Appendix A

Report of Jerome H. Heckman,
SPI Counsel
To
Food Packaging Materials Committee
Americana Hotel

September 20, 1967

Gentlemen:

Another half a year has elapsed since our last regular meeting of the Food Packaging Materials Committee, held on February 16, 1967. As I am sure many of you have gathered from our correspondence with the full Committee during the past month or two, the time is most propitious for consideration of some very significant recent developments. Indeed, we have every reason to anticipate that the happenings of recent weeks may well serve to give us the foothold we have sought for so long in our efforts to effectuate much needed reform in the regulation of incidental additives.

Actually, the cause for our most recent burst of very cautious optimism stems from the opportunity which FDA has provided us in the form of its proposed new set of "Procedural Regulations" governing direct and indirect food additive petitions. As was observed in my August 11 letter to you, when any governmental agency issues such proposals for rule making purposes, the Administrative Procedure Act provides interested parties with the right to submit comments on the proposals, and, if the agency in question does not give due consideration to the comments it receives, the courts have jurisdiction to review the agency's decision.

Before I undertake to discuss in more detail my personal observations and recommendations on the substantive and procedural aspects of these proposals, let me first give you a run-down on some other matters of interest.

Publication of SPI Manual entitled "Plastics Packaging for Drug Products--The Regulatory Story"

At our last meeting, you will recall, I gave a rather lengthy report on our efforts to develop a basic information document relative to the regulatory aspects involved in the use of plastics materials for drug packaging applications. At that time, you will also recall I made a particular effort to distinguish the regulatory procedures incident to the use of plastics in drug applications from those involved where food contact applications are anticipated.

As most of you are probably aware from our August 11, 1967 letter, SPI has now "gone to press" with the publication of the Manual, which will, among other things, describe in detail the so-called "Master File" procedure, and the way in which drug regulation of packaging materials differs from food additive regulation so that a completely distinct approach is necessary in assisting customers in establishing the suitability of a particular plastic material for drug use.

Unfortunately, we were unable to obtain the covering letter for the Manual from Dr. Goddard as we had hoped. It seems that some of Commissioner Goddard's staff-advisors felt that such a letter would likely lead to the misconception that he was somehow endorsing plastics for drug applications in preference to other packaging materials. Our own feeling was that such a letter would not be so construed out of context and that FDA was being unduly cautious in evidencing its characteristic over-sensitivity to possible criticism.

In any event, we did not feel that we were in a position to press the issue so, in lieu of the type of covering letter we had desired from Dr. Goddard, we have included a brief acknowledgment statement at the beginning of the Manual thanking Dr. Earl Meyers of FDA, and Dr. W. W. Hilty of Eli Lilly Company and the Plastics Committee of the Pharmaceutical Manufacturers' Association (PMA) for their valued assistance in reviewing and commenting on our preliminary drafts and final version of the Manual. Although we would certainly have preferred a letter from

Dr. Goddard, we are hopeful that our expressions of gratitude to Dr. Meyers will give the Manual the desired aura of FDA participation and approval we intended.

We are also quite hopeful that the Manual will be of assistance to both the plastics and drug industries in providing a better understanding of how one should proceed in dealing with any regulatory problems presented by proposed drug applications of plastics packaging materials.

As soon as published editions of the Manual are available, each of you will be sent a complimentary copy.

FDA "Guidelines for Chemistry and Technology Requirements" of Food Additives Petitions" - Status of FDA Consideration of SPI Comments

Unfortunately, I have nothing of real substance to report on our "Guidelines" comments, which as you recall, were submitted to FDA last April upon the recommendation of Mr. Lessel Ramsey of FDA. We have been promised several times that we will be receiving formal reactions on our comments "in due course." However, as yet we have only received FDA's expressions of gratitude for the suggestions made.

We attempted to contact Mr. Ramsey late last week to get an "up-to-the-minute" status report but were informed that Mr. Ramsey was out of his office and would not return until sometime this week - too late for us to get any "hard-line" information in time for this meeting. For the moment the best we can do is to promise that we shall keep checking regularly with Mr. Ramsey and will advise the Committee as soon as we have anything definitive to report.

New FDA Proposed "Procedural Regulations" - Relationship to "Guidelines," Food Additive Petition Policies, Recent Court Decisions, etc. - Some Observations

Now for a discussion of the new FDA proposed "Procedural Regulations" which I alluded to at the beginning of my remarks.

As those of you who were present at our December 14, 1966 question and answer session with Mr. Ramsey and Dr. McLaughlin of FDA will recall, Mr. Ramsey indicated that FDA was, at that time, considering the publication of a completely new set of "Procedural Regulations" to govern the filing and handling of Food Additive Petitions in the future.

Mr. Ramsey's promise has now come to bear with the publication of a rather comprehensive set of proposals in the August 8, 1967 Federal Register. We made a special effort to provide all of the Committee members with reproductions of the proposals, so I am sure that all of you have now had an opportunity to review them.

Before I open the floor for suggestions and general discussion, let me just give you some of my personal observations concerning a few of the procedural and substantive aspects of these proposals. As we go along, I will point out a few of the sections which I believe deserve particular close attention for future comment, and will appreciate receiving your thoughts and suggestions as they occur to you.

Perhaps I should first point out that the newly conceived Procedural Regulations are to be considered separate and apart from the so-called "Guidelines" on which we have already submitted extensive comments. The items certainly are somewhat connected and overlapping, but the major distinction between the two is that, at least in theory, the Guidelines are not "official" rules, which, by the way, is why Mr. Ramsey said that FDA did not deem it necessary to publish them in proposed form. I need not remind you that, in actual practice, the Guidelines are used as a stringent check-off list for food additive petitions, and are, in a very real sense, "unofficially official". However, procedurally speaking, the Guidelines do not have official status. Thus, the new proposals, which definitely do have official status, are in my opinion, exceptionally significant from the legal point of view for several reasons which I shall attempt to explain.

As I have already mentioned, and without going into the fundamentals of administrative law at great length, it should be noted that, since these proposals were issued in a formal framework, the requirements of the Administrative

Procedure Act apply. From a procedural standpoint, this means that any interested party has sixty days from the date of publication - i.e. August 8, 1967 - within which to file comments expressing his opinion on and/or objections to the proposals.1/ Under the Act, FDA will be required to give due consideration to any and all such comments filed in response to its proposal, and, should FDA promulgate the Regulations in final form without due regard for rational objections expressed within the time allotted, the law permits an appeal to the courts for the purpose of determining whether or not the agency based its final decision upon substantial evidence adequately supported by the record.

These procedural factors are important because, at long last, we may have a suitable framework within which to challenge those unwritten FDA policies and procedures on Food Additive Petitions which have created the presently almost intolerable confusion and delay in obtaining packaging materials clearances. One of the reasons we say this is that, in this instance, the challenge might be possible without placing the reputation of any particular manufacturer or product in any unfavorable light. As most of you have heard me say on many occasions, one of the truly agonizing "facts of life" that a lawyer engaged in food and drug practice has to live with is the fact that, all too often, no matter how unfairly and arbitrarily FDA may treat his client, he will nevertheless be helpless to challenge the improprieties in open administrative or judicial hearings. This is because clients are generally unwilling to run the risk of an FDA trial by press release which might cause serious damage to a company's name or to any hopes it might have had for the marketing of a particular product. This ever present, though usually exaggerated, threat of "trial by press release" is, as you all have heard

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1/ As a result of discussion at the meeting, a Resolution was adopted authorizing Counsel to submit a request, on behalf of the Committee, for a 60 day extension of the time allowed for filing comments. Accordingly, a letter-petition was filed with the Hearing Clerk, Department of Health, Education, and Welfare on September 27, 1967 requesting that the time for comment be extended 60 days to December 6, 1967. Subsequently, Counsel was advised by FDA on October 4 that the deadline date would be extended, but for only 30 days, making the new deadline date November 7, 1967.

me say many times, one of the most effective weapons in FDA's arsenal.

The ever present existence of this threat is one reason why we believe you should be particularly interested in the opportunity afforded us by the official publication of the new FDA proposals since action in response to them may make it possible to contest basic FDA policies in the name of the SPI Food Packaging Materials Committee without jeopardizing the position of any individual company or product.

Those of you who are familiar with the relatively recent Supreme Court decisions whereby drug and cosmetic manufacturers, through their respective trade associations, challenged other general regulations issued by the Food and Drug Administration may have a better inkling of the possibilities I am trying to bring into play here. For the benefit of those who may not be familiar with the Supreme Court decisions in The Toilet Goods Association, Inc. v. Gardner and Abbot Laboratories v. Gardner cases--the latter having been instituted by the Pharmaceutical Manufacturers' Association--these cases hold, in effect, that the courts have jurisdiction to review FDA regulations prior to any enforcement actions on the part of FDA to implement the regulations. While it is true that the majority opinions confined pre-enforcement judicial review to the drug and cosmetic industry regulations at issue, it is generally conceded that these cases pave the way for the same type of challenge as to any FDA broad rulemaking activity.

The main significance of these cases lies in their re-enunciation of the concept that FDA regulations can be judicially reviewed before they are actually implemented and enforced, and before any actual damages have been suffered by those who are adversely affected by the regulations. For our purposes, it is also important to note that a trade association can have standing to judicially challenge administrative rulings and policies where the interests of its industry members are at issue.

Those who would challenge FDA regulations or rulings will still be required to "exhaust their administrative remedies," but, once this has been done, and the regulations or rulings have become effective, there is now specific judicial precedent to the effect that the courts have the

power to review FDA action before the agency attempts to implement or enforce the regulations or rulings.

Relating all of this to our immediate situation involving the recent FDA proposals, the point here is that the issuance of the so-called "Procedural Regulations" by FDA could provide us with the long-awaited opportunity to test FDA's powers on such questions as the "no-migration" theory or fallacy, depending on your point of view. We may also be able to test some of the other unwritten policies that have come into effect since the enactment of the 1958 Food Additives Amendment.

If our Committee does decide to prepare and file comments, using the FDA proposal as a platform to challenge some of its regulatory policies and statutory misapplications, we may now be able to move into a more objective forum to test the validity of FDA's interpretation of the law, especially on the "no-migration" question.

My feeling, and one that I am sure is shared by many, if not all of you, is that these "Procedural Regulations" presuppose the existence of certain underlying substantive policies including the one governing "no-migration" situations, as well as the highly questionable policy, which seems to be gaining increasing momentum at FDA, whereby petitioners are put to the task of demonstrating the minimum amount of an incidental additive needed to accomplish an "intended technical effect."

If at all possible, I believe we should find ways to open these subjects in any comments we might want to submit as a way of setting the stage for a court challenge if FDA does not revise its present approaches.

To more or less "get the ball rolling" for what I anticipate will be a rather free-wheeling discussion on the proposed Regulations, I have made a short list of some of the more pertinent sections of the proposal that I feel bear substantive discussion.

My list is by no means comprehensive so, as we go along I hope you will give me your own thoughts on these sections and any other sections or subsections you are concerned with. This will give us a workable foundation upon which to build a detailed set of comments. We, of course,

encourage any of you who care to do so, to forward us any ideas you might have in written form to facilitate our drafting operation. Your Steering Committee has set a tentative deadline of October 9, to receive your suggestions.

The first section I have on my list is 121.50(a). You will note that the penultimate sentence of this section requires that petitions include "identification of the scientists who did the work and their pertinent qualifications." It seems to me that we will want to question this requirement. Aside from the fact that there is no statutory basis for this provision, it has, to the best of my knowledge, never been required in the past except in the special case of scientists involved in work relative to New Drug Applications. In the case of food additive petitions, it has long been the practice to identify the name of any laboratory responsible for the work on a particular petition. It seems to me that such disclosure is adequate and should preclude the need for identifying and qualifying each scientist employed by a laboratory to work on such a project.

Several of you have expressed concern over the provisions of the proposed section 121.50(c) which sets forth specifications for the paper, margins and hole punching to be used in assembling petitions. This is another section on which we shall want to comment briefly, but without wasting too much verbiage on what amounts to a nuisance item.

Section 121.50(e) is most noteworthy because of its substantive references to many of the FDA policies with which we take issue. Subsection I of this Section specifies the format to be used in the Introduction to the petition, and for the most part, is merely a summation of the information required in the body of the petition. However, I would like to direct your particular attention to Subsection I B.5 of this Section [121.50(e)] entitled "Toxicology."

Putting aside, for the moment, the requirement for a statement bearing on the "no-effect level in the most sensitive species of test animals," which I am sure you will want clarified, the concluding sentence of this paragraph is most interesting, to say the very least. The sentence reads, "If safety depends upon virtual lack of migration, the rationale shall be explained briefly."

It is quite obvious from the tenor of this sentence that FDA is attempting to formalize its long standing erroneous interpretation of the law which has required the filing of petitions for substances not rationally expected to become components of food. The law, in fact, exempts from regulation those substances which are not "reasonably expected to become components of foods," i.e. substances which are virtual non-migrants! I think this sentence bears particular attention because it is the only place in the proposal where FDA's "no-migration misconception" is alluded to specifically.

We ought to use this opportunity to go on record in attempting, once again, to impress upon FDA the necessity for changing its "no-migration" policy into something workable. If we could somehow resolve this continually plaguing issue, we might eliminate the cause for the greatest percentage of our problems in the food-packaging regulatory area.

Moving along to some of the other sections, Section 121.50(e) II, A, 2, entitled "Indirect additive-nomenclature and formulas," states that indirect additives "include substances incidentally present in a final product because of addition for functional use elsewhere in the production operation and substances that may reasonably be expected to become a component of food <u>because of their presence in food contact surfaces</u>." (Emphasis supplied.)

It seems to me that this particular statement could use much clarification. More specifically, we ought to know what the phrase ". . . incidentally present in a final product. . ." means. Does it mean <u>food</u> products, as the law intends, or does it also mean finished packaging materials?

Also, we should make effort to correct the misconception that may be read into the phrase". . . substances that may reasonably be expected to become a component of food <u>because of their presence in food-contact surfaces</u> . . .". As presently worded, this phrase could be read to imply that the mere presence of a substance in a food contact surface means that it may "reasonably be expected to become a component of food." Again, this brings to bear in a tangential way the arguments we will want to make to clarify the "no-migration" concept.

Section 121.50(e) II, A, 2, b, iii, which requires a description of the manufacturing process, ". . . including for food-contact surfaces the raw materials and their specifications that encompass the basic resin polymers and the adjuvants (such as plasticizers, stabilizers, preservatives, fillers, colorants, catalysts, etc.) . . ." might give the erroneous impression that it is necessary to clear formulations wherein substances are mixed which are either GRAS, prior sanctioned or otherwise covered by existing regulations. Also, this section might lead one to believe that it is necessary to obtain regulations for catalysts or other reaction control agents used during the manufacturing process.

Those of you who attended our December 14, 1966 meeting with FDA Staff members will readily recall that Dr. McLaughlin of FDA defined the term basic, or base, polymer as the final product which comes out of the polymerization process. He further added that if catalysts, cross-linking agents and other reaction control agents are necessary in the production of the polymer, they may be considered as included in the definition of the basic polymer and need not be otherwise identified or classified for regulatory purposes. Dr. McLaughlin's statements in this regard were printed in our formal set of Minutes for that meeting, which were approved by both Mr. Ramsey and Dr. McLaughlin. Therefore, they have some "official" basis in fact.

Perhaps we will want to point these facts out to FDA and seek to have this section clarified.

The provisions of Section 121.50 II, B, 4, b, require petitioners to demonstrate ". . . that the proposed usage level of the substance in the food-contact article is the level reasonably required to accomplish the intended effect in such article. . ." We continue to take exception to this requirement which, as we see it, has absolutely no statutory foundation. We argued this point at length in our "Guidelines" comments, so I will not belabor it here. Suffice it to say that we continue in our contention that a proper interpretation of the 1958 Food Additives Amendment requires a showing of intended technical effect only in cases where a proposed food additive requires a true "tolerance" to assure safe use; this is almost never the case with an indirect additive.

Requiring petitioners seeking clearances for incidental, i.e. indirect, additives to show intended technical effect in packaging materials has become standard operating procedure at FDA during the past year or two--beginning when the "efficacy" question in drugs started making headlines. As we see it, Congress never intended FDA to have the power to regulate the art of packaging per se, but only that it should regulate packaging materials and components insofar as they have a measurable effect on the safety of our food supply.

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There are probably many other sections and subsections in these proposals on which you will want to comment. In fact there are many parallels to the very types of requirements we voiced objection to in our "Guidelines" comments. We are anxious to have your views based on your knowledge and experience in these areas.

Impact of "Freedom of Information Act" (P.L. 89-487) on data submitted in Food Additive Petitions

We have had several recent inquiries concerning the impact that the recently effective "Freedom of Information Act" might have on data submitted in Food Additive Petitions, particularly on toxicological and analytical data included in a petition.

Of course, any data in a petition that is in the nature of a method or process entitled to protection as a trade secret will be held in strict confidence by the Food and Drug Administration, as required by law. The Regulations promulgated by the Department of Health, Education and Welfare pursuant to the Freedom of Information Act do nothing to change this long-standing exemption for "trade secret" information. Incidentally, the Regulations to which I refer were published in the June 30, 1967 Federal Register, Volume 32, Number 126, on Pages 9315 thru 9319.

With regard to the status of analytical and toxicological data under the Act, some of you are undoubtedly concerned by the provision in Section 121.50(f) of the new proposed Procedural Regulations, which states that ". . . (T)he scientific bases of safety on which any food additive regulation rests including food additive analytical methods and a

summary of the toxicological data are not considered confidential. . ."

Actually, as most of you are probably aware, there is, from time to time, considerable impetus for the release of toxicological information submitted to the Food and Drug Administration because many in the scientific community throughout the world believe that these types of data should not be considered proprietary. This may also be true of some analytical information.

Nevertheless, the wording of the section I am referring to puzzles me somewhat because just a few days prior to the publication of the proposed Procedural Regulations, I had occasion to elicit FDA's views on the status of this type of data under the Freedom of Information Act and was told, at that time, that FDA was giving no consideration at all to the release of such data since they viewed Section 552(b)(4) of the referenced Act, which refers to trade secrets, as including an exemption for this type of information from the disclosure requirements of the Act.

Furthermore, the HEW Regulations, which appeared in the June 30 Federal Register I have already mentioned, included an Appendix listing "Examples of Kinds of Exempt Records." Number 11 of this Appendix referred to the Food and Drug Administration and described as exempt ". . . data (submitted) in support of petitions relating to pesticide chemicals, food standards, food additives, and color additives, and master files relating thereto." This statement is certainly in line with our understanding of FDA's policy with regard to analytical and toxicological data.

Since this asserted agency posture does not seem completely compatible with Section 121.50(f) of the newly proposed Procedural Regulations, we may well want to comment on this section to seek a clarification as to what FDA's intentions really are.

Some Recent Judicial Decisions of Interest

Two recent products' liability cases involving injuries occasioned by drug products, which had been approved by FDA, might be of some general interest to you, at least as a means of showing how "government approvals" can bear on civil suit responsibility.

The first case, O'Hare v. Merck & Co., Inc., CCH Products Liability Reports Par. 5813, provides an almost classic discussion of what we consider to be the great majority weight of judicial opinion on cases involving situations where injury arises even though a drug manufacturer has taken all reasonable care in evaluating his product, and has had it approved by FDA.

In this case, the user of a diuretic claimed that he suffered injury due to the manufacturer's negligence in failing to engage in more extensive research and testing before marketing the drug. The facts of record demonstrate that, prior to the marketing of the drug, tests were conducted on human beings by a number of clinical investigators, and that these tests established the safety and efficacy of the drug under normal conditions. Furthermore, at the time of the plaintiff's injury in 1964, there was no forseeable risk of harm to potential users in light of current scientific and medical knowledge.

The court, correctly in our opinion, found Merck without negligence and, therefore, ruled against the plaintiff on appeal.

The decision is significant, I believe, from the viewpoint that an FDA approval or sanction of a particular product is at least strong "make weight" for a manufacturer who is trying to establish that he is without negligence and could not reasonably be expected to foresee any injury resulting from the use of his product.

The second case, Toole v. Richardson Merrell, Inc., CCH Products Liability Reports, Par. 5814, is another of those involving Richardson-Merrell's MER/29. In this case, the court concluded that the record contained evidence from which the jury could conclude that the appellant drug company brought its drug to market, and maintained it on the market, in reckless disregard of the possibility that it would visit serious injury upon persons using it. It, therefore, awarded substantial damages to the plaintiff-user.

The decision here could be said to stand for the principle that a drug manufacturer's liability will be found in any case where it has withheld facts from the Food and Drug Administration to secure an approval, or has otherwise acted in such a way as to make possible a finding that its

advertising or other representations were inadequate in light of existing information which it had, or should have had.

Petition Processing

Finally, I might make mention of the fact that FDA now hopes to speed up its paperwork--presumably including the processing of petitions--by use of a computer. Just how the "mechanical marvel" will be able to move the "FDA wheels" in quicker fashion is not entirely clear, but "hope springs eternal" so perhaps we will be witnessing some noteworthy improvements in this regard during the coming months.

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Thank you for your usual patience.