

4160-01-F

DUB

Display Date	6. 2 .94
Publication Date	6. 3
Certifier	C. W. W. DAY

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99C-1455]

Genzyme Surgical Products Corp.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Genzyme Surgical Products Corp. has filed a petition proposing that the color additive regulations be amended to provide for the safe use of D&C Violet No. 2 as a color additive in absorbable sutures prepared from homopolymers of glycolide for general surgery. The petitioner also proposes that the nomenclature polyglactin 910 (glycolic-lactic acid polyester) be revised to the generic nomenclature-copolymers of 90 percent glycolide and 10 percent L-lactide.

FOR FURTHER INFORMATION CONTACT:

Ellen M. Waldron,

Center for Food Safety and Applied Nutrition (HFS-217),

Food and Drug Administration,

200 C St. SW.,

Washington, DC 20204,

202-418-3089.

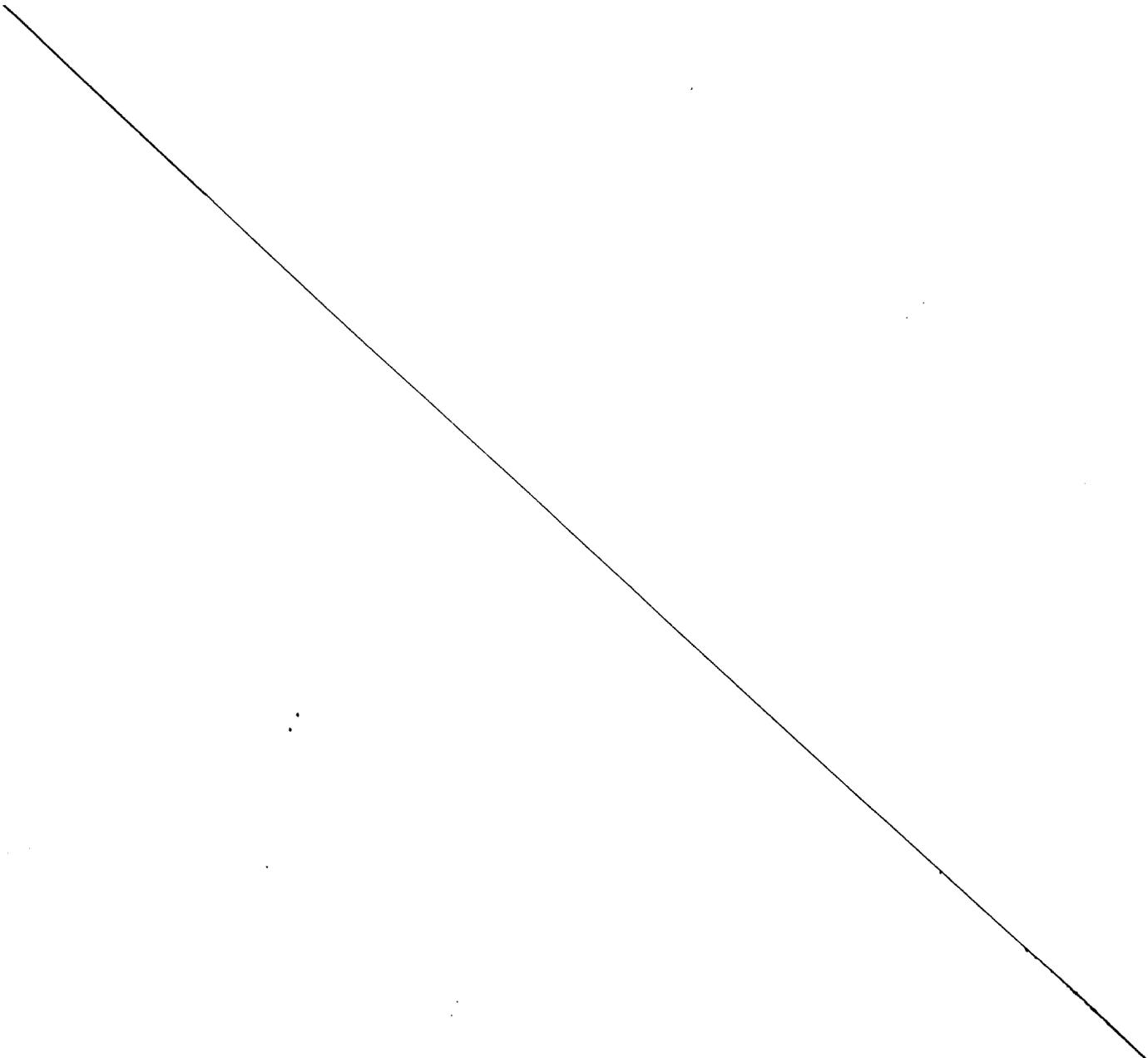
SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that a color additive petition (CAP 9C0266) has been filed by Genzyme Surgical Products Corp., 600 Airport Rd., Fall River, MA 02720.

cf9970

NFL 1

The petition proposes to amend the color additive regulations in § 74.3602 D&C Violet No. 2 (21 CFR 74.3602) to provide for the safe use of D&C Violet No. 2 as a color additive in absorbable sutures prepared from homopolymers of glycolide for general surgery. The petitioner also proposes that the nomenclature polyglactin 910 (glycolic-lactic acid polyester) be revised to the generic nomenclature 90 percent glycolide and 10 percent L-lactide.

The agency has determined under 21 CFR 25.32(l) that this action is of a type that does not individually or



cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: May 5, 1999  
May 5, 1999

Alan M. Rulis

Alan M. Rulis  
Director  
Office of Premarket Approval  
Center for Food Safety and Applied Nutrition

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

*[Handwritten Signature]*