

BFGoodrich

The BFGoodrich Company
Geon Vinyl Division
6100 Oak Tree Boulevard
Cleveland, Ohio 44131
216-447-6000

AN-5626
de lott

February 12, 1992

Nicholas A. Marra
Arzco Medical Systems, Inc.
New Product Development Group
1029 Butterfield Rd.
Vernon Hills, IN 60061

Re: Geon 86312 Trans 002

Dear Mr. Marra:

Recent correspondence to Wallace C. Bachtel, who is deceased, has been directed to my attention.

The technical data sheet on Geon® 86312 Trans 002 is no longer valid. There has been a change in the formulation due to a pigment ingredient which FDA has removed from their clearance list. Consequently, the compound does not meet the current FDA requirements under 21CFR. ~~175~~ 175.300, 177.1210, and does not have GRAS (Generally Recognized As Safe) or Prior Sanctioned status.

Geon® 86312 Trans has been replaced with Geon® 86412 which has FDA acceptance, but has not been tested to meet USP requirements.

If I can be of further assistance, give me a call on 216/447-7831.

Sincerely,

THE BFGOODRICH COMPANY



Connie N. Dillon
Regulatory and Data System Specialist
(216) 447-7831

CN/rm
ARZCO

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