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HEARING CLERK
FOOD AND DRUG ADMINISTRATION
ROOM 6-86

RE: DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
FOOD AND DRUG ADMINISTRATION (21 CFR PARTS 121,126,133)

PROPOSED RULEMAKING ON ASBESTOS PARTICULES IN FOOD AND DRUGS
AS PRINTED IN FEDERAL REGISTER, VOL. 38, NO. 198, 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.
WHEREVER POSSIBLE, FINAL FILTRATION WITH ASBESTOS-FREE NON
FIBRE RELEASING FILTERS IS LONG SINCE CARRIED OUT IN PHARMA-
CEUTICAL TECHNIQS 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) ++

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