

# Organics, Inc.

PHARMACEUTICAL MANUFACTURERS

7125 N CLARK STREET CHICAGO, ILLINOIS 60626

312 - 764-6700

March 17, 1976

Office of the Hearing Clerk  
Room 4-65  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20852

Re: Federal Register Vol. 41,  
No. 31, 2-13-76, p. 6888

Gentlemen:

Regarding the Proposed Rules subpart D, "Equipment", regulation 211.72, paragraphs a, b and c in the above publication, we would like to comment on this subject relative to our manufacture of Repository Corticotropin Injection USP XIX (our NDA #10-831).

In the heat degradation of gelatin, which is used as a repository vehicle in Repository Corticotropin, a very minute amount of mucoprotein is precipitated as a haze.

We remove the haze by filtering the heat degraded gelatin through an asbestos filter. After the gelatin has been polished by filtration the appropriate amount of corticotropin concentrate is added to the gelatin and the gelatin concentration, volume and potency are adjusted to 100% of the labeled potency for the particular strength involved (i.e., 40 unit or 80 unit per ml.). The product in gelatin at 25° C is then filtered through a sterile 0.45 micron millipore membrane for sterilization prior to filling into sterile vials.

Upon examination of the gelatin microscopically using a 300 magnification lens we are unable to detect any signs of asbestos fibers. However, it is possible that there are asbestos fibers of such minute size that the ordinary microscope will not pick them up.

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We are, therefore, submitting at random samples to an outside laboratory for study under electron microscopy for the purpose of determining whether minute asbestos fibers do or do not exist in our product.

As soon as the information on the electron microscopy is available we will forward copies of the results to you.

In the meantime, we have investigated other methods of filtration such as those suggested by Millipore Corporation involving filtration through a fiberglass element and subsequently through a 0.45 micron membrane.

Although the new system works equally well as our filtration system it, nevertheless, presents the possibility of fiberglass particles existing in the final product, which we feel would be as detrimental as asbestos fibers.

Furthermore, we would like to point out that the product which we market nationally through distributors is labeled "For Intramuscular or Subcutaneous Injection Only". Of course, we have no control over a hospital, doctor or clinic giving our product intravenously.

In our minds it is extremely doubtful that ultra-fine particles of asbestos or fiberglass would ever get into the vascular system and thereby come in contact with lung tissue.

Therefore, we would like to protest the above proposed rule particularly wherein it involves the filtration of small volume parenterals that are administered intramuscularly or subcutaneously because, in our experience, it is extremely doubtful whether any other system of filtration would accomplish better filtration than that which we now use.

Other possible methods for the filtration of such parenterals might possibly involve the use of acid-washed (iron free) hyflo-supercel to accomplish the removal of muco-proteins, but certainly extremely fine particles of such a filter media would be far more likely to pass through

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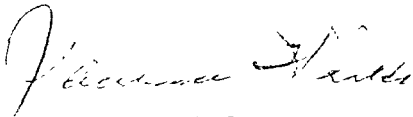
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either a 0.45 micron or a 0.22 micron membrane than would asbestos fibers or fiberglass fibers because, generally speaking, they are spherical in nature whereas the fibers are longitudinal in nature.

Your comments would be appreciated.

Very truly yours,

ORGANICS, INC.

A handwritten signature in cursive script, appearing to read "Lawrence Hicks".

Lawrence Hicks  
President

LH/la

DEPARTMENT OF  
HEALTH, EDUCATION, AND WELFARE  
**CROSS-REFERENCE SHEET**

File No. 75N-0339-C0013

See File: 75P-0261-C0073

From

To

Date

Summary: