MAY 22 1967

MONSANTO COMPANY
St. Louis, Missouri

cc: E. P. Benzing
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R. J. Christman
Jack Early - Washington
P. R. Graham
S. A. Heininger
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DEV. DEPT. CALL REPORT NO. 40-67

Food & Drug Administration
Washington, D.C.

DATE OF CALL: May 11, 1967

df: PC - FDA
PC - Binders - Coatings

FOR FDA	FOR MONSANTO
Herbert Blumenthal	Wm. Hunt
Willard Orr	Robt. Keller
K. P. Misra	M. V. Merchant
Joseph McLaughlin	
Al Holtz	

PURPOSE OF CALL: To review extraction data on pigment binder PB-702. This meeting proceeded smoothly. A cursory review of our data brought forth a favorable response that we should proceed to submit a petition for approval. Additional information was requested pertaining to characterization of the polymer film and analysis of the emulsion for free acrylamid.

DETAILS:

The meeting opened with a review of coating applications to paper and paperboard and the methods employed by Monsanto to prepare papers for extraction. The makeup of our polymer system was also discussed. A series of questions which were asked by the FDA personnel included:

"Have you supplied validation for your analytical procedures?"

"What coat weights have you applied and why this level?"

"Have you tested the emulsion for free acrylamid?"

"Will you provide polymer characterization data?"

"What solvent may be used to dissolve or swell your polymer?"

In summation, it was suggested that Monsanto proceed to file a petition to modify the sections of the Federal Register pertaining to use of chemicals in the manufacture of paper and paperboard which will come into contact with dry, aqueous and fatty foods. Information to be

added to the report should include polymer characterization data, such as molecular weight and solvent swelling data, also viscosity of the emulsion and finally the analysis for free acrylamid in the emulsion.

On the subject of analysis of free acrylamids in the emulsion, it was pointed out that techniques for analysis had been published by Hercules and Dow in their previous petition to FDA for wet end addition of poly acrylamid polymers. They agreed to provide us with information on this analysis but stated that our results might be different based on the effects of different extraneous materials.

M. V. Merchant

/ds