

# MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

TO : A. Rothschild  
Petitions Control Branch, BF-334

DATE: December 8, 1971

AD



FROM : *GH* G. Higginbotham  
Organic and Additives Chemistry Branch, BF-144

*DR 12/15/71*

SUBJECT: FAP 1B2571 - E.I. DuPont. Evaluation of 11/16/71 submission

In response to your 11/2/70 reject letter, the petitioner has submitted validation data and sample calculations to substantiate the reliability of the methods for determining fluoride ion. The requested cottonseed oil extraction data, summarized on pages 3 & 4, are adequate to cover the proposed regulation.

Applying our correction factor of 6 for uncoated paper, we estimate that migration of the petitioned additive, **(b) (4)** to fatty and aqueous foods would not exceed 0.07 ppm (0.42/6) and 0.09 ppm (0.5 1/6) respectively.

We estimate the contribution to the total daily diet as:

$$[(0.09)(0.9) + (0.07)(0.1)] \times 0.05 = 0.0044 \text{ ppm or } < 5 \text{ ppb.}$$

We have no further questions.

*G. Higginbotham*  
G. Higginbotham

*Fluoride*

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DUPLICATE

12/8/71

A. Rothschild  
Petitions Control Branch, BF-334

G. Higginbotham  
Organic and Additives Chemistry Branch, BF-144

YAP 1B2571 - E.I. DuPont. Evaluation of 11/16/71 submission

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RD:init:AHoltz  
cc:  
HFischbach/BF-100  
EOHaenni/BF-140  
GHigginbotham/BF-144  
Div. Tox./BF-152  
LLRamsey/BF-301  
Pet. Con./BF-334  
JWHoward/BF-144  
GHigginbotham/vvK

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