
- Rio Tinto to request additional meeting in writing
- Rio Tinto to submit information to FDA on Chinese talc issues

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Rev/edit: LMKatz 3/22/10
Rev/edit: JGasper 3/22/10
Rev/edit: FHurley 3/22/10
Rev/edit: BBronaugh 4/19/10
Rev/edit: PHansen; 4/19/10
Rev/edit: LMKatz 4/21/10