FILE NAME: Talc (TALC)

DATE: 1975 Mar 17

DOC#: TALC089

DOCUMENT DESCRIPTION: Article from Food Chemical News - FDA Delays Action on Asbestos-Containing Talc in Food

March 17, 1975

FDA DELAYS ACTION ON ASBESTOS-CONTAINING TALC IN FOOD

The Food and Drug Administration on March 14 said that currently-available information does not warrant a ban on asbestos-containing talc in foods, acknowledging that it will delay any action on its long-pending proposal to institute such a ban (See FOOD CHEMICAL NEWS, Oct. 1, 1973, Page 37).

At the same time, FDA withdrew its proposal to tie the "generally recognized as safe" use of talc in food-packaging paper and paperboard to the absence of asbestos-form particles. The agency also reaffirmed its decision not to propose limitations on use of asbestos-containing filters in food and beverage processing.

The agency did issue a regulation dealing with asbestos-form particles in drugs for parenteral injection, and at the same time discussed at length the comments filed on its proposals dealing with talc in food, drugs, and in packaging (See FOOD CHEMICAL NEWS, Oct. 22, 1973, Page 18; Dec. 3, 1973, Page 2; Dec. 10, 1973, Page 3; Dec. 24, 1973, Page 20; Jan. 7, 1974, Page 30; Jan. 14, 1974, Page 30; and Feb. 18, 1974, Page 16).

FDA noted that it plans, in conjunction with other agencies, "extensive experiments to determine if long term exposure to ingested asbestos fibers represents a definitive hazard to human health." Until the study is completed or other data are available, the agency concluded "that a prohibition of the use of asbestos-containing filters in the processing of food and beverages, and of asbestos-containing talc as a food or food additive or in drugs or drug ingredients is unwarranted due to lack of sufficient data."

Industry Investigations Urged by FDA

However, FDA urged manufacturers "to investigate all means of eliminating the use of such filters and talc, and to keep the FDA informed about changes in formulation and processing of this type."

As expected, FDA decided to delay any final regulations for talc until "an acceptable method for determining the presence of asbestos particles can be developed for this substance" (See FOOD CHEMICAL NEWS, Feb. 17, Page 32). The agency said it is actively pursuing research on methodology.

FDA did not agree with comments "that the designated optical crystallographic method is unreliable when used by those experienced in the art," but did recognize "that an effective compliance method must have greater utility and acceptance than indicated by the comments on the proposed method."

Most of those who commented did not actually use the proposed method, FDA said, but reflected their general experience with optical crystallography, or "a personal preference for other analytical methods." The proposed method was supported in none of the comments. Most commonly-expressed objection was the difficulty in using the method. A collaborative study by members of one trade association resulted in inconsistent results, and four of the ten participants could not use the method, the agency said.

"Although detection was limited by the bulk of ash recovered from other products, such as fresh wrapped and frozen meat, dry packaged macaroni, dried milk, rice, and corn flakes, the comment also demonstrated that these products contain less than 10 p.p.b. asbestos under test and market conditions," FDA said.

Concluding that the salt study "represents a practical upper limit of migration of asbestos from food-contact paper and paperboard," FDA explained that the conclusion "is based upon consideration of the extreme abrasive nature of salt as compared to other dry foods, and the unusually high tremolitic asbestos content of the test paper (6%), as compared to reported levels of use (0.02-0.4%) in food-contact paper and paperboard."

FDA delayed "the promulgation of any regulation on the prohibition of use of asbestos filters for the preparation of foods and nonparenteral drugs until more reliable data can be obtained on the background concentration of asbestos in drinking water and the role of asbestos filters in regard to the addition of fibers to ingestible products."

The agency had stated in its proposal that it had decided not to issue a regulation governing the use of asbestos filters in food and beverage processing. Some comments urged that use of filters be regulated on the basis of a lack of evidence to show that the ingestion of small amounts of asbestos is safe. FDA said:

> "The Commissioner agrees that uniform and consistent regulations should be adopted on an industry-wide basis. In this instance, the lack of available reproducible methodology for determining asbestos-form fibers in beverages and other foods led the Commissioner to propose the regulation of talc before handling other related matters. In any event, the comment has now become moot since the Commissioner has decided to delay a final ruling on talc as a direct food or drug ingredient."

FDA also said that "neither the available data on the addition of fibers to foods and nonparenteral drugs by use of asbestos filters nor the data on the asbestos content of municipal water are sufficiently reliable to permit promulgation of regulatory controls at this time." Noting asbestos content in some municipal watersupplies, FDA said a Canadian study indicated that asbestos content of beverages is comparable to the background levels in areas of the U. S.

Noting its analysis of the comments, a re-review of the methodology, and the "controversial nature of evidence to demonstrate the hazard to health presented by ingestion of the amounts of asbestos fibers normally to be expected in talc used in food or drugs, or in food or drug packaging containing talc, or in beverages, other foods and nonparenteral drugs prepared with the use of asbestos filters," FDA concluded that --

> "... The promulgation of regulations on the limitations or prohibition of the use of asbestos filters for the preparation of foods and nonparenteral drugs and of the amount of asbestos fibers in talc for use in food and drugs or which