APPENDIX B

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Prepared for

MARCH 15, 1972 MEETING
SPI FOOD, DRUG AND COSMETICS
PACKAGING MATERIALS COMMITTEE

Gentlemen:

Since our last full Committee meeting on June 3, 1971, there have been so many developments in so many divergent areas of interest to this Committee that I can only hope to mention the "stand-outs" briefly. I imagine we will fill in the gaps through our usual type of cross discussion.

Before even getting into the "nitty-gritty" of my regular assignment, I thought I would try to give you something of an over-view of recent changes in tone at the Food and Drug Administration which could be more significant for the future than the immediate happenings that necessarily command the most direct attention.

In this vein, it occured to me that a historical note might be of interest to some of you. We are meeting here on the Ides of March just 15 years and 15 days after the very first meeting of what was then the precursor of your group given the name "SPI Food Packaging Committee." The meeting was held at the Pierre Hotel beginning at 12:30 PM on March 1, 1957 at a time when the Food Additives Amendment was still something of a "gleam" in the eyes of the now famous, or infamous (according to your tastes) Congressman Delaney, and a number of his associates on the Hill. The Delaney hearings had been in progress for about six years but even the Administration sponsored legislation which was to form the basis for the Food Additives Amendment of 1958, Public Law 85-929, had not yet been introduced. There were two bills pending which were enough, however, to give us great cause for concern.

It might also be interesting to you if I noted that not a single person present at that first meeting, other

than Charlie Condit and myself, is active on our Committee today. Despite this fact, I doubt we will soon forget the tremendous work done by the initial group of 19 people who forsaw some of the many difficulties we have had to live with since 1958. I know that I, for one, will always remember and try to remain in touch with the people like Fred Adams, Elliot Balestier, John Kuniholme, George Rowland, Howard Scopp and George Scriba who were among the leading industry lights at that first session. Suffice it to say that we were concerned then that FDA's impending move into the packaging regulatory area would create enormous problems out of all proportion to the public interest to be served. Very little has happened since to do anything but justify this concern.

From my point of view, one of the problems we discussed only in passing at that first meeting remains a serious problem today, that problem being the matter of what really is, or should be called a "food additive." I suppose the thing that keeps many of us going is the hope that there may yet be some sensible solution to this question in our time. Incidentally, to give you an idea of how the framework within which we work has been changed, I might note that on March 1, 1957, George Scriba pointed out to those of us who were then relative novices in the field that the matter of obtaining FDA clearances could be expensive as well as vexatious when he noted, for example, that two year feeding studies could cost as much as $40,000. Suffice it to say that current estimates as to the cost of such studies and everything that must go with them more nearly approximate $150,000.

Now, in the vein of pointing out why hope does somehow continually seem to spring from the human breast, let me note here, as I have in some of our recent correspondence to the Committee, that we believe the new General Counsel*/ of the Food and Drug Administration, Peter B. Hutt, has much more of an understanding of some of our problems. I also feel it is fair to say that he has recently indicated to me that our causes should not be viewed as hopeless. He has advised me informally that one of his prime objectives in his new position will be

*/ This title is used for convenience since it does really describe the job although the official title is Assistant General Counsel, Food, Drugs and Environmental Health Division, Department of Health, Education and Welfare.

to try to bring into focus and resolve in a definitive way the many unclear FDA policies which have caused concern for as long as 12 or 15 years.

I have reason to believe that the matter of defining what is a food additive as this term relates to indirect additives is one of the matters he will be attempting to cope with. At the very least, I can assure you that we are conferring with the General Counsel's office on this subject, plan to increase the build-up of information, and then hope to bring about a tangible degree of progress.

Before explaining this a little further, I would like to mention the fact that we believe Mr. Hutt has already shown his inclination to be a part of solutions, rather than merely a contributor to confusion, by the actions he has taken to: (1) assign attorneys to work on a more or less day-to-day basis with the Food and Drug Administration Bureaus, Stephen McNamara being the young attorney to whom we will look on Bureau of Foods matters; (2) issue a memorandum making it completely clear that FDA has no power under the Food Additives Amendment to revoke prior sanctions as some believed it had done when it released its peculiar prior sanction letter revocation "Statement of Policy" on April 9, 1970; and (3) bring about the introduction of a new form of proposed device legislation which should at least be more understandable than previous proposals.

As for the assignment of attorneys to work on a day-to-day basis with the Bureaus, I think you all know that this is something I have personally advocated for at least the past six or eight years. I am committed to the view that the Food and Drug Administration's modern role is every bit as much regulatory, and, therefore, legal, as it is scientific. This is why I have given papers such as the one entitled "Why Lawyers and Scientists Must Increase Cooperation and Mutual Understanding in Dealing with Food and Drug Problems" at meetings like those of the Federal Bar Association.

Among other things, I was especially pleased to hear about Peter Hutt's action because I feel that lawyers are perhaps more impressed by statutory requirements than is the rank and file of the FDA Staff. To put the matter in a more practical light, I suppose what I am saying to

you is that I am hopeful, and plan to discuss with Mr. McNamara in due course, my belief that Congress meant what it said when it indicated that Food Additives Petitions should be fully acted upon within 90 days, or at least a maximum 180 days. Maybe we will even be able to do away with the current "Federal Register Rag" whereby it has often taken as much as two or three months for a regulation or notice to be published even where there is no substantive problem remaining to be resolved.

On the prior sanctions question, here again I am personally gratified by Mr. Hutt's memorandum in which he advised Dr. Wodicka that the Food and Drug Administration has no power to revoke prior sanctions. Some of you may remember that, at your June 10, 1970 meeting, I stated as follows:

> "Let me stress this next point. FDA does not have the power to revoke the status of the 'prior sanctioned' or GRAS substances without due process....in essence, we view the Statement of Policy as a meaningless notice--a grandstand play for the press--which only serves to confuse the situation concerning the statuses of important and safe substances in general use."

At that same meeting, we recommended that you ignore the Statement of Policy to the greatest extent possible consistent with the necessity for reassuring your customers about the compliance of your products with applicable FDA regulations. I think that Mr. Hutt's memorandum has justified this position fully.

As to the new proposed devices legislation, I will not take your time to describe the legislation now since you will be hearing more about this in the Lawyers Advisory Sub-committee report. However, I do think that, after this report is given, the Committee should consider what if any position we should take regarding the FDA sponsored bill. Among other things, we would like to know whether you believe testimony should be prepared for the House Committee on Interstate and Foreign Commerce which will ultimately hold hearings on H.R. 12316 although none have been scheduled yet, and immediate consideration of the measure is not anticipated.

Of more immediate importance since it does require some prompt action on our part, we would like to have your instructions about the invitation we have received from the Food and Drug Administration to supply it with information about an SPI Subcommittee which can be called upon to work with the Division of Standards of the Office of Medical Devices with a view towards development of future device standards, where needed. We certainly feel that the plastics industry has a big stake in this area and should have a compact but effective Subcommittee of this Committee which can play its proper role in working with other groups on the device standardization problem.

As far as other changes in the Food and Drug Administration atmosphere are concerned, most of you know by now that Tom Brown has been replaced as the Head of the Office of Compliance of the Bureau of Foods by Mr. Robert Angelotti. We have not yet had occasion to work directly with Mr. Angelotti since most of our recent dealings have been directly with Mr. Hutt and Dr. Wodicka, the Director of the Bureau of Foods. I am sure that we will have occasion to be dealing with Mr. Angelotti in the near future. Perhaps we will want to have him attend one of our next meetings if there is any reason to believe that he might prove more informative, and more likely to keep commitments, than have some of his predecessors in their variously named positions.

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Now let me direct myself in what will amount to something of a "potpurri" to the items listed under my report on your Agenda.

Results of Petition Processing Survey and Indications for Action Flowing Therefrom

Dan Dixler of our office has been working with the petitions processing surveys so many of you were good enough to send to us. Frankly, the data is a little difficult to summarize because it is so random in many respects. It is about as random as FDA's policies so we were not surprised to see what you had to say, and how much difficulty responding caused you.

Dan's conclusions thus far on the survey have been summarized by him as follows:

"We received 19 replies covering 129 petitions relating to indirect additives. Some of the responders excluded joint petitions such as those of the type filed by the Committeee on Food Additive Status of Polyethylene in 1962 and the various group petitions for adhesives and paper coating ingredients; others included reports on their participation in these efforts so there is a little inconsistency here.

"Based upon the replies in hand, we can say that prior to the 1966 FDA shift in petition processing policies, there was an average delay of a little over four months per petition before acceptance for filing, and an additional average delay of 13 1/2 months before regulations issued. The shortest reported were one-half month for acceptance and an issue time of two months in one case, but these were not for the same petition.

"As to the post-1966 filings, the average processing time was 12 1/2 months per petition. The shortest time for promulgation reported for a simple Regulation amendment was four months. Many indicated petition handling periods of over three years.

"Of the petitions reported on, 39 were filed since 1966, 51 prior to 1966, and the other 39 spanned the pre and post 1966 eras."

Dan is here, of course, so he can answer any questions you might have on the survey and our plans for reporting more fully on the data.

As far as follow-up action is concerned, and as I mentioned above, I have been discussing our definition and procedural problems with Mr. Hutt relatively frequently lately. Depending on the nature of some additional input which I hope to receive from him as we continue to confer, we may well have more tangible recommendations to make on follow-up action at your next meeting. I would prefer to

defer once more until then since we believe a degree of clarification could come about on FDA's initiative. In addition, however, we have by no means discarded the idea of a broad rulemaking petition, somewhat along the lines of the cosmetics industry's petition, which might look towards bringing about an entirely new regulatory structure for indirect additives. Obviously, nothing will be done in this respect without your seeing anything we draft well in advance of its formal use.

National Environmental Policy Act vis-a-vis FDA Impact; Alcohol, Tobacco and Firearms Division PVC Bottles Experience

As reported in my letter to you of December 28, 1971, the Food and Drug Administration is planning to issue guidelines on environmental impact statements believed to be required under the National Environmental Policy Act. As of last week, I was advised that the guidelines are still "in process" so we shall simply have to await further information in this connection.

On behalf of the Plastics Bottle Division of SPI, we have recently had considerable experience with the so-called "Environmental Impact Statement" problem so many of you will not be novices when the FDA guidelines are proposed or issued.

In light of the length of my report, I will not dwell on the difficulties the preparation of such statements entail other than to inform you that having to go through the procedure can be expected to add at least three to six months to the processing of any petition which requires such a statement; that we submitted an 18 page presentation with 19 exhibits of about 50 pages to the Alcohol, Tobacco and Firearms Division of the Internal Revenue Service to help it with its preparation of such a statement on a proposed approval of PVC liquor bottles; and that you can get a look at what an Environmental Impact Statement relating to a packaging material involves by writing for a copy of the document designated PB 206 561-D and entitled "Approval of Polyvinyl Chloride Liquor Bottles Draft Environmental Impact Statement."

To obtain the ATFD document, you should write to the National Technical Information Service, Springfield, Virginia, 22151, and include a payment of $3. Incidentally,

we would strongly recommend that as many of you as possible obtain a copy of this document since I believe in reading it you will see how much is involved, and what an important contribution the Society was able to make by providing the data ATFD needed and requested.

The "GRAS" List Revision and Its Impact on Packaging Materials

The GRAS list review of direct additives is progressing although the degree of progress is a little unclear to us since we know that many companies are having difficulty with the NAS-NRC questionnaires they have been asked to prepare. As far as indirect additives are concerned, our earlier advice to the effect that you should watch for any FDA actions on direct additives and make your needs known promptly if a previously GRAS substance is to have its status changed stands. This would have applied, for example, if any of you were using sacharrin as an indirect additive.

Otherwise, you can probably ignore the current GRAS list review until such time as the Bureau of Foods follows through on the indication given me by Dr. Wodicka in his October 29, 1971 letter to the effect that FDA intends "to develop a set of GRAS criteria for indirect additives to supplement the ones that have already been published on direct additives."

I would imagine that such action will take place with the usual degree of rapidity that characterizes FDA follow-through on indirect additives problems. As you know, the speed with which the Agency acts depends entirely on such readily measurable and predictable factors as "how interested is Ralph Nader or James Turner," or "has there been anything embarassing in Morton Mintz, or Jack Anderson's column lately."

FDA's Extraction Guidelines Revision and Proposed Toxicological Guidelines

Promptly after our interesting June 18, 1971 Seminar with the Food and Drug Administration Staff, Dan Dixler met with Al Holtz and others in the Bureau of Foods to help revise the current "FDA Guidelines for Chemistry and Technology Requirements of Food Additive Petitions."

Dan certainly did his part on this matter promptly and we really do not understand why the Administration has not published something in this area even though it has been seven months since the last meeting on the subject. Here again, as in the case of the anticipated new colorants for plastics regulation, and toxicological guidelines, all we can say is that we keep receiving indications that something will be happening "soon." Obviously, in a couple of these areas we are in no hurry so we are not pressing for action. On the other hand, we certainly would like to see something done to justify the effort expended in the cooperative work on the chemistry and technology requirements subject. We will continue to do our best under the usual difficult circumstances.

Status of USDA Proposed Amendments to Meat Inspection Regulations

The status of the USDA proposed amendments to the meat inspection regulations is a rather interesting subject. The reason I say this is because our latest information, obtained from a most reliable source, is to the effect that, for all practical purposes, the long outstanding proposals relating to packaging materials and labeling are "dead." We are told that this is partly because the USDA Staff member originally in charge of the matter is no longer on hand and his replacement is not anxious to proceed. We are further told that another reason for not going forward is because USDA does not feel it has a serious problem in this area--nor do we, by the way--and that the proposed regulations should not be implemented due to Staff shortages.

Our contact has advised that if this issue is revived, there will probably be a completely new notice of proposed rulemaking in the Federal Register. We will watch for this prospect but otherwise consider the matter in limbo for the time being.

At the same time, I should point out that we have been supplied with a copy of a USDA information bulletin designated MPI Notice 69 which, in effect, instructs all official establishment inspectors to look for FDA guarantees or other assurances that "non-meat food ingredients" comply with applicable FDA or USDA regulations. Mr. Bennett of the Consumer and Marketing Service has advised us that this

internal instruction was intended to relate only to direct additives, not packaging materials although this may not be clear from certain parts of the Notice if they are read out of context.

As far as we are aware, MPI Notice 69 is not causing serious problems for packaging materials suppliers. Our experience is that inspectors are still being adequately satisfied by the type of USDA approval letters which have heretofore served such a useful purpose. Nevertheless, a copy of MPI Notice 69 will be attached to my report so that you will have a copy when the Minutes are distributed.

General Comments on FDA Product Safety Activity, Plasticizer Problem, and Other Matters

Taking the plasticizer problem first, we have been maintaining close contact with Dr. Rubin; the Society has given him a grant of $1,000 to help with his metabolic fate studies; and we are now awaiting additional reports from him. The publicity given this matter of phthalate plasticizers has caused a great deal of concern.

As indicated in my letter of January 24, we believe that this is a subject which should be discussed by this group, and that perhaps recommendations should be given to other operating units in the Society on the subject. Other than to let you know that we do not believe this is a subject which can be ignored, especially since we have been contacted directly on it by such parties as Senator Gaylord Nelson, I would propose that we defer additional discussion on it until you receive your usual report about the activities of the Manufacturing Chemists Association. This is because I know that MCA has had an important meeting on the question and is probably planning some activity which we should take into account to make our coverage of the subject well informed.

As to the activities of the Bureau of Products Safety of FDA, two major topics need to be brought to your attention:

1. As many of you know, in November (November 2, 1971 Fed. Reg. pps. 20985, 20986) the Bureau proposed rulemaking to ban, limit content, or require special labeling of paints or "other surface

coatings" where the same might contain various heavy metals and are used in such a way that children might chew on interior or exterior residential surfaces, toys, or other articles containing them. At the request of members of your Steering Committee, we were in touch with the Bureau of Products Safety to clarify the intended application of the November 2, 1971 FDA proposal as it related to so-called "surface coating" materials. In so doing, we were informed by the FDA Staff that the rulemaking was not intended to apply to "plastic coatings with structural integrity which would make the chewing hazard unlikely."

On the strength of this assurance, it was decided to go no further with this matter although we did suggest to the Bureau that it consider changing the language in its proposal so that it would relate to "paints and other surface coating materials similarily applied" as a means of clarification.

The final version of the FDA rulemaking was published in the Saturday, March 11 Federal Register on pages 5229 through 5231. This version was substantially changed from the original proposal. For example, it does not now deal with metals other than lead. However, it will ultimately ban the use of paints containing lead at a level of more than 0.06 percent of the total weight of the contained solids or dried paint films for interior and exterior surfaces.

As far as our problem is concerned, we were gratified to see that the Bureau has heeded our recommendation by changing the language of the new rules so that they will pertain only to "paint or other similar surface-coating material." We have been informed by the Bureau that this change was made to accomodate our recommendation and, therefore, there is no need for any further

concern about products of the type that do not lend themselves to the chewing of fragments such as paint peelings.

2. One other Bureau of Products Safety matter has been called to our attention with a request that we seek the advice of industry on a proposal advanced to the Bureau of Products Safety by the State of Connecticut. The Bureau has been requested to investigate a suggestion made by a Dr. Slover that it would be advantageous if plastics which might be swallowed, particularly parts of toys, could be impregnated with barium so that X-Rays could more readily detect a swallowed substance. Copies of the correspondence we have received from Dr. Weinstein of the Bureau of Products Safety in this connection will be attached to my report.

We really are not quite certain as to precisely what might best be done about this matter and so advised Dr. Weinstein who indicated that he has taken the matter up with the Toy Manufacturers Association also. His specific question of us was whether the use of barium in this way would adversely affect the materials used to make toys.

Our off-hand reaction was that this could probably be done if the Food and Drug Administration so desired (my having been given this preliminary opinion by Dan Dixler), except in the case of articles which are necessarily clear rather than pigmented. However, I informed Dr. Weinstein that we would prefer to ask the Food, Drug and Cosmetic Packaging Materials Committee about the matter before advising him more definitely. Thus, I would appreciate your views on the subject at this time so that we can evidence our usual cooperation with the Bureau of Products Safety by responding more firmly to Dr. Weinstein promptly.

The PCB Problem

As a late edition to the shock reporting portion of this meeting, a couple of additional items bear mention. Firstly, and although I will not belabor the point, we have received sufficient inquiries from a number of you to note that we believe almost all suppliers of packaging materials of all types can expect to receive continuing inquiries and requests for certifications from their customers relative to polychlorinated biphenyls, more familiarly known as PCBs. While the problem of PCB contamination arose in the paper industry, many users of packaging materials are now asking their suppliers to certify that their products are not PCB contaminated regardless of the raw material involved.

A reasonably accurate report on the way in which the PCB problem is being handled by the Food and Drug Administration with Monsanto cooperation appeared in a recent edition of the Wall Street Journal. For your information, a copy of the Wall Street Journal report will also be attached to the Minutes as one of the appendices to my presentation.

As a way of responding to those of you who have asked us about test methodology which you can use to put yourselves in a position to provide the PCB-free "certificates" your customers are apparently demanding, we might refer you to Mr. W. B. Papageorge of Monsanto in St. Louis since we believe the method he has supplied to others in this connection might be helpful to you.

In due course, it is anticipated that FDA will develop firm standards on this matter, adopt and publish "official" test methodology, and probably impose a 5 parts per million PCB contamination limit or tolerance. Pending such action, there really is no firm FDA regulation on the subject but, as usual, your food industry customers must be satisfied so you will probably have to deal with the problem on the basis of the rumored solutions under consideration.

The "Brown N' Bag" Controversy

Unhappily, a great deal of confusion has arisen in recent weeks as a result of the reports which appeared in the lay press about oven fires caused by products which have

become known as "Brown N' Bags" even though this is really one company's trade name. In our opinion, this matter has been handled reasonably satisfactorily now by a labeling agreement, and by the promulgation on an unusually expedited basis of a new Food Additives Regulation to cover cuprous iodide and cuprous bromide. What all of this activity has come down to is rather uncharacteristically prompt and rational action by FDA to put "an aberration to bed." In essence, the Agency has affirmed the satisfactory food additives status of Nylon 66 for the application in question, and has now approved the stabilizer used in the cooking bags so that everyone is essentially "home free" to sell the bags for either home use, or now as food packages.

The only aspect of this entire matter which has given us cause for concern is that we believe, in handling the situation, FDA lost sight of that part of the legislative history of the Food Additives Amendment of 1958 which we have relied upon for the position that the law was not intended to apply to home utensils or housewares. Another bit of evidence that FDA is over-looking this reasonably clear cut exemption from the coverage of the Food Additives Amendment is a statement that appeared in an article in the April, 1971 edition of FDA Papers wherein it was said that: "Earthenware as a food contact surface is covered under the Food Additive provisions of the Federal Food, Drug, and Cosmetic Act."

We have had occasion to discuss this matter informally with the General Counsel's office, and have called his attention to the legislative history involved. I believe this was a helpful thing to do and might be especially worthwhile in the future.

However, I should note that FDA will apparently take the position in the future that if you file a Food Additive Petition on a substance, it is inconsistent for you to sell a product containing the substance for any food contact application until the petition is granted. Frankly, I disagree with this point of view, believe it to have come about through an oversight of the legislative history, and hope that no additional incidents will arise to cause this concept to be applied. Nevertheless, since it does seem to be the rule in vogue for the moment,

perhaps you should take the history of the Brown N' Bags case into account and proceed with caution in the future in light of its teaching.

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I suspect that this may have been one of the most wide-ranging reports I have ever given to any committee at anytime. I do thank you for being so patient.