

Under the direction of General Chairman, Robert M. Miller, Hercules, Inc., an overall meeting of the SPI Food, Drug and Cosmetic Packaging Materials Committee convened in the Commodore Hotel, New York City, on Thursday, June 3, at 9:15 A. M.

Following the detailed Agenda which had been circulated prior to the day's business session, Mr. Miller asked for the usual self-introductions.

Minutes of Last Meeting Approved

Referring to previously circulated Minutes of the January 13, 1971, meeting, Mr. Miller asked for corrections or additions; there being none, he declared them approved as distributed.

Preliminary Remarks by Mr. Miller

In his preliminary remarks, Mr. Miller referred to the Second Annual Meeting of Voting Representatives of SPI held in Boston, Massachusetts, just the previous week; and then spoke about the SPI's new dues system which becomes effective on June 1, 1971 the beginning of the Society's fiscal year. He pointed out that the old dues system, in which companies paid dues on a self-assessment basis, broke down. Therefore, the Board of Directors decided on a new dues system which simply calls for a company to divulge, on a confidential basis, to the SPI dues auditor, Young & Company, a company's full net total sales related to the plastics industry. It was determined at last week's meeting of the Board of Directors that the assessment to each company would be 35 cents per \$1,000, with the Board establishing that for the 1971-72 fiscal year, the minimum dues would be \$250 and the maximum dues would be \$16,500.

Of the approximately 1,200 corporate members within the United States who received the sales information survey, there are approximately 400 companies yet to be heard from. In this regard, Mr. Miller said that every attempt is being made by those members of the Board of Directors and members of the Staff at SPI to make personal contacts with the companies from whom no sales information survey has been received.

At yesterday's meeting of the Steering Committee, Mr. Miller concluded, it was determined that before the next meeting of the overall SPI Food, Drug and Cosmetic Packaging Materials Committee, the Secretary would be asked to cull the roster in order to remove the names of individuals from companies which are not members of the SPI by the time of the Fall meeting of the Committee.

Report of SPI General Counsel

Mr. Miller at this point in the meeting introduced Jerome H. Heckman, Keller and Heckman, and SPI General Counsel, who delivered the following report:

Report of SPI General Counsel

"In some ways it's probably good to be meeting here in New York again after holding our last few sessions in the city of empty promises, Les Ramsey and Alan Spiher. A great deal and very little has happened since our January session where most of you were with us to hear our regular reports, and some real pearls from a good sprinkling of officials of that most thermoplastic body in Washington, the Food and Drug Administration. It gives, it can be heated, beaten, and reground, but it always seems to retain its unbelievable shape.

"Before going into a little more detail, and meeting my obligations under the Agenda, I would like to make a few brief announcements.

"Firstly, I'd like to advise you that my law firm and I have faced up to the fact that it may well be that people who are well versed in chemistry and toxicology can be of real help to us on a much more direct basis. That is why you heard Dan Dixler introduce himself this morning as with Keller and Heckman. Dan is now on our staff and is working closely with me on Food and Drug Administration matters.

"Next, I do hope that the next stop on your personal roadshow will be the SPI-FDA Seminar which is now planned for June 18. Most of you have received notices, I think, about the Seminar, and Charlie Condit has already received somewhere in the neighborhood of fifty reservations. If you haven't sent a reservation in yet, and are anxious to attend, please do so promptly because we may have to cut the attendance list off soon. We are planning to have the session transcribed by court reporters--much like the National Conference on Indirect Food Additives was recorded--and the transcripts will be available in due course. They will probably be sold by SPI for \$25 which is the cost of the registration fee for the Seminar. Thus, there is no bargain in staying away and not being there will deprive you of an excellent opportunity to ask your questions.

"The other point I should make clear is that in many ways, this is an FDA show so we are experiencing delay in getting a firmed up Agenda or program from the agency. We do know now who the principal speakers are going to be. They will include Al Holtz, on the analytical chemistry side, Joe McLaughlin on toxicology, and either Dr. Haenni or Dr. Howard, who have in the past been responsible primarily for matters relating to polynuclear aromatics type of testing. Lou Buckley or Al Rothschild of Petitions Control will also talk, and Tom Brown is expected to be on hand. The session will be moderated

by General Delmore, whom most of you have met.

"The FDAers know that what we expect to get out of the Seminar is a better idea of what they expect to see in indirect additive petitions. Thus, the papers are supposed to set the stage for questions that any of you might have on how you can improve your petitions. We expect to be able to use some of that information ourselves for any number of reasons, and we think that the transcript might prove to be a valuable thing to have in the future. It will not be totally definitive because they change the ground rules every other day, but it should be helpful. It will at least give us a basing point to start telling you where the changes are taking place.

"The next announcement is one I have been asked to make by the Polytechnic Institute of Brooklyn which is having a two-day seminar on June 24 and June 25 at the Institute, 333 Jay Street in Brooklyn, New York. The title of the Seminar is 'Packaging with Plastics.' I promised Dr. Bruins at the Institute that I would pass out the Seminar announcements and let you know that I am on the program to conduct a question and answer session on FDA problems.

"Finally, and here I'll ask you to forgive what might appear to be a lack of modesty, I want to mention to you that, at the request of Modern Plastics Magazine, and under instructions from Ralph Harding, I'm going to be writing a monthly column for Modern Plastics on legal topics of interest. The main reason I am noting the fact here is that, in the first column which will presumably appear in the July issue, I devoted at least half the column to a discussion of this whole matter of the use of the phrase, 'FDA approved,' and when it's improper, which is 90% of the time. The column also discusses the kind of requests you receive on whether or not a material is cleared under the Toy Safety Act, and other nebulous type FDA enabling acts. The point is that this first column might be helpful to you in educating some of your sales people, and even some of your customers.

"Now we can get down to the 'nitty-gritty' of the Report called for by the Agenda. At the request of Charlie Condit, I'm going to background the first item on the Agenda designated 'Status of Continuing Action to Effect Action on the Ramsey Proposal,' to make certain that everyone is 'in the picture' on the entire subject.

"The way we look at the situation, it all started in 1966 at that famous or infamous American Chemical Society Symposium.

A number of us appeared there and it was then that Jack Frawley of Hercules first put forth what has come to be known as the 'Frawley Proposal.' In general, at that time we severely criticized the way the Food and Drug Administration was handling its responsibilities under the Food Additives Amendment of 1958. In fact, the title of my paper at that meeting was 'It's Time for a Change in the Law.'

"There were some FDA people at the ACS meeting, one of whom promptly transferred to the Federal Trade Commission, our good friend Mr. Fred Cassidy. It's very hard to catalyze FDA into anything except inaction, however, so the papers given were spread on the winds. FDA was aware of them and there was talk in the halls about how they were considering things like the Frawley Proposal but we really weren't going very far on this basis.

"In due course, however, a congressman, Congressman Dingell of Michigan, became interested enough to ask Dr. Goddard, then FDA Commissioner, a couple of questions about indirect additives at an unrelated hearing on drugs. The questions were rather searching, primarily because they were suggested to Mr. Dingell by people somewhat versed in packaging problems, and FDA had quite a bit of difficulty with them.

"Instead of answering all of them directly, the agency decided that maybe the best way to satisfy Mr. Dingell temporarily would be to call a National Conference on Indirect Food Additives, which they did. FDA gave us in industry, as I recall, a month or a month and a half's notice, and asked for papers. I think they were a little surprised when industry got together and did quite a job. And when I say industry, I don't just mean the plastics industry. We all put together an inter-industry group, coordinated our ideas, and set forth quite an array of recommendations at the National Conference on Indirect Food Additives.

"Incidentally, FDA had promised Congressman Dingell, and there is a statement of record in the official transcript of the National Conference proceedings that Food and Drug would report to Congress in about sixty days on some definite actions that it could take to improve its activities in this area. That was February, 1968. The promised FDA report to Mr. Dingell has yet to be filed, as far as we know. You see, we're not the only ones to get the promises, promises routine.

"No action took place after that Conference that you could call tangible--despite all sorts of efforts to bring about action--until May of 1969 when Mr. Ramsey wrote to us and others in industry. He happened to sign the letter so the proposal he sent along has been called the 'Ramsey proposal' ever since although I believe the 'Ramsey proposal' was something that was prepared by the FDA staff as a group effort. In any case, it's easier to give tags to such things, so we've called it the Ramsey proposal ever since.

"The Ramsey letter was sent to us on May 6, 1969, and simultaneously to representatives of all of the groups the agency could identify as having an interest in this subject. In his letter Mr. Ramsey characterized what they were sending us as: '...the attached discussion draft Notice of Proposed Rulemaking that we have under consideration as a first response to comments received after the February 13-14, 1968, Conference on Indirect Food Additives.' That proposal was the one wherein FDA suggested changes in the so-called Good Manufacturing Practices Regulation, Section 121.2500, which would eliminate the necessity for filing food additive petitions in situations where you were dealing with dry foods, adhesives, repeated use food contact surface items, and components of defoaming agents. I think it is fair to say that this much of the proposal was reasonably satisfactory to everybody. The one controversial concept included in the proposal was a plan whereby it would be ruled unnecessary to file a food additive petition if a substance was to be a component of a food contact article, but would contribute no more than 0.05 parts per million to the contacted food as determined by analysis of the food, by appropriate extraction studies, or by calculation assuming 100% migration.

"We reviewed that proposal in good faith and brought our Inter-Industry Committee together to discuss it. In due course, we reported a joint position to FDA in an August 29, 1969, letter and met with the FDA staff on September 3, 1969. And again I remind you that everybody really was in agreement on everything except the 0.05 ppm question. We wanted the level to be raised to 0.5 ppm, and they insisted it be left at 0.05.

"After the September 3 meeting we were told the FDA Staff would consider what we said, and come back to us. There then ensued another period of 'no word' during which there was no FDA action at all despite the fact that we invited Mr. Ramsey to our meetings at least twice to tell us

what was happening. We also suggested to him on several occasions, both informally and formally that if the 0.05 ppm or 0.5 ppm problem was too much of a difficulty, why not go forward with the rest of the proposal. We could thus make one small step forward. Nevertheless, nothing happened in this respect.

"The only intervening act that was helpful was that Tom Brown came in to head up the FDA Office of Compliance in the Bureau of Foods and we were able to elicit from him the so-called 'Tom Brown letter' that I think most of you are familiar with. This is the one that, after ten long years of doubt, reaffirmed the Statute and said that you really could say that something was not a food additive if it may not reasonably be expected to migrate to foods. That might seem like nothing too significant to some of you, but the Tom Brown letter of August 21, 1970, has been extremely helpful to us, and, I believe, to some of you in assuring your customers that you do not have a food additive problem in certain circumstances. By the way, that letter was reviewed by Billy Goodrich, who has just officially announced his retirement from the Food and Drug Administration.

"Aside from these collateral developments, which did not involve Mr. Ramsey or the other members of the FDA Staff directly, nothing really took place on the Ramsey proposal until our January 13, 1971 meeting where many of you were witnesses to some promises made by the Food and Drug Administration Staff. One promise was that we would have a Seminar, and this promise is being kept, as you heard earlier.

"The most important promise was one that Tom Brown more or less pushed his people into, as you could tell if you were at the meeting, to have a session with us wherein 'we should be able to settle something about the Ramsey proposal in two or three weeks.' I hope most of you remember Tom Brown said that, and I'm glad it was said in an open meeting. It was said in an open meeting, and we then set about promptly conducting the clearance program we had to conduct because in this case we were working with all of the industries--we couldn't just do this by ourselves. We had to get them to agree to a delegation to meet with FDA. It took us from January 13 'til about the end of the month to go about the clearance procedure, and we met with the FDA Staff on February 3. Thus, I don't think we were delinquent in any way in going forward as proposed.

"At the meeting with the FDA Staff, which it would be hard to describe, especially through the tears and pain, we discussed the various phases of the kinds of actions that could be taken. Among other things, we talked to the FDA Staff about partial action, unrelated to the parts per million concept. We supplied them with some ideas for a substance use notification system, since some of the members of the Staff were concerned that if they went along with any part of the proposal, they might never know what was going into food contact items. We came up with some ideas on that--a tear-off form that might even be used if that's the direction they wanted to go in.

"By the way, Tom Brown was not at that meeting. I subsequently found out he really did not have any idea of how the meeting was going to go, which I consider most unfortunate because the only way I know how to describe what happened to us at that meeting, after the opening exchanges I have mentioned above, is that we were 'Ramsified.' At the session, the statement was made not once but several times by Mr. Ramsey that 'we still think that these proposals that we advanced are scientifically sound, but they are administratively or politically impossible at the present time.' I feel this was Ramsey's way of saying that even though indirect additive regulation is a low-priority area at FDA, we're too afraid to go ahead with anything that will cut down on clearance requirements in any area.

"This Ramsey pronouncement came as quite a blow after Tom Brown's promise at our January meeting. To say we were shocked would be to put it mildly. I was furious myself. I personally believe that a number of the members of the FDA Staff who were there, like Mr. Buckley, Dr. McLaughlin and Mr. Holtz may have been as shocked as we were at how the meeting came out. I do not believe they anticipated the turn of events, and that's why I say we were 'Ramsified.'

"Well, we could not very well leave the situation in this posture so I talked with Tom Brown as soon as I could get to him. (He was out of town but I talked to him the following week). He was, I think, tactfully apologetic but, nonetheless, once a member of your staff to whom you have delegated responsibility has taken action, you really do not have much choice other than to find a middle position and at least appear to back him.

"Thus, Mr. Brown could only suggest that we prepare a petition, the exact nature of which was not clear to me, and I did as much probing as I could. What he said in substance was that, 'I suggest you prepare a petition to bring this problem into focus, and I will promise you that the

Commissioner will consider the petition despite what Ramsey said, Ramsey having said that if we were to press the matter, he could not recommend it to the Commissioner.

"Since that time, we have not had an adequate opportunity to work the petition problem out. But we are working on one; we have some drafts; we are in the process of preparing what you might call a petition. I can tell you that what we are trying to prepare is what amounts to a report on the history of this whole sordid affair, along with a request for relief. We are really attempting to prepare a packaged proposal so that it can be filed with FDA all right. However, it could also be supplied to other authorities and speak for itself if, for example, a Congressman were interested in reading it and taking some kind of constructive action. Thus, the draft petition is very apt to mention the background about how FDA did not keep its 1968 promise to Congress.

"We also have some ideas about the nature of the relief we would like to see that may appear somewhat different and slightly revolutionary to you when you read it. I do not want to get into that right now because I think it would be premature, but we will try to send a draft out to you, as we did on the GRAS list comments, well in advance of your next meeting so that we can use part of the next meeting to discuss the draft.

"Now, there is some help we could use from you. During the course of discussions with Tom Brown, he suggested that our 'petition' should be backed up with data, and I kept asking data like what? I even said: 'Suppose I attach a copy of the National Conference on Indirect Food Additives transcript, would this be "data" in this context?' He indicated that probably would not help too much.

"The nub of the matter is that in trying to think about what kind of data we can provide to show that we really do have a problem and FDA can and should help do something about it, we expect to get some data on how much the extraction test methods now used exaggerate real extraction after Bob Miller has a chance to analyze fully some of the data he'll be telling you about later in the day in connection with his European report. The additional data that we would like to have will be requested of you. With the permission of your Steering Committee, we are going to send out a questionnaire to attempt to obtain this data, probably within the next month or two. It should not be too difficult to complete and will be designed to elicit your experience, time-wise, on any food additive petitions you may have filed. In other words, it will ask you

just simple questions such as (1) what the subject of a petition was, (2) when it was submitted to FDA, (3) when you were advised that it was accepted for filing, (4) when the Notice of Filing appeared, and (5) when final action was taken on the petition in the nature of some form of regulation issued. Incidentally, just so those of you who are devoted CCH readers will not think we are asking for something partly available in the literature, let me point out that we realize we can get some of the information mentioned from CCH and Food Chemical News and we will. However, we would like to have documentation from you because of the data gathering 'image' this will provide.

"We hope you will cooperate since we would like as many of those questionnaire forms as we can get back.

"That's really the status of the Ramsey proposal as it now stands. I hope I have given you enough background to understand what we're doing. We have once again been asked to face up to the fact that, as much trouble as the indirect additives field is to all of us, it is by no means high priority with FDA. I don't know of any way to get real Commissioner-level attention for it without being able to package the product. In summary, we are now faced with the necessity of packaging up all of our woes and suggestions for relief, and placing them in a readily available container so that the package can be given to the people that might be able to help. That's what we now believe we have to do, and we're working on it.

"Does anybody have any questions about the status of the Ramsey proposal?

Max Goldfrank: 'When we sent out the request for the Inter-industry Committee, you asked us for suggestions. I made the suggestion of how about going back to Congressman Dingell? Or is he no longer interested?'

Heckman: 'I'll be glad to answer that question. I thought I had implied the answer in what I said earlier. This is another case where I don't think we can make any progress unless we package our product. That's true for two reasons. In the first place, Mr. Dingell was originally interested in the problem because Greg Potvin who worked for him was a close friend and was interested in sitting down for a couple of hours to listen to the background. Even after listening to it, he said that he wouldn't have time to read all of the papers I gave him. He, therefore, asked that a series of questions be prepared that could be submitted to Commissioner

Goddard when he was appearing before the Small Business Subcommittee on a matter relating to drugs that really had nothing to do with food additives. So the reason we could not easily go back to Dingell is because I think we need the package to do the job. We need to give him something to read at his leisure and, then, in that way we would hope we could focus his attention on it so that he will take an interest. I think he might take an interest, if we do it that way, and if we can say we have exhausted all our avenues with FDA.

Heckman: (in response to an unidentified question) Our questionnaire will be designed only to elicit what amounts to chronology. It should be very simple, provided you can remember what petitions you have filed. If any of you feel that you don't want your company identified when you send your questionnaires back, please let us know that. I frankly hope that you won't feel that way but if you do, we can identify the companies as A, B, C, D, E, F, if we have to.

"Let me turn now to the status of the GRAS proposal which is the next item on the Agenda. I am assuming that all of you are relatively familiar with what I'm talking about. This relates to the FDA proposal written by Alan Spiher that is supposed to set up new criteria for how FDA is going to operate in the future relative to things that have been heretofore GRAS. I spoke with Mr. Spiher just before I left Washington and was advised that the proposal, as drafted--and this is the one that was published in the December 8, 1970, Federal Register--is in the General Counsel's office for review. In due course I am sure that they will put out some form of this notice.

"Really, as I see it, all this Notice does, and we did file Comments on it if you'll recall, is say somewhat vaguely what FDA thinks it's going to do in the future with regard to GRAS items. I have been told by Mr. Spiher that the Comments we filed are not going to be explicitly mentioned in any way in the final Order, presumably adopting the proposed new Section 121.3. Instead, we've been told that the thing to focus on is that no status changes will be made--and this is now in the proposal--until the Food and Drug Administration has had an opportunity to evaluate any new findings about specific GRAS items.

"From our point of view, what this really means is that you can consider the GRAS list, Section 121.101, anything that is not on the list, but that you know is GRAS for other reasons, to be intact until FDA comes forward with a proposal to de-list, put out an interim regulation or promulgate a new regulation on a

particular GRAS item. According to what has been said by FDA, the evaluations are going to be made in categories according to the order of hazard of substances and their uses. Thus, once again packaging materials will be low priority and will probably maintain present status for a long time.

"The one thing that I think you probably really should pay attention to is, when orders start appearing, if they propose to de-list, regulate, interim regulate, or what have you, any GRAS item that you actually use in your formulations. You will want to be alert, especially in those cases where a proposed action affects a direct additive you happen to use in an indirect additive application. If this happens, you would seem to have three alternatives. One, you can reformulate that item out of your product if the new list is not going to cover it. The second one is to substitute another GRAS item. And the third one is to propose to FDA in response to any specific notice that any change in the status of the substance be made so that you can use that material in indirect food additive applications. For the moment then, all I am really saying to you is to stay alert to future action on the GRAS list matter and be prepared to protect your interests.

"Now, in this connection, a number of things are being tied together at FDA these days that should be mentioned. For those of you who may not have read it, I would strongly recommend that you read, beginning on page 17 of the May 10 issue of Food Chemical News, where there is an article called 'Toxicological Criteria for Additives Previewed.' It's a lengthy discussion so I really can not cover it here. To show you about some of the vagaries of FDA activity, here are a couple of quotes from this article:

'It has been known that FDAers have been working on toxicological criteria for additives and Agency officials recently disclosed that either they would be proposed this year or abandoned. Kolbye this year (he's the Deputy Director of the Bureau of Foods) told the annual meeting of the Flavors and Extract Manufacturers Association that he expects the criteria to be proposed in the Federal Register although not at least for a month.'

"This set of testing criteria is supposed to, in some way or another, replace or incorporate the idea of toxicological insignificance. Presumably FDA is going to set up toxicological criteria so that, for some things that are believed to be toxicologically insignificant, you might only have to do LD 50's while on other things, you might have to do 90 days studies, and so forth. All of this is going to play into the GRAS list concept, too, as the Food Chemical News article discusses.

"After you read the May 10 article, for fun and games, you might take a look at this week's issue where the same matter is dis-

cussed again. In this case Deputy Commissioner James B. Grant is quoted as follows, relative to the GRAS list and the toxicological criteria matter:

'The comments seem to indicate an underlying concern in industry circles that FDA is planning arbitrary and unilateral actions in revising the GRAS list. I can assure you that this is simply not so. A proposal will be published that will name a specific substance or substances whose status is being considered. Time will be provided for comments from any interested party. This is the time during which we hope you will come forward with any specific data which you believe will support either GRAS listing or will indicate the level of regulation that you feel is required if a regulation is to issue.'

In the same presentation, Grant said flatly:

'that within the next six to eight months FDA will publish its toxicological guidelines.'

"That shows you how timing works at FDA. First, you hear they will publish guidelines soon or abandon the idea. Then they will 'be out in perhaps a month or a little longer'; now it's six to eight months. All we can do is wait to see what really happens.

"On the USDA proposed changes in its regulations which we discussed at some length at the last meeting, if you'll recall, and on which we filed comments, 'the quick and dirty way' to tell you about this is to tell you that more than 70 sets of comments have been filed so considerable delay is to be expected. One group of Western Meat Packers filed a statement demanding a hearing and contesting the constitutionality of USDA's right to prescribe labeling. The hearing was denied promptly.

"As far as I'm aware, our friends at USDA at least agree with the comments we filed, which were fairly simple. Mr. Sloan is operating as in the past and is not too concerned about when the rulemaking is finalized so he can not give me any prediction and I can not give you one.

"Meanwhile, I think that you can just say that we can continue to operate as we have in the past on USDA and that's all to the good.

"The last thing I want to mention is really a perennial. It comes up in so many and strange ways that I thought I would caution you at this opportunity once again about this matter of guaranties. I just want to urge all of you once more, that, before you sign a guarantee form submitted to you by a customer, you check with your legal counsel, and, at the very least, read carefully the guaranty

you are asked to sign.

"One form that I will probably use as a horrible example from now on came to my attention recently. It included the stock language that you all see but including some extra clauses which could only terrify a legal department. Here are some examples of what you would have been agreeing to do if you had signed this guaranty:

'...does hereby agree to indemnify and save the buyer harmless from and against any and all charges and proceedings brought by any governmental authority against the article or buyer for or on account of any alleged adulteration or misbranding of any such article described in Paragraph 1 hereof for which seller is responsible hereunder, including the loss and reasonable expenses, including attorneys' fees incurred by buyer as a result thereof.'

"That first paragraph only relates to governmental action. Catch the next clause:

'...does hereby agree to indemnify and save the buyer harmless from and against any and all claims, demands, actions, and class actions and causes of action which are hereafter made or brought against the buyer by any person for the recovery of damages for the injury, illness and/or death of any person or animal which is caused or alleged to have been caused by the handling, consumption, or used by such person or animal or any article shipped or delivered hereunder by seller or buyer, including without limitation any judgment rendered against buyer in any such action, and the reasonable fees and costs, if any, incurred by or on behalf of buyer in connection therewith.'

"Now I'm not telling you not to sign this kind of guaranty if you want to. All I am telling you is that you should realize that if you sign a guaranty like that, you are not only in the plastics business, you are in the insurance business so the least you should do is consider collecting some type of premium for the policy.

"Thank you."

Reports on Liaison With Other Organizations

Mr. Miller noted that those present would next hear the usual reports on the activities of other organizations relating to the interests of the Committee.

Drug Packaging Materials Subcommittee

(Formerly PMA-SPI Liaison Group)

Chairman Miller called upon W. B. Ackart, Union Carbide Corporation, to deliver the following report relative to the PMA-SPI Liaison Group:

"The January 13, 1971, report of this group stated that the final draft of our proposal for regulating polyolefins for packaging dry drugs and the associated test methodology had been submitted to the quality control section of the PMA. The methodology section of our proposal was accepted by the Q.C. section and was thereupon submitted for publication in the National Formulary and U. S. Pharmacopeia. The section dealing with proposals for regulatory changes was deemed beyond the scope of the Q.C. section and we were referred to the Vice President for Scientific Affairs of the PMA for any joint activity in this area.

"In the discussion that followed this report, it became obvious that the level of activity in the drug packaging field is rising rapidly and that a much larger and more active group will be necessary. Additional volunteers were recruited and a reorganizational meeting was held on March 24 at the office of Mr. Heckman in Washington. This committee now consists of the following:

P. E. Campbell (Phillips Petroleum), D. S. Dixler (Keller and Heckman), G. H. Fuchs (Allied Chemical), J. Roy (Kerr Glass), P. M. Sanders (Eli Lilly), M. E. Smith (O. I.), E. J. Szymanski (Monsanto), W. M. Westveer (Dow), and Jerome H. Heckman.

"Subjects considered at this meeting included: (1) personnel changes at FDA, (2) the polyolefin containers for dry drugs publication, (3) FDA's guidelines for IND's and NDA's, (4) FDA statement of policy regarding new drug marketing practices and NDA's, (5) contaminated intravenous fluids, (6) migration of phthalate plasticizers from blood storage bags, (7) safety closures, (8) renewed activity regarding testing of plastics for containers for parenterals, and finally (9) a more appropriate name for this subcommittee.

"Major consideration was given to item (2) our publication on polyolefin containers for packaging dry drugs and its current status with the PMA. Due to faulty communications, it appeared that the PMA