

TGG: JCL: MMG: RF ^A

XF: FDA-PVC

TO: D. W. Hollis

FROM: J. C. Ledvina

DATE: December 16, 1986

Interoffice
Communication

SUBJ: FDA STATUS OF X-42 (5415)

VISTA

Keller and Heckman has given Vista its opinion that X-42 (5415) PVC resin can be considered FDA-allowed if formulated with BHT as an antioxidant. As always, this opinion is contingent upon use of manufacturing, storage, and transportation procedures which will insure that the FDA-allowed status is maintained.

As the letters from Peter de la Cruz point out, films containing Isonox 132 and Naugard 492 would need to be subjected to extraction tests before an opinion on FDA status can be provided. As I understand it, Vista anticipates limited sales of 5415 into FDA markets and that the effort required to obtain extraction results may not be justified. Unless I hear differently, I am assuming that no extraction work will be done on 5415 made with Isonox 132 and Naugard 492.

The Keller and Heckman opinion letters are attached. Give me a call if you would like to discuss.


J. C. Ledvina

ajo/4

Attachment

cc RES, HRF, ELK, JFN, JF, BHB, RPC, HJH, RBQ, LGH, JHM

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