Exhibit A

Report of
Jerome H. Heckman, SPI Counsel
Prepared for SPI Food, Drug and
Cosmetics Packaging Materials Committee
Meeting
Washington, D. C.
November 7, 1968

Gentlemen:

It is good to see so many of you again. Please let me start by thanking all of you who were so understanding about my being unable to attend your last meeting in April. My family was very grateful for the many expressions of sympathy received regarding my father's passing. It was a trying time so your understanding was deeply appreciated.

I would also like to publicly thank my very capable associate, Tom Hughes, for filling in on my behalf on extremely short notice. From what I have heard since April, Tom did a great job. As a result, of course, he will now have to pay the usual price for his success. Thus, you will have noted that he is listed on the Agenda to give you a report a little later on today on some of the overseas developments which have come to our attention recently.

In accordance with our custom, I will try to "hit some of the high spots" here on a variety of matters. In many instances, I have attempted to abbreviate my own discussion of some of the topics since, even with some abbreviation, I am afraid I must preempt a rather substantial amount of your time at this meeting. What I will try to do today, as best I can, is to report on what I consider my major topics, alluding only briefly to those which I believe others will be covering in greater depth. Again, in accordance with our custom, I hope you will feel entirely free to interrupt at any time for such questions, discussion, or even actions, you deem appropriate.

National Conference on Indirect Food Additives

In Tom's report at the last meeting, he, and I am sure some of the others who were present at, or participated in, the National Conference on Indirect Food Additives briefed you on how the Conference came to be, and how we organized industry participation in it. Since I was not present in April, I might merely add here that we believe the Conference was a most worthwhile undertaking, if for no other reason than because of the record it provided relative

to industry's problems with the present regulatory scheme relating to incidental food additives.

As of this moment, we cannot say that the Conference has brought about patently obvious tangible results. It may well be that our FDA guests at today's luncheon will change this status by giving us a more "official" insight into what steps the Food and Drug Administration is planning as an aftermath of the February sessions. In the meantime, however, I should at least remind all of you--including especially those who were not at the Conference--that the proceedings were fully transcribed. This, in and of itself, constitutes a real contribution as we see it.

I might also mention that we still have a fairly substantial supply of the complete transcripts of the Conference in our office so any of you who might like to have the background information which the transcript provides are invited to let us know. We can arrange to send you a copy but the transcript is some 309 pages long so I am sure you will forgive us if, in mailing the material, we make use of the lower class mailing rates, and ask you to anticipate the slight delay this might occasion.

Aside from whatever benefits in the way of background information the transcript provides to interested parties in both this country and overseas--and we have had occasion to send copies to contacts overseas who have found the transcript quite useful--we believe that some psychological benefits of regulatory significance have already accrued as a result of the Conference, and that other, more recognizable benefits, will be forthcoming.

On the psychological side, and you will appreciate that this is by no means easy to explain or understand, we have the strong feeling that the FDA Staff has taken some of the points made at the National Conference on Indirect Food Additives into account in its day-to-day handling of Food Additive Petitions. As a result, we believe that the staff is asking for at least slightly less in the way of data in connection with some petitions than might otherwise have been the case. Likewise, we believe there is a growing understanding at staff level of the need for delimiting those areas where petitions will have to be filed in the future. In other words, while it cannot be said that the so-called "Frawley concept" has been or will be wholeheartedly embraced by the regulatory agency, it does appear that some of the FDA thinking is proceeding down more moderate lines with the necessity for such a shift having been indicated by the forceful way in which the Frawley approach has been presented and supported.

Hopefully, Mr. Ramsey will be giving us some clearer indications in this connection later today. He may even be in a position to let us know more firmly whether the FDA staff proposal for significant changes in the Food Additive Regulations which

would limit the necessity for filing petitions is making real progress at the top levels in the agency.

All of the information we have received up to now, and much of this has already been called to your attention in our correspondence and by the trade press, indicates that the FDA staff believes the necessity for filing petitions on indirect food additives could be reduced by the adoption of added provisions to the so-called "good manufacturing practices" regulation set forth as Section 121.2500 of the present Food Additive Regulations.

At the risk of being repetitious, but so that those of you who may not be aware of the movement, will have a clear idea of what we understand the staff is proposing to do, let me point out here that if the staff recommendations are adopted, Section 121.2500 will be amended to, in effect, classify the following items as "non-additives," which may be used without petition type clearance, as a matter of good manufacturing practice. The language we have seen to accomplish this change would result in the addition of the following new Section (d)(5) to Section 121.2500:

"§121.2500 General provisions applicable to Subpart F.

* * *

"(d) Substances that under conditions of good manufacturing practice may be safely used as components of articles that contact food include the following, subject to any prescribed limitations:

* * * *

"(5) Substances (except heavy metals, as defined in Food Chemicals Codex, and compounds of such heavy metals; 'economic poisons', as defined in §2a of the Federal Insecticide, Rodenticide, and Fungicide Act; and substances prohibited under §409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act) as provided under subsection (i), (ii), (iii), (iv) or (v) of this subparagraph:

"(i) As components of food-contact articles provided any substance so used contributes no more than 0.05 ppm of additives to the contacted food.

"(ii) As components of articles intended for use in contact with dry food of type VIII described in table 1 of §121.2526(c) provided the finished food-contact surface contains no free oils not otherwise permitted for such use.

"(iii) As components of articles intended for repeated use in contact with bulk quantities of food provided the finished food-contact article is thoroughly cleansed prior to first use in contact with food.

"(iv) As components of defoaming agents employed prior to or during the sheet-forming operation in the manufacture of paper and paperboard intended for use in contact with food.

"(v) As components of food-packaging adhesives complying with §121.2520."

According to the best advice we have, if and when FDA's "topside" approves such a change in the regulations, it will not be published immediately but, instead will be discussed informally with representatives of the industries who participated in the National Conference on Indirect Food Additives. Presumably, at least, this would give all of those interested an opportunity to suggest changes in the proposal even before it is published and time is allowed for official "Comment," as is required by the Administrative Procedures Act.

If the matter does develop in this way procedurally, we may well want to meet again with representatives of other industries, as we did prior to the National Conference on Indirect Food Additives, so that industry positions can be as coherent, and therefore as effective, as possible.

Among other things, and again assuming that the proposals we have seen are eventually advanced to us in an official or semi-official way by FDA, I, for one, would like to see a degree of clarification of at least one of the major proposals we know about now. The one I have in mind is the one that would eliminate the need for Food Additive Petitions on "components of food contact articles provided any substance so used contributes no more than 0.05 ppm of additives to the contacted food."

In our view, this provision would need considerable clarification to make it of any real value since, what we would hope, is that it is intended to eliminate the need for petitions on substances where "no more than 0.05 ppm of additives" are detected in food simulating solvents under realistically established tests. If the presently contemplated language were revised to make this intent clear, we believe a forward step of consequence would have been taken. On the other hand, if the language is left as it is, and thus remains open to the interpretation that petitions may be avoided only where an in-food test--usually wholly impractical--shows that no more than 0.05 ppm finds its way into the food, or if it is interpreted so that it will cover only substances which would lead to no more than an 0.05 ppm addition to food if all of the substance migrated from the package, the provision will be virtually useless.

Without going into greater detail, let it suffice to say that we believe the language we have seen is inadequate at the moment, so we must hope that FDA will provide an opportunity for clarification at the earliest possible opportunity. Other aspects of the proposal could likewise point the way towards a necessity for meeting with our sister packaging groups, and working diligently to make reforms as useful as possible, all towards the end of continued protection of the public but with less of an unnecessary burden on industry.

With the various procedural possibilities in mind, one of our first recommendations to you today is that you empower your Steering Committee to act on your behalf in any negotiations which may become necessary, or appear desirable, as far as meeting with other industry groups, or the FDA Staff is concerned. We believe that your best interests will be served if you provide such authority here so that the Steering Committee can act promptly and effectively on your behalf as circumstances dictate.

Before leaving the subject of the National Conference on Indirect Food Additives to report more specifically on the still pending proposed revision of the FDA Food Additive Procedural Regulations, I would like to call your attention to a collateral development which, it seems to us, has a sort of overlapping bearing on both of these matters.

In the October 28 issue of Food Chemical News, a story appeared announcing that the Food and Drug Administration is establishing a "compliance policy guidance system" which will enable the agency to make public more of its current regulatory policies. According to the FCN article, the new system is being established in FDA's Division of Case Guidance and "will update and identify current FDA regulatory policies." The article indicates that the system "will include procedures for making public advisory opinions, trade correspondence, and other formal and informal regulatory policies."

If this system does indeed come to be, we believe that this will constitute a response, albeit an oblique one, to the recommendation we made to the Food and Drug Administration in both our SPI Comments on the Procedural Regulations and, again, in our presentation at the National Conference on Indirect Food Additives. If you will recall, in both of these presentations, we urged the agency to do something about the communications gap that exists because those other than parties dealing on a day-to-day basis with FDA have no way of knowing about the shifting sands of regulatory policy which are brought to bear in the handling of Food Additive Petitions, as well as in the handling of very important requests for advisory opinions about product status. In our Comments we went into considerable

detail on this point and urged the agency to adopt a system similar to that used by the Federal Trade Commission for publishing Advisory Opinions without revealing the names of inquirers, or the details relative to any particular product.

We have the very definite impression that the procedure FDA is apparently planning to install as a new "compliance policy guidance system" will, in actuality, be along the lines that we suggested.* If this is so, we can be grateful for a modicum of progress in the slow process of bringing about meaningful regulatory reform.

Status of FDA Proposed "Procedural Regulations"

To place this part of my report in perspective, let me remind you that comments on the FDA proposal for a complete revision of its Procedural Regulations were submitted in a 69 page document we filed on your behalf on November 6, 1967. Among other things, we strongly urged that FDA do nothing in the way of adopting new Procedural Regulations until such time as some of the more basic problems relating to incidental additive regulations had been thoroughly aired, and agonizingly reappraised. It was in this set of Comments that we first advanced the idea of establishment of an Industry-Government Advisory Committee to do the job of working over the regulatory scheme in a truly comprehensive way.

This recommendation for the establishment of an Industry-Government Advisory Committee was carried forward even more forcefully in the National Conference on Indirect Food Additives. Indeed, in summarizing the Conference, most of the FDA spokesmen noted that the one point that they had heard supported most unanimously by all of the industries represented was the request

*/ Subsequent to the giving of this report, and during the question and answer session held with Mr. L. L. Ramsey of the Food and Drug Administration at the meeting, it was learned that the so-called "compliance policy guidance system" will not really be along the lines of the Advisory Opinion procedure previously recommended by SPI in its November 6, 1967 comments on the proposed Procedural Regulations. Instead, Mr. Ramsey advised that this new system will be reflected by publication of some sort of manual to recap the enforcement policies communicated confidentially to the field staff of FDA during the past ten or fifteen years. He further advised that the only thing really "new" about the matter is that the policies will now be made public information for the first time. He further indicated that the last estimate he had heard of a possible publication date leads to a conclusion that the availability of the material in question is at least three years away.

for establishment of an Industry-Government Advisory Committee to reevaluate and deal with all aspects of the incidental additives regulatory problem.

Strangely enough, we have not heard a great deal from FDA about the Industry-Government Advisory Committee proposal in recent months although we have been hearing much about the FDA Staff plan to revise the "good manufacturing practices regulation" to eliminate the need for petitions in a number of areas. Whether this means that FDA is of the opinion that the Industry-Government Advisory Committee suggestion can be sidestepped by the finalization of some proposal to eliminate the need for the filing of petitions in specific areas is not clear yet.

In our view, the Industry-Government Advisory Committee concept should continue to be pressed as a matter of policy. Further, we are of the opinion that FDA should perhaps again be urged to forego the publication of any final revision of the procedural Regulations until such time as an Industry-Government Advisory Committee has been formed, and has made an effort to come up with more realistic changes.

As far as we are aware at the moment, consideration of the Procedural Regulations is in a state of limbo, the likelihood being that no moves will be made on this score until more definite National Conference "aftermath action" is taken. Nevertheless, we believe it might be in order for this Committee of SPI to consider reemphasizing our interest in having FDA appoint an Industry-Government Advisory Committee, and delay publication of any new Procedural Regulations, unless and until such an Advisory Committee has studied the situation, and has given the agency the benefits of its thinking on how Procedural Regulations should be written to facilitate industry, as well as FDA, action required under the Food Additives Amendment. It seems to us that a suitable Resolution in this connection might well be considered with a view towards forwarding the same to the Food and Drug Administration at such time as this might appear tactically desirable.

Consideration of SPI Petitions Manual

While on this subject of the Procedural Regulations, and to take up a point which I believe was discussed, but more or less left in abeyance at your last meeting, I would like to raise with you now a possibility for constructive Committee work which I believe would prove helpful to the Food and Drug Administration, as well as to plastics and other packaging interests. I might note here that I have discussed my embryonic idea in this connection with members of your Steering Committee, and indeed in an informal way with our friends on the FDA Staff, on a number of occasions during the past year. Everyone seems to

feel that the idea has merit although it is also recognized that the task it would involve would be a formidable one, demanding a substantial expenditure of time and effort, as well as government-industry cooperation.

In a way at least, I first raised this idea in a semi-official way in my own paper at the National Conference on Indirect Food Additives when I asked the following question:

> "On this matter of what petitions should contain, would it not be better for FDA to avoid the adoption of unduly restrictive procedural regulations such as those recently proposed and, instead, work closely with industry (perhaps through its trade association spokesmen of the type here represented) to develop more informative educational materials such as manuals depicting in 'dummy form' how various types of petitions should be structured?"

Since that time I have found that many FDA Staff members do feel that it would be very constructive if publications could be developed by a trade association such as SPI to depict concretely what a good petition should look like to facilitate consideration by the administrative agency, and, therefore, to facilitate and expedite satisfactory regulatory action. My feeling is that this is an activity which should be undertaken, perhaps as a cooperative effort by members of the Technical Information Subcommittee, and the Lawyers' Advisory Subcommittee, since the problems involved would undoubtedly bring into play both the scientific and legal disciplines.

For your consideration, I would therefore recommend that your Chairman be empowered to appoint a special committee to develop a "Food Additives Petition Manual" which could eventually be published as an SPI document and would, hopefully, set forth sample Food Additive Petitions, using as prototypes fictitious or real components, as you deem best. Recognizing the fact that, in actual petition situations, different types of substances must be treated differently as a matter of common sense, it would seem to us that such a Manual, to be as worthwhile as possible, would need to include sample petitions relating to (1) a substance which is only an adjuvant used with other packaging materials, (2) a total formulation case, and (3) a basic polymer case.

There may be other areas which would need to be covered, and certainly much thought would have to be given to the development of a practical, as well as a suitable format for such a publication. Among other things, any committee appointed to work on this project would need to decide whether extensive example data on actual migration and/or toxicological studies would need to be included, or whether it would suffice if this type of material was simply blocked out in brief form, but with sufficient particularity to provide a real guide for prospective petitioners.

It seems to me that, if nothing else is accomplished, any manual of this type which we undertake to prepare, and ultimately publish, should stress a syllogistic approach to the preparation and filing of Food Additive Petitions. While it may not be possible to prepare a Manual which will answer every question that might come up in the course of a petition problem, the examples of such petitions set forth should at least make it clear that a petition is, after all, a document which should be fully self-contained, and in the purest possible sense logically dispositive of all questions that can be reasonably anticipated.

My point here is difficult to make understood in the abstract. What I am trying to convey is the idea that, in our opinion, a sound Manual should make it apparent that a good petition must meet the following requirements, as we see it:

1. The petition should first set forth sufficient background about the petitioner and its interest in the incidental food additive to set the stage for the more detailed logical and technical exposition in the Petition. Very often, a complete explanation of how the substance was "discovered" for the particular use contemplated will cast a great deal of helpful light on the overall situation, and will obviate the need for extensive explanations about such subjects as the usefulness of the product.

2. The petition should state in narrative form how the petitioner analyzed his regulatory problem, and set about undertaking whatever test work he deemed necessary to provide the Food and Drug Administration with a sound and complete basis for promulgating a regulation. On occasion, this type of explanation, provided a sound and thorough rationale is given, can help demonstrate why it might be unnecessary to perform certain extraction or other analytical work which might be required in other circumstances. Furthermore, this type of explanation can, on occasion, set forth a reasonable basis for satisfactory arguments that additional toxicological studies are not needed. In this discussion, incidentally, such subjects as an estimate of how much of the diet might be packaged in materials containing the substance of the petition can be set forth to provide FDA with a rational basis for concurrence in the petitioner's point of view about the amount of technical data required to give adequate assurances of safety.

3. Obviously, the petition will always need to discuss the ultimate conclusions reached in connection with the technical work done to support safety of the additive. As I have on occasion indicated to the laboratory people with whom we have worked on Food Additive Petitions, we recommend that their work, and their reports, be prepared in the same way that they would prepare documentation if they were readying themselves to be expert witnesses in a lawsuit, or administrative hearing. We always seem to have some difficulty in making our intent in this connection clear.

The idea, as we see it, is that the people who prepare either analytical or toxicological data to be used as appendices for petitions--and we normally like to supply the complete technical data as appendices, referring only to the conclusions to be drawn from the technical reports in the body of a petition--should recognize that they are, in effect, preparing expert testimony which the Food and Drug Administration will be relying upon in its analysis of the total petition.

For those of you who may not have had much occasion to prepare expert testimony, let us point out here that, to be effective, such testimony must always be fully explanatory in and of itself. Nothing should be left to the imagination on the assumption that the data will be reviewed by another expert who "will know what you mean." In other words, we believe that an analytical report should state in clear, complete, and narrative form why certain tests were selected for the work, how one could be assured that these tests were valid for the intended analytical purpose, and how the tests were actually conducted. The report should also, obviously, include the data obtained but the expert, because he is an expert, should not leave the matter there.

As an absolute essential--as the "punch line" for the technical report, if you will--it should state the expert's conclusions based on the data he has compiled. It should also include any relevant observations that can be made on the basis of the scientist's general expertise in the field. An expert witness who simply performs technical studies and cannot explain what the studies demonstrate in support of a petition, or set forth how his expertise permits further relevant conclusions, is virtually useless. The same is true of an

analytical report which assumes that those who review the data will understand why it was accumulated in the way it was, and what it is intended to demonstrate. The by-word should be "assume nothing" and "explain everything."

4. The body of the petition should be used to rationalize all of its parts, including any appendices. In every case one of those appendices should be a proposed regulation in precisely the form in which the petitioner believes the Food and Drug Administration should promulgate a response to his filing.

I realize that many of you have probably filed petitions which meet the essentials of this listing. On the other hand, I know from my own experience, and from what various FDA Staff members have told us that this is by no means universally true. Indeed, dissatisfaction with so many of the petitions filed thus far is what led to the proposal for revised Procedural Regulations. We happen to think that this is the wrong way to solve the problem, and that a better way would be to prepare sample petitions as an educational tool to improve the situation. It is for this reason that we recommend the approach I have been discussing.

As a final word on this subject, I might point out here that we have discussed this idea with many members of the FDA Staff, and have reason to believe that we could count on the agency's cooperation if we set about preparing a manual of the type suggested. This type of cooperation would certainly include FDA's help in reviewing our drafts, and making suggestions as might be indicated. It might even include some type of FDA letter or other note of approval which might be included in the manual although this is not entirely necessary, nor can we say that there is any advance commitment in this connection.

Regulatory Developments Regarding Plastics for Drug Use

As I hope all of you are aware by now, the SPI Manual entitled "Plastics Packaging for Drug Products--the Regulatory Story" has been available for quite some time and has, we believe, been widely disseminated. Even so, we find ourselves continually explaining how regulation of packaging materials for drugs and cosmetics differs substantially from the regulatory approach employed in the case of food packaging materials. We still hear the plaguing question: "Is this product FDA approved for drug packaging?" from a great many drug people, as well as from packaging suppliers. The availability of the drug manual does help to answer some of these questions.

Aside from the educational effort that this Manual is intended to further, there has been progress in the work with the Pharmaceutical Manufacturers Association but I will leave a discussion of this subject to Wat Ackart who will be talking with you later.

The main development or item I would like to call to your attention relates to a Notice published by the Food and Drug Administration in the July 11 Federal Register at Pages 9954 through 9955. This Notice amended various sections of the New Drug Procedural Regulations dealing with so-called "Supplemental Applications" so as to eliminate the need for filing such Supplemental New Drug Applications under certain conditions. As a result of this Notice, it is no longer necessary for drug companies to file Supplemental New Drug Applications in cases where, among other things, they are planning "a different container size for solid oral dosage forms where container and closure are of the same materials as those provided for in the approved application." Other situations involving relatively minor changes in drug production were relieved of the requirement for the filing of Supplemental New Drug Applications.

Perhaps of even greater significance is the fact that, in issuing this Notice, FDA stated that "the Food and Drug Administration will consider any categories suggested by interested persons of changes that may be appropriate for inclusion in Section 130.9(a)(5) as not requiring prior approval of a Supplemental Application for implementation." The reason this could become significant is because it seems to us that, for the first time, the agency has provided an avenue whereby we might be able to eliminate the drug manufacturers' need for filing supplemental applications on other changes in his packaging program, assuming, of course, that we can identify areas where such changes should not present a cause of concern to FDA, and, therefore, might be listed as exempt from the Supplemental New Drug Application requirement.

Whether or not, for example, FDA might be willing to take the position that Supplemental New Drug Applications need not be filed for a change in the packaging of all dry drugs from currently used materials to olefin polymer bottles is a question we think might be explored. Depending on your wishes in this connection, it may well be that we could consider setting up a conference with the appropriate FDA Staff people to discuss this area and determine further what the possibilities are.

I am sure that I need not point out that, if it were possible to exempt such an area as the one I have used as an exemple from the necessity for the filing of Supplemental New Drug Applications, some interesting new markets might be opened up, or at least made less difficult to enter. For this reason, we recommend that the Committee consider instructing the

Pharmaceutical Manufacturers Association-SPI Liaison group, or some other ad hoc committee, to take this possibility up with the Pharmaceutical Manufacturers if you think necessary, and then be empowered to explore the situation with the Food and Drug Administration Staff. We would, of course, be very happy to help with this project.

Publications of Interest

During the past several months there have been, as always, a number of articles and publications which many of you would find of interest. We do not compile bibliographies of such items for these meetings but I do try to mention any which seem to us to be of particular significance.

In this vein, I would like to call your attention to the availability of the first volume in a planned series being published by the Institute of European Studies of the Food Law Research Center of Brussels University. This first volume is entitled "Fundamental Principles and Objectives of a Comparative Food Law". The publication seems to us to be of unusual value because of the survey type treatment, and commentary, it provides on the basic concepts of food and food additive regulation throughout the world.

As far as we know, the best way to obtain the book is through a Mr. Albert J. Phiebig, Post Office Box 352, White Plains, New York, 10602. Mr. Phiebig, I believe, serves as the American agent handling this publication, and perhaps others. The price tag on this first volume, by the way, is $6.

In this same area, and for those who may not have seen it, you may want to look at the September issue of Modern Packaging which contains articles by Alan Spiher and Jack Frawley under the heading "Ten Years of Food Law--Has it Been Worth the Effort?" Jack's paper while, as usual, excellent, constitutes only an abbreviated restatement of what I believe we can call the industry point of view on the Food Additives Amendment. Mr. Spiher's statement, as you might expect in light of Mr. Spiher's background at FDA, is a general apologia for regulation of food additives. I doubt that it will contribute a great deal to your knowledge but you might want to look the article over.

One other article that I have noted lately appeared in the October 10, 1968 issue of the Food and Drug Packager. This article was entitled "PVC for Foods--Some Points to Ponder" and was written by Mr. William A. Larkin, Market Manager for Plastic Product Activities at M & T Chemicals Inc. To a degree at least, Mr. Larkin has attempted to provide some of the background on the only tin stabilizer regulation thus far promulgated by the Food and Drug Administration.

This article does point up the one major problem that exists as a result of the regulatory approach used in the tin stabilizer regulation. That approach, as all of you undoubtedly know, involves the necessity for applying a so-called "in-food" test. The use of such a test imposes a burden on the food processor who is the only one that can apply it, and this undoubtedly explains why we have not yet seen a great influx of tin stabilized PVC bottles in the food packaging area.

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There have, of course, been other developments of interest during the several months that have elapsed since our last meeting. Information about some of them will be conveyed to you by subsequent reports today. Due to the length of my report, let me conclude by simply noting that there is a possibility that, by the time of our next meeting, the latest Department of Health, Education, and Welfare reorganization plan may have been put into effect. I will not dwell on this subject other than to say that, as far as we can determine, while FDA may then be operating under the aegis of the new Consumer Protection and Environmental Health Service, and while there may or may not be a change in the Office of the Commissioner, it appears to us that the reorganization will not directly affect any of your activities or interests. To put it simply, all that we are seeing or anticipate are some additional title changes, office shifts, and more "musical chairs" playing, but no real revisions of substance for those interested in incidental food additives.

I thank you sincerely for your patience.