

Quality Control and
Government Regulations Division

December 19, 1973

Hearing Clerk
Food and Drug Administration
Room 6-86
5600 Fishers Lane
Rockville, Maryland

Gentlemen:

As a manufacturer of biological and pharmaceutical (both oral and parenteral) products, Parke, Davis & Company is an interested person concerning the Commissioner's proposals and related petition on asbestos in food and drugs as published in the Federal Register of September 28, 1973, page 27076.

We are, of course, aware of the occupational risks in asbestos mines causing asbestosis. The risks of inhalation of dusts seem well established. The evidence of risk of malignancy following injection of asbestos particles in liquid suspension or the ingestion of asbestos particles, as in talc, however, is as stated, contradictory and inconclusive.

Asbestos-containing filters have long been used in the manufacture of biological products. Their advantages include their basic effectiveness as filters as well as reported depyrogenizing effects and the adsorption of undesirable components including active viral particles in the manufacture of tissue culture vaccines.

The proposals contained in the notice have been carefully considered by our people responsible for development and production of filtered products. In general, we believe the proposal to replace asbestos-containing filters with membrane filtration systems (including a follow-up filter to pick up asbestos particles) may be possible except for application to certain high concentration blood-protein products. These include such important products as Immune Serum Globulin (Human), Tetanus Immune Globulin (Human) and 25% Normal Serum Albumin (Human).

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While efforts are being made to develop filtration processes to meet the proposed requirements of §133.8, p. 27080, current evidence is that these products prepared from the source materials we use cannot be membrane filtered at temperatures required to prevent the possible development of pyrogens. Required proof that the use of non-asbestos-containing membrane filters will compromise the safety or potency of these products is not available and would require considerable time to develop, assuming it is possible to do so at all.

For this reason, we conclude that we cannot fully meet the proposed stipulations of §133.8 currently and in the foreseeable future. Certainly before any such requirement were to be made effective we must request time to permit the development of suitable filters and techniques to assure continuation of the manufacture of these biologicals so vital to the public health.

With respect to the proposal in §133.6 to require talc to pass the test specified in 121.2006, talc meeting this specification is available from certain vendor sources and, as far as is known, should continue to be supplied.

Our technical people have expressed the opinion that the proposed analytical procedures and maximum allowable limits based on such proposed analytical methods in §121.2006 are satisfactory for the two general categories of asbestos, i.e. chrysotile and amphibole asbestos (amosite; crocidolite; and fibrous anthophyllite, tremolite, and actinolite). However, we request that equal acceptance and recognition be given to microscopical dispersion staining techniques, especially those dispersion staining procedures applicable to the detection and identification of chrysotile asbestos. It is recommended that the use of the dispersion staining approach be accepted to simplify and improve microscopic evaluation of talc for chrysotile and, where applicable, for tremolite and other amphibole asbestos.

We appreciate the opportunity to comment on this proposal. As requested, five copies of this letter are enclosed.

Very truly yours,

PARKE, DAVIS & COMPANY


J. M. LUECK, Ph.D.

Vice President, Quality Control
and Government Regulations

LMJ/DEM:ldw