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Mr. Robert M. Miller
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Dear Bob:

The purpose of this letter is to give you and the members of the Food, Drug and Cosmetic Packaging Materials Committee a bit of an interim report on recent "developments" regarding our long awaited expectations of some action from the Food and Drug Administration as an aftermath to last February's National Conference on Indirect Food Additives.

As I am sure you will recall, at the last full Committee meeting, I reported in some detail on the type of possible improvements in the present situation known to be under consideration by FDA. Rather than recap all of this background comprehensively here, let me simply digress a moment to advise those who were not present at our last meeting that the Minutes will be distributed in about another week so anyone who wishes to learn about, or refresh his recollection regarding the rules revision concepts FDA has had under consideration will be able to do so by reviewing Exhibit A of the Minutes, i.e. my report to the Committee.

After I gave this report you will remember that, at our luncheon, Mr. Lessel Ramsey disappointed all of us (due to no fault of his, and contrary to what he anticipated he would be able to do when he accepted our invitation) by advising that, while he could not give us any definitive information, it could be expected that FDA would take some action soon to relieve industry of some of its burdens as far as incidental food additives regulation is concerned.

Mr. Ramsey's comments in this connection were reaffirmed, again without any definitive promise as to when something would be done, by Commissioner Ley in response to questions submitted by us, and perhaps others, at the Food and Drug Administration-Food and Drug Law

Institute meeting early in December. Despite these affirmations about forthcoming action, nothing truly definitive has taken place as yet, and we are not really in a position to report concrete progress.

In the past week or so, however, we have learned that the Food Protection Committee of the National Academy of Sciences and the National Research Council has approved publication of a report which will be entitled "Quantitative Guidelines for Toxicologically Insignificant Levels of Chemical Additives in Food," and that this report has now been supplied to the FDA Staff in an unprinted form, although it has not been officially released for general distribution. The report was prepared by an outstanding group of toxicologists composing a special task force of the Food Protection Committee. Among those who participated extensively in this work was, of course, Jack Frawley who has long been expressing his views (with which we have always generally concurred) on the necessity for doing away with excessive regulation of "toxicologically insignificant" additions to food.

Although we cannot advise you in detail about the Food Protection Committee report since it has not been published, or even formally released as yet, we can say that the basic recommendation of the Committee will call for a general adoption of the principle that, certain substances such as heavy metals and pesticides aside, levels of addition to foods which will result in concentrations of less than .1 ppm of a substance in the diet should be considered toxicologically insignificant. There is good reason to believe that the Food and Drug Administration will accept this basic principle.

The problem here is that, for obvious reasons, all the toxicologists could do within their legitimate sphere of expertise was to agree upon a toxicologically insignificant level in the diet. They could not relate this level to what might be considered toxicologically insignificant additions of components to specific packaging materials, since this would require non-toxicological base information (or estimates) on such questions as how much of what foods are wrapped in the different packaging materials, and what part of the diet each such food might represent. In short, some empirical extrapolations will have to be made to bring the Food Protection Committee's conclusion into play in specific incidental additive situations. Nevertheless, the report, when it is published, and assuming it is generally

accepted by FDA as well as industry, will provide a new toxicological base for present and future consideration which could lead to improvements in the present regulatory situation, i.e. by at least making it possible for FDA to set some levels of addition where it can be said that Food Additive Petitions will not be required for clearance of relatively minor packaging materials components.

The main reason I am brining the status of the Food Protection Committee work to your attention is because we have now been told that, since FDA learned that the report might be forthcoming, it has been delaying its plans to revise the "Good Manufacturing Practices" provisions of Section 121.2500 of the Food Additive Regulations along the lines I discussed at length in my report at our last meeting. Mr. Ramsey indicated in a conversation I had with him yesterday that, now that he has the aforementioned Food Protection Committee report, he and the rest of the staff will be reviewing their previous thinking in various respects. Among other things, we gather that consideration will be given to further liberalizing the projected FDA idea I reported on at our meeting whereby the so-called "Good Manufacturing Practices" regulation, Section 121.2500, would be revised to indicate, in effect, that petitions need not be filed for most packaging materials components used at a level which would result in additions of less than 0.05 ppm to food. It would appear that the FPC conclusion on toxicologically insignificant additive level determinations may induce FDA to raise the regulatory requirement threshold level a bit from the 0.05 ppm point, although certainly this cannot be assumed at this stage. All that can be said is that the report, which has now been in FDA's hands for less than two weeks, will apparently have some effects of consequence and that, until FDA feels it has had adequate time to study the report and reconsider its earlier thinking in light of it, no overt action is to be expected. Our hope is that this will not require too much longer but it would be wholly unrealistic to make any predictions of prompt action right now.

Two other collateral points which came up during my talk with Mr. Ramsey yesterday may well be of interest to the Committee, as they were to us.

Firstly, in response to one of my inquiries, Mr. Ramsey advised that it is still his intention and desire to have any conclusions reached by the FDA Staff discussed informally with industry--probably representatives

of all of those groups who participated in the National Conference on Indirect Food Additives--before any formal proposals for rules changes are published in the Federal Register. Mr. Ramsey indicated that this was the course of action he would recommend to the Commissioner, and that he has every reason to believe that this recommendation will be followed.

The second point I raised related to whether or not we could continue to assume that there will be no final move to adopt the proposed new "Procedural Regulations" until such time as something more definitive is done as an aftermath of the National Conference. Here again, Mr. Ramsey assured me that no new Procedural Regulations based on the proposal published on August 8, 1967 will be promulgated until something definite has been done as a reaction to the recommendations made at last February's National Conference. If anything, Mr. Ramsey was more definite than he has ever been before in giving us this assurance.

I hope that the information conveyed by means of this letter will serve to bring all of the members of the Committee reasonably up to date on the current thinking of the Food and Drug Administration with regard to our problems at this time. As always, we would be glad to receive any comments or questions that you or any of the other members of the Committee may care to give us.

Cordially yours,

Jerome W. Hackman

cc SPI-FDCPMC