DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food and Drug Administration

Memorandum

Date November 12, 2009

From PRA Specialist, Paperwork Reduction and Records Management Staff
Office of Information Management

Subject Request for Approval of FDA Rapid Response Survey, "Survey of Suppliers of Cosmetic-Grade Talc to the U.S. Market"; OMB Control No. 0910-0500

To Human Resources and Housing Branch
Office of Information and Regulatory Affairs, OMB
Through: HHS Reports Clearance Officer _____

The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), is seeking Office of Management and Budget (OMB) approval under the generic clearance 0910-0500 to conduct a rapid response survey, "Survey of Suppliers of Cosmetic-Grade Talc to the U.S. Market." In this survey, which involves sending a two page letter to five U.S. firms and three foreign firms that are suppliers of cosmetic-grade talc to the U.S. market, FDA is asking the firms to respond voluntarily to a limited series of questions that relate to product sourcing, processing, testing, and quality assurance. Without this information, it will be difficult for the agency to assess in a timely manner whether there are any potential safety issues. FDA is particularly concerned about the safety of talc-containing products used on infants.

Justification:

FDA is seeking the information in the wake of the recent discovery that some talc-containing products, including baby powder, produced and sold in foreign markets were found to be contaminated with asbestos, which is known to cause cancer if inhaled. FDA's survey letter is seeking data from the small number of suppliers of cosmetic-grade talc to the U.S. market, including information about sources, processing, and testing and other steps to ensure that the talc being used in products that are manufactured and marketed in the United States is safe.

FDA is the regulatory agency responsible for the safety and proper labeling of cosmetic products and ingredients. It derives its regulatory authority from the Federal Food, Drug and Cosmetic Act (the act). The act prohibits the distribution of cosmetics that are adulterated or misbranded. Violations of the act involving cosmetic product composition--whether they result from ingredients, contaminants, processing, packaging, or shipping and handling--cause cosmetics to

be adulterated and/or misbranded and are subject to regulatory action. It is the responsibility of cosmetic manufacturers to introduce only safe cosmetic products into the marketplace. FDA is responsible for providing guidance and regulatory oversight of industry's efforts.

Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding cosmetics in situations involving imminent danger to health, or gross deception of the consumer. Section 903(d)(2) (C) of the act (21 U.S.C. 393(d)(2)(C)) authorizes the Commissioner of the FDA to implement general powers (including conducting research) to carry out effectively the mission of the FDA. These sections of the act enable FDA to enhance consumer protection from risks associated with cosmetic product usage that are not foreseen or apparent prior to marketing.

The requested information collection would provide FDA with the means to quickly obtain vital information from firms that are suppliers of talc to the U.S. market. With this information, FDA will be in a better position to assess in a timely manner whether there are any potential safety issues in the United States involving talc supplies or related products in the United States similar to those that recently arose in foreign markets. FDA plans to conduct the survey by mail. The survey instrument is a letter to suppliers of cosmetic-grade talc to the U.S. market (Appendix A). The letter contains questions that call for written responses, and in some cases, supporting test result information. This is a voluntary information collection. The data collection will begin as quickly as possible after OMB approval is received.

The respondents to this information collection are suppliers of cosmetic-grade talc to the U.S. market. The letter will be sent to all known firms. Thus, there will be eight respondents. FDA estimates that the total one time burden for this information collection will be 120 hours. The data collection is estimated to take an average of 15 hours per firm to complete. Thus, the hour burden associated with the data collection is estimated to be 120 hours (8 respondents x 15 hours = 120 hours).

FDA estimates that the response rate will be 75 percent (75%) based upon its experience with past rapid response surveys. In the event that the initial response rate is not achieved, FDA does not plan to follow up with non-respondents. FDA expects that confidential commercial information will be provided in response to the survey. The agency has provided the following assurance of confidentiality: "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." Only information that is releasable under the agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by Section 301(j) of the act (21 U.S.C. 331(j)) and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

No other part of the agency currently is collecting the type of information being sought in this information collection. The agency has communicated with the Personal Care Products Council (PCPC), and has also met with PCPC and several of its members. It is not FDA policy to pay or provide gifts to rapid response survey respondents. The information collection involves no questions of a personally sensitive nature. The agency anticipates that it may disseminate information gained from the survey, in a manner consistent with the assurance of confidentiality provided to respondents.

If you have any questions, please contact Denver Presley at (301) 796-3793.

Attachment