

BUNDESVERBAND DER PHARMAZEUTISCHEN INDUSTRIE E.V.

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Food and Drug Administration
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Ihr Zeichen

Ihre Nachricht vom

Unsere Zeichen

Tag

Dr.Aut/do

December 19, 1973

Betr: Department of Health, Education and Welfare
Food and Drug Administration (21 CFR Parts 121, 126, 133)
Proposed rulemaking on Asbestos Particles in Food and Drugs
as printed in Federal Register, Vol. 38, No. 188, Friday,
September 28, 1973

Dear Sir:

The above-mentioned memorandum on "Asbestos particles in Food and Drugs" covers the principal question of a possible health risk through parenteral drugs containing asbestos particles.

This subject had been discussed in a meeting of an expert committee of the Bundesverband der Pharmazeutischen Industrie, the West-German Pharmaceutical Manufacturers' Association. The participants welcomed and supported FDA efforts to aim at asbestos-free solutions for parenteral application. However, the use of asbestos-filters in the manufacture of parenteral drugs cannot be avoided completely, especially as concerns highly concentrated and highly viscous solutions or certain sera and vaccines. For other solutions it may also be convenient to use asbestos-containing filters in order to remove possible pyrogenous particles. It therefore seems to us impossible to give up asbestos-containing filter pads in general.

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Wherever possible, final filtration with asbestos-free non fibre releasing filters is long since carried out in pharmaceutical technics according to Good Manufacturing Practices. For this purpose one generally uses those filters which reliably remove fibres which are not tolerated according to the proposed method HSM 72-10267 (1972). In our opinion it is therefore not necessary to confirm this by final filtration guaranteed effect through an additional method of test.

We do hope having contributed with our comments to this for the pharmaceutical industry highly important subject.

Respectfully yours,

BUNDESVERBAND DER
PHARMAZEUTISCHEN INDUSTRIE E.V.
Direction
(Dr. Marris) (Dr. Auterhoff)