



ORTHO DIAGNOSTICS

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Vice President

Manufacturing

Area Code 201 524-2406

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Hearing Clerk
Food & Drug Administration
Room 6-86
5600 Fishers Lane
Rockville, Md. 20852

Ref.: Federal Register Notice, Vol. 38, No. 188, 9/28/73

Gentlemen:

Regarding 21 CFR Part 133.8 - Production and control procedures, we have been manufacturing Rh₀ (D) Immune Globulin (Human), a human blood plasma fractionated product, for the past seven years and this product requires two filtrations using asbestos filtered pads.

The first filtration is during the fractionation where Supernatant III is filtered prior to precipitation of Precipitate II. We use an Ertel #9 asbestos pad, a tight pad, which is necessary in order to obtain a clear filtrate. We precoat the pad with filter aid to increase the surface area, otherwise the pad would clog. To date, an effective substitute for -50°C protein methanol suspensions is not available.

The second filtration is the sterile filtration of the bulk solution. The solution is filtered through Hormann D-8 asbestos filter pads with a lint-free paper backing.

We are presently doing development work on replacement of a membrane cartridge in the solution filtration, however, we have been unable to find an effective substitute for the in-process filtration of our fractionated material.

In the absence of an acceptable substitute, we would strongly object to regulations requiring the exclusion of asbestos filtration during processing however, our work to date indicates that the final filtration through membrane rather than asbestos will be acceptable.

Very truly yours,

D. T. McKeithan

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