DEPARTMENT OF HEALTH & HUMAN SERVICES

OCT 0 3 1991
Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

SEP 25 1991

MAF-379

AN-5463
Deleted

Robert K. Hinderer, Ph.D.
Manager, Health and Toxicology
Environment, Health and
Safety Management Systems
The BFGoodrich Company
3925 Embassy Parkway
Akron, Ohio 44313-1799

Dear Dr. Hinderer:

This acknowledges receipt of your submission dated August 13, 1991 pertaining to Geon® 86155 Transparent 0027.

This material is retained as a Master File for a device, and it has been assigned the number MAF-379. You may amend this master file to include additional information at any time. All amendments shall be submitted in duplicate, identified with the above MAF number, and addressed to:

Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

Information in your MAF may be incorporated by your client in their premarket approval applications (PMAs), investigational device exemptions (IDEs), premarket notification submissions, reclassification petitions, color additive petitions or other submissions to FDA.

Reference to your MAF can only be authorized by you. In order that your client's submission will not be found deficient for lack of an authorizing letter and to expedite processing, please provide it directly to your client with the instruction that the original of your letter be included in the original copy of the client's submission along with a copy in each additional copy. Under this approach your MAF need not be amended to include the letter of authorization.

If you require assistance regarding device master files procedures, you may contact the Premarket Approval (PMA) Section at (301) 427-1186.

Sincerely yours,

Mary Jo Robinson
Assistant to the Director
Premarket Approval Section
Center for Devices and
Radiological Health

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