

cc: Mr. A. J. Dragon tte  
Mr. H. F. Robertson  
Mr. G. T. Scriba  
Dr. H. F. Smyth, Jr.✓

May 7, 1956

Dr. A. J. Lehman, Chief  
Division of Pharmacology  
Food and Drug Administration  
Department of Health, Education, and Welfare  
Washington 25, D. C.

Dear Dr. Lehman:

In previous correspondence both you and Mr. Mehurin have voiced no objection to the use of Bakelite rigid vinyl sheeting for food packaging such as boxes in which dressed poultry, etc., might be packed. Our Bakelite Company has now called to our attention the fact that they wish to use a colorant in this composition. They also propose to use a cast vinyl film for sealing the tops of these boxes.

The following is the composition of the sheeting material:

VCAA 3400 Yellow 523  
VCAA 3400 Yellow 524

| <u>Ingredient</u>                                                           | <u>Percentage</u>        |
|-----------------------------------------------------------------------------|--------------------------|
| VYNS vinyl resin (90/10 vinyl chloride/<br>vinyl acetate ratio)             | 97.3 (minus<br>colorant) |
| Magnesium epoxystearate<br>(prepared from G-60)                             | 2.0 - 3.0                |
| Zinc stearate                                                               | .2                       |
| External D & C Yellow No. 3 Lake<br>(K7150)<br>(H. Kohnstamm & Co., N.Y.C.) | .50 - 1.00               |
| Titanium dioxide                                                            | .25 - .50                |

Based upon our previous correspondence, no objection would be raised to the use of the above composition without the colorant.

I am informed by the manufacturer, H. Kohnstamm and Company, Inc., that External D & C Yellow No. 3 is a certified color with classification and C.I. No. Pyrazolene 696. The

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chemical name is monosodium salt of 5-hydroxy-3-methyl-4-phenylazo-1-p-sulfophenylpyrazole.

The clear cast film to be used as tops for these boxes is known as VBAB 9023 Natural and has the following formulation:

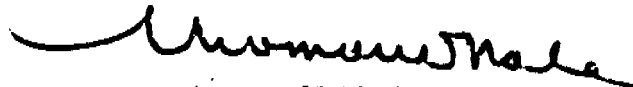
VBAB 9023 Natural

| <u>Ingredient</u>                                              | <u>Percentage</u> |
|----------------------------------------------------------------|-------------------|
| VYNW vinyl resin (95/5 vinyl chloride/<br>vinyl acetate ratio) | 73.5              |
| DOP                                                            | 24.0              |
| G-60 (Rohm & Haas)                                             | 2.0               |
| Acrax C                                                        | .17               |
| Durocer wax                                                    | .33               |

The components of this formulation have been found acceptable for food packaging use in the past.

Will you kindly let us have your opinion as to the safety of these formulations for use in food packaging.

Very truly yours,



MEDICAL DIRECTOR

Thomas W. Hale, M. D.

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Copy to Mr. R. M. Mehurin

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