

AN' 4690
decker

June 30, 1989

C. V. Purko
Avon Lake Tech Center

SUBJECT: FDA STATUS CODE G-92

There are no specific FDA regulations for PVC bottles, rather those substances that may be used are either listed on an applicable regulation, or GRAS, or prior sanctioned. In this case, clearance under 178.3740 "Plasticizers in Polymeric Substances" without use limitations provides authority for the use of triethylene glycol in foodgrade PVC bottles.

There are no regulations which list those substances that may be used in medical devices. However, most customers require such materials to be of a food grade quality. Therefore, there is no apparent reason why G-92 could not be used in the Bausch and Lomb lens compound.



W. C. Bachtel

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cc: H. Forysth
B. Kazmer
B. Pazur

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