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August 6, 1971

Mr. George Ingle
Monsanto Company
1101 17th Street, N.W.
Washington, D. C. 20036

Dear George:

In accordance with the information you gave us earlier this week, we have now advised John Singleton of the Food and Drug Administration that the plastics industry does indeed want all of the colorants and pigments set forth in Section 121.2514 (b)(3) of the Food Additive Regulations included in the colorants for plastics Regulation now being prepared for publication by FDA. A copy of our letter to John Singleton in this connection is enclosed herewith for your information, and that of the rest of the full Food, Drug and Cosmetic Packaging Materials Committee.

Although you and the members of the Pigments Task Group have been kept informed on the background of this matter, and the full Committee has been advised about FDA's immediate intentions in the colorants for plastics area at several of our recent meetings, perhaps it would be well to remind everyone that the Regulation expected to be promulgated is not being produced at our request, but actually on the Agency's initiative. Indeed, we are certain that many members of our Committee would prefer to see no Regulation of this type whatsoever since it may well create questions and problems as regards colorants which will not be listed in the first promulgation.

At the moment, it is our guess that this Regulation will only cover the Section 121.2514 (b)(3) substances, and perhaps a few others for which individual company petitions have been pending. This may inevitably lead some parties to question the use of unlisted colorants even though their continued use should be perfectly appropriate under the revitalized "no migration" doctrine, i.e. revitalized by the Tom Brown letter of August 21, 1971. The truth, of course,

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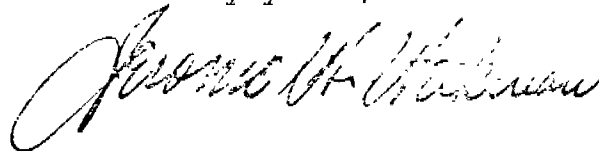
Mr. George Ingle
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is that FDA really hopes that the publication of this Regulation will lead to the filing of many additional plastics colorants petitions.

I do hope that the full Committee will understand that it was necessary for us to respond to John Singleton's inquiry immediately, rather than delay for any type of general circulation or comment. Furthermore, we trust everyone will agree that the response given can only be helpful since the question posed was not whether we had other colorants we would like added to the Regulation, but only whether we could assert a need for coverage of the Section 121.2514 substances.

Needless to say, we shall now be watching for publication of the anticipated FDA Regulation and will keep you posted on developments. If you have any questions in the meantime, please do not hesitate to let us know.

Cordially yours,

A handwritten signature in cursive script, appearing to read "Joseph H. H. H. H.", written in dark ink.

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August 6, 1971

Mr. John Singleton
Division of Petitions Processing
Bureau of Foods
Food and Drug Administration
Department of Health, Education,
and Welfare
Washington, D. C. 20204

Re: Colorants For Plastics
Food Additive Regulations

Dear John:

Following up on our recent telephone conversations of July 29 and August 2, and the information I gave you orally on the latter date, this is simply to advise you, on behalf of the Society of the Plastics Industry, Inc., that we would appreciate the inclusion of all of the pigments and colorants now set forth in Section 121.2514 (b)(3) of the regulations in the new colorants for plastics Regulation the Food and Drug Administration is planning to promulgate.

As I indicated to you, I did check with George Ingle, Chairman of our SPI Food, Drug and Cosmetic Packaging Materials Committee's Pigments Task Group as promptly as I could after I first talked with you. Mr. Ingle informed me that all of the pigments and colorants you alluded to are being used, or could be used in manufacturing plastics food contact surfaces. Actually, George advised that the only reason he is qualifying his statement with the "could be used" comment is because he does not have first hand knowledge of the use of burnt umber or raw sienna in the industry, but perhaps they could be used and are so innocuous as to provide no reason for eliminating them from the list.

It is our understanding that what is contemplated here is the promulgation of an opening

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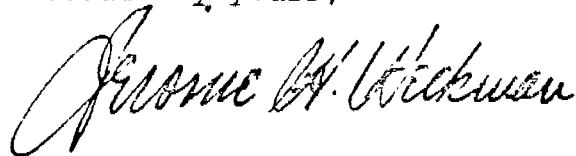
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regulation by FDA which will list a number of colorants and pigments, including all of those in the present Section 121.2514, and perhaps other substances which have been the subject of separate petitions. We also gather that this regulation will permit the use of these colorants in plastics without any limitations except as regards some special limits relative to cobalt oxide-aluminum oxide, zinc carbonate, and zinc oxide.

It will probably be somewhat helpful to the industry to have an FDA regulation of this type although, as I pointed out to you, we are certain that many additions will ultimately have to be made to the list to satisfy the industry's needs. We are equally certain that some colorants which heretofore have been used under the "informal moratorium" system relative to colorants which were on the extension list, and many others not reasonably expected to migrate to foods under the intended conditions of use, will continue to be employed. Nevertheless, the action you are taking may partially help to clarify a difficult problem.

I hope that this letter will be fully responsive to your request of us. If there is anything more we can do to be of assistance in connection with your project, however, please do not hesitate to let us know.

Cordially yours,

A handwritten signature in dark ink, reading "Jerome W. Wickman". The signature is written in a cursive style with a large, flowing "J" and "W".

ASI-PR 0001085