Secretary

D.C.

JUL 1 1974

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Mr. Marcus G. Grodberg
Director, Research and Development
Davies Rose Hoyt
Pharmaceutical Division of
the Kendall Company
633 Highland Avenue
Needham, Massachusetts 02194

Dear Mr. Grodberg:

On January 21, 1974, you were informed by the Commission that your petition for the exemption of "Luride" and "Thera-Flur" from the child protection packaging standards for human prescription drugs in oral dosage forms (16 CFR 1700.14(a)(10)) was denied without prejudice because there was insufficient information submitted in support of the requested exemption.

Subsequently, on February 19, 1974, you submitted additional information as requested by the Commission.

Having considered the supplemental submission and other relevant information, the Commission concludes that with respect to the product, "Luride," reasonable grounds exist to propose an exemption from the subject regulation. A Federal Register notice proposing the exemption and staying the effective date of the regulation as to the product, "Luride," will therefore be published in the near future.

In reviewing your supplemental submission, the Commission has concluded that the product, "Thera-Flur Gel-Drops," is not in a dosage form for oral administration and therefore is not subject to § 1700.14(a)(10). This conclusion is consistent with prior determinations that preparations intended for

CONSUMER PRODUCT SAFETY COMMISSION
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ADVISORY OPINION

topical application to the teeth, gums, or elsewhere within the mouth are not dosage forms for oral administration.

Sincerely,
ORIGINAL SIGNED BY
SADYE DUNN

Sadye E. Dunn
Secretary

cc:

R. E. DIETZ COMPANY

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"DIETZ" SYRACUSENEWYORK

225 WILKINSON STREET
BOX 1214
SYRACUSE, N. Y. 13201 U.S.A.

SINCE 1840

June 24, 1974

Secretary
Product Safety Commission
1750 K Street N.W.
Washington, D.C. 20207

Dear Sir:

We have been following with interest the publication in the Federal Register of information pertinent to the consumer safety act of the Product Safety Commission and have also been reading information along this line as put forth by other media, such as trade magazines and news publications.

Frankly, we are a little confused as to what steps, if any, we should be taking as manufacturers and distributors of a line of automotive safety lighting and accessories, and a companion line of hazard warning safety lights and equipment.

We are enclosing herewith recent catalogs which will give you some idea of the scope and diversity of the line, or lines, that we manufacture and distribute. We would very much appreciate advice from your office as to what steps if any we should be taking to be sure that we are complying with the Product Safety Commission's directives. Any information you can give us in this matter will be greatly appreciated.

Yours very truly,

G.L. Petrie
Vice President - Corporate Planning

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