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

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


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, to fatty and aqueous foods would not exceed 0.07 ppm (0.42/6) and 0.09 ppm (0.51/6) respectively.

We estimate the contribution to the total daily diet as:

\[(0.09)(0.9) + (0.07)(0.1)\] x 0.05 = 0.0044 ppm or < 5 ppb.

We have no further questions.

G. Higginbotham
A. Rothschild  
Petitions Control Branch, BW-334

G. Higginbothen  
Organic and Additives Chemistry Branch, BW-144

YAP 122571 - E.I. DuPont. Evaluation of 11/16/71 submission

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To: init:Aholtz  
cc:  
BFiischbach/BW-100  
EOHaenni/BW-140  
GHiigginbothen/BW-144  
Div. Tox./BW-152  
LRamsey/BF-301  
Pet. Con./BW-334  
JHHoward/BF-144  
GHiigginbothen/vwK