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To the Members of the Food, Drug and Cosmetic Packaging Materials Committee

Gentlemen:

As you are aware from some of our previous correspondence--particularly our letter of June 11, 1968--we have been anxiously awaiting some more definitive action from the Food and Drug Administration as an aftermath to the positions enunciated by plastics and other industry representatives at the National Conference on Indirect Food Additives held in February. You will recall our writing to you in the aforementioned letter to advise you about some of our anticipations in this connection. At that time, we pointed out that we expected FDA to move in the near future on some staff recommendations which would bring about welcome limitations on the type of substances for which incidental food additive petitions might have to be filed in the future.

We indicated we had information to the effect that the staff was recommending the issuance of some type of policy statement which, among other things, would eliminate from Food Additive Amendment coverage (1) "minor" ingredients used in so-called repeated use applications, (2) substances used in manufacturing packaging materials which substances would result in migration of less than .05 ppm., and (3) perhaps substances used in manufacturing packaging materials employed solely in adhesives or for the packaging of dry foods.

During the past week we have learned that the staff recommendations apparently have now been thoroughly reviewed by the General Counsel's Office (William Goodrich), as well as the Office of the Associate Commissioner for

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Compliance (J. Kenneth Kirk), so that something more definite in the way of FDA action is now to be anticipated Exactly what form this action will take is not yet entirely clear but the prevailing opinion seems to be that FDA will soon call on the industry associations which appeared on the program at the National Conference on Indirect Food Additives for private consultations to review a set of proposals for changes in the incidental food additive regulatory posture. The plan, as we understand it, is to discuss the changes being favorably contemplated informally with industry representatives prior to formal publication of them as official proposals. We are further told that, once such conferences are concluded, the proposals will be published in the form of a proposed rule making to modify Section 121.2500 of the Regulations--the so-called "good manufacturing practices" regulation--in such a way as to further delimit therein the substances that must be covered by Food Additive Petitions.

As of this writing, we must still be somewhat indefinite about the specifics of the changes now foreseen. However, we have reason to believe that there may be some further coverage of the entire subject in next week's issue of Food Chemical News. Since I will be away from my desk all of next week, I have alerted Tom Hughes of my office to what is taking place so that he can send each of you copies of the Food Chemical News coverage, if and when it appears. Thereafter, we shall be following up on the matter more fully and shall keep you posted on our progress.

Developments along these lines could well necessitate moves on our part to have further meetings with the other industry groups we contacted prior to the National Conference on Indirect Food Additives. Such developments may also indicate the need for scheduling a Food, Drug and Cosmetic Packaging Materials Committee meeting sometime in October.

In any event, Bob Miller is well aware of what is taking place so you may be assured that our Committee

will be kept informed, and that its leadership is ready to move in whatever way appears appropriate.

Cordially yours,

Jerome M. Eckman