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November 6, 1967

M E M O R A N D U M

The attached is a copy of the Comments of The Society of the Plastics Industry, Inc. filed with the Food and Drug Administration on November 6, 1967. The original was submitted to the agency, complete with all of the Exhibits referenced in the footnotes and elsewhere.

To reduce bulk, and thereby facilitate mailing, the attached reproduction has been printed on both sides of the page and merely references the more lengthy Exhibits by means of a summary sheet attached at the end of the statement. Copies of Exhibits F, G and H are attached to this reproduction because they constitute relatively short documents not heretofore called to the immediate attention of the SPI Food Packaging Materials Committee or other correspondents.

The copies of this filing submitted to the Food and Drug Administration included all of the Exhibits and were prepared by printing on only one side of each sheet.

Jerome H. Heckman

List of Exhibits Supplied
to FDA With Originals of Comments

Exhibit A -- April 10, 1967 letter to Mr. Lessel L. Ramsey, Assistant Director for Regulatory Programs, Bureau of Science, Food and Drug Administration. Letter reference was "FDA Guidelines for Chemistry and Technology Requirements of Food Additive Petitions." Document was 30 page set of SPI Comments on Guidelines.

Exhibit B -- Reproduction of ACS Symposium paper entitled "The Packaging Industries and the Food Additives Amendment of 1958--It's Time for a Change in the Law" by Jerome H. Heckman.

Exhibit C -- Reproduction of ACS Symposium paper entitled "Safety Criteria for Flexible Packaging Materials" by Dr. Seymour G. Gilbert, Rutgers University.

Note: Only these two of the ACS papers were submitted under the "blanket" footnote 3 because (1) most of the other papers were not as "critique" oriented, and (2) Drs. Frawley's and Ingle's papers, which were "critique" oriented,have been updated since the ACS Symposium and are, therefore, referenced in other ways in our statement.

Exhibit D -- "On Regulating Additives From Food Contact Materials" by Dr. George W. Ingle, Monsanto Company.

Exhibit E -- The following Federal Communications Commission Releases:

FCC 66-1004; 90954 Notice of Inquiry re "Regulatory and Policy Problems Presented by the Interdependence of Computer and Communication Services and Facilities"

FCC 67-239; 94872 Supplemental Notice of Inquiry re same topic.

FCC 64-266; 48884 Public Notice of March 27, 1964 entitled "FCC Establishes Advisory Committee for the Land Mobile Service." This Notice includes a copy of Executive Order 11007 which sets forth "Regulations for the Formation and Use of Advisory Committees."

Copies of Exhibits F through H are attached hereto.

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296-2700
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November 6, 1967

Hearing Clerk
Department of Health,
Education, and Welfare
Washington, D. C.

Re: Food and Drug Administration's
Proposed Food Additives Procedural
Regulations (32 Fed. Reg. 152,
p. 11443)

Dear Sir:

Pursuant to Section 4 of the Administrative Procedure Act, as amended (5 U.S.C.A. § 1003(b); 5 U.S.C. § 553(c)), and the referenced Food and Drug Administration Notice of Proposed Rule Making published on August 8, 1967, The Society of the Plastics Industry, Inc. (SPI), by its attorneys, and acting through its Food Packaging Materials Committee, 1/ hereby respectfully submits its views with regard to the above-identified proposed amendments to the Procedural Regulations governing the filing of Food Additives Petitions.

1/ The Society of the Plastics Industry, Inc. (SPI) is a corporation organized under the Membership Corporation Law of the State of New York. It is composed of approximately 2500 member companies and individuals who supply raw materials; process or manufacture plastics or plastics products; engineer or construct molds or similar accessory equipment for the plastics industry; and engage in the manufacture of machinery used to make plastics products or materials of all types. SPI is the major national trade association of the plastics industry, its membership being responsible for an estimated 85 to 90% of the total dollar volume of sales of plastics in this country. (cont.)

I
INTRODUCTION AND PRELIMINARY STATEMENT OF POSITION

The instant proceeding presents those directly interested in the day-to-day administration of the Food Additives Amendment of 1958 with the first formal opportunity since shortly after Public Law 85-929 was passed to deal with a myriad of problems which have arisen in Food Additive Petition processing, particularly in the so-called "incidental additives" area. 2/ While this opportunity is welcomed by the plastics industry, it should be understood that the framework within which it is offered

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1/ (cont.) The Food and Drug Administration is quite familiar with the constitution and activities of the Society as a result of our many filings in other proceedings of direct consequence to plastics producers. Copies of SPI membership directories, organization charts, and the like have been supplied to FDA in connection with some of these filings. (See, for example, the FDA file on Food Additive Petition FAP 6B0662.) Any further background information desired can be supplied immediately upon request by the Food and Drug Administration.

2/ An informal opportunity to comment on some of the procedures relating to Food Additive Petitions was provided when members of the Food and Drug Administration Staff invited interested parties to submit suggestions with regard to the "FDA Guidelines for Chemistry and Technology Requirements of Food Additive Petitions", which were issued on an informal basis by FDA's Bureau of Science in August of 1966. This invitation occasioned the filing of extensive comments on behalf of the Society on April 10, 1967. Thus far, we have received no reaction from the Food and Drug Administration concerning our suggestions. Since much of what was said in these earlier comments is applicable here, a copy of the earlier statement is appended hereto as Exhibit A. We respectfully request that the points covered in our April 10 filing be taken into account in this proceeding, as well as in connection with any revision of the Guidelines which may ultimately take place.

also presents us with something of an enigma. This is because the procedural rules changes which the Food and Drug Administration has advanced on its own motion (1) presuppose the correctness of a number of underlying policies--largely unwritten, or at least uncodified--which we deem questionable, at best; (2) ignore the need for a number of substantive guidelines of far greater urgency than the need for paper size specifications, and the like; and (3) look toward the imposition of ever-increasing burdens on industry without any due regard for the relevance of such requirements to the public interest, much less that of industry or sound regulatory policy.

While The Society of the Plastics Industry is completely in sympathy with, and has itself strongly advocated effective moves to clarify the regulatory requirements governing the filing and handling of Food Additive Petitions, especially in the "indirect additive" field, we cannot agree that the instant proposal affords a real promise of progress, nor indeed any cause for optimism about the accomplishment of the objectives the Administration has announced. Our reason for sincere disappointment in the proposal arises from its basic superficiality and the fact that it in no sense bespeaks the

agency's awareness of and responsiveness to the many indications it has received in the past year or two about the need for responsible and thorough reevaluation of the "incidental additives" problem. 3/ This despite the fact that the Commissioner and FDA Staff members have advised on a number of occasions (in writing, as well as orally) that cooperative steps should be taken to permit more effective regulatory approaches in this field.

We respectfully submit that adoption of the instant proposal can only result in a continuing exaltation of form over substance, possibly because the proposal is and will continue to be wholly untimely until there is a careful reappraisal of some of the essential policies which now have such great and unfortunate impact on the

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3/ In this connection, we are hereby transmitting for the record as Exhibits B and C reproductions of two of the papers presented at the September, 1966 meeting of the Division of Organic Coatings and Plastics Chemistry of the American Chemical Society. The contents of most, if not all, of the papers given at the meeting are already well known to FDA Staff members since copies were previously supplied to them, and since a member of the Staff participated in the program.

More recently, at least two other papers have been presented advocating substantial regulatory reforms. One of these has already been incorporated in the "Procedural Regulations" docket by means of Dr. John P. Frawley's comments submitted on October 23, 1967. A copy of the other, delivered by Dr. George W. Ingle of Monsanto Company at an April 28, 1967 Conference in Mayaguez, Puerto Rico, and entitled "On Regulating Additives From Food Contact Materials" is submitted as Exhibit D, hereto. (cont.)

food packaging materials industries. In our view this impact goes far beyond what Congress intended when the Food Additives Amendment was enacted since the legislative history and, indeed, the language of the law leaves no doubt but that Congress intended it to require "pre-clearance" of components of food packaging or processing equipment materials in limited circumstances. As the law is now administered, the coverage demanded is all embracing and this has led to consequences best described as "grotesque".

In keeping with what we conceive to be our responsibility to the Food and Drug Administration, and in light of the foregoing, we have divided our Comments on this proposal into several main parts.

In the first section, we discuss once more the basic policy issues which we believe must be dealt with realistically and responsibly to make procedural regulations on Food Additive Petition formats meaningful.

In the second major portion of this filing will be found our industry's comments on the specific regulatory proposals advanced in the FDA Notice of Proposed Rule-making of August 8, 1967. It should be clearly understood that the

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3/. (cont.) Without dealing in any detail with the substance of any of these presentations, and without advocating any of the solutions suggested therein, suffice it to say that they leave no doubt but that there is a most urgent need for in-depth re-evaluation of the "incidental additives" problem with a view towards effecting basic reforms in present policies, practices, and procedures.

recommendations and suggestions made in connection with the language of the specific proposals constitute only an attempt to deal with these areas on the assumption that some of the more essential questions raised herein are considered and handled. The difficulty of operating on such an assumption will be immediately apparent. Perhaps it will also serve to make self-evident the correctness of our view that more detailed regulations to prescribe mandatory data and formalities for Food Additive Petitions should be delayed until the Administration has met the greater need in this field, i.e. that of adopting long overdue substantive regulations covering such matters as FDA's concept of its jurisdiction over food packaging materials under the Food Additives Amendment of 1958.

Finally, in the third section of this filing, we have set forth a number of recommendations which we believe merit FDA consideration simply because they could pave the way for better industry understanding of FDA policies and procedures in all areas, thereby truly smoothing the regulatory path for all concerned.

We respectfully request that these Comments be given the most careful study and attention. Further, we strongly recommend that, before the proposed Procedural Regulations contemplated by this proceeding are disposed of, they and the underlying concepts hereinafter covered, (a) be made the subject of a

public legislative type hearing before the Commissioner, or (b) in the alternative, that an Industry-Government Advisory Committee be established to study the administration of the Food Additives Amendment of 1958, as it relates to "incidental additives", and report back to the Commissioner with detailed findings and recommendations as promptly as possible--in any case before any new so-called "Procedural Regulations" are enacted. The plastics industry stands ready to participate fully in any hearings or Advisory Committee work, whichever might be deemed best. We cannot urge too strongly that some action of this type be instituted immediately.[4/]

II

THE INSTANT PROPOSALS SHOULD BE WITHDRAWN OR THEIR ADOPTION DELAYED UNTIL THE FOOD AND DRUG ADMINISTRATION HAS TAKEN EFFECTIVE ACTION TO RESOLVE THE JURISDICTIONAL PROBLEM WHICH NOW BEDEVILS ALL OTHER ISSUES

There can be no question but that, contrary to FDA expectations and the predictions made to Congress at the time Public Law 85-929 was enacted, it is the regulation of

4/ Attached hereto as Exhibit E is a set of Federal Communications Commission releases which should serve to provide the Food and Drug Administration with an example of how other federal agencies have used both the legislative type hearing and Advisory Committee procedures to make a sound record in support of progressive changes in the administration of the laws under which they operate. Exhibit E is comprised of a "Notice of Inquiry" and a "Supplemental Notice of Inquiry" issued by the Federal Communications Commission in Docket No. 16979 for the purpose of gathering facts to facilitate regulation of the various uses of electronic computers; and a Public Notice issued by the FCC on March 27, 1964 whereby the Commission established an Advisory Committee to study frequency congestion problems affecting land mobile service radio users.

"incidental additives", not the regulation of "direct additives", which has proven the most complex, and the most time consuming activity in this entire area. The contrast in the degree of complexity in these two fields is most graphically demonstrated when one notes that the average processing time for handling indirect additive petitions probably averages more than a year, whereas petitions relating to direct additives are almost always handled to completion, i.e. publication of a Food Additive Regulation, within the 180 day statutory deadline for such action. Further, the 200 regulations covering direct additives for use in animal feeds, as well as human food, along with all of the present procedural and other collateral regulations, require no more of the more than 1,000 pages of regulatory verbiage than does Subpart F, the incidental additives section.

We believe that the reason for the way in which the situation has developed to an almost hopeless state lies in the failure of the Food and Drug Administration to adhere to sound regulatory precepts with special emphasis on its obligation to carve out and distinguish in a practical way between those areas requiring close regulatory control, and those where excessive regulation serves no useful purpose.

At the risk of further overburdening this filing, but because of our belief that an understanding of how the current jurisdictional status came about is essential to deal with the problem at hand, some discussion of the history of this threshold question seems imperative.

A. Historical Development of the Present "No Migration" Rulings Policy

Despite the packaging industries' severe misgivings about being subjected to the rigors of the Food Additives Amendment, at least some fears were laid to rest during the legislative proceedings by (1) FDA assurances that the incidental additives problem would be a minor one as contrasted to the regulation of direct additives, and would be treated as such under the law, and (2) the generally held industry belief that Section 201(s) of the Act, (2 U.S.C.A. § 321(s)) defining the term "food additive" as ". . . any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . ." /Emphasis supplied./, would have a sound limiting effect on the application of the law. The anticipation was that the reasonably-expected-to-become-a-component-of-food criterion would provide a basis upon which FDA could continue to act promptly in specific cases, as it had before

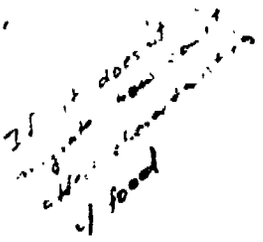
1958, by concurring in "non-additive" status on the basis of simulating solvent extraction data and expert opinion (including FDA's) showing that no migration of a given food packaging or processing material component might reasonably be expected to occur under stated intended conditions of use.

Indeed, for the first two years of FDA's administration of the Food Additives Amendment, it appeared that this "no migration" concept was fully embraced by the Administration, and would be used effectively to put reasonable bounds on petition filing, thus assuring, inter alia, that any formal regulations issued would be purposeful and meaningful. In countless speeches presented by able FDA Staff members assigned to deal with the day-to-day handling of food additives problems, the official administration policy in this area was carefully enunciated. Thus, for example, in one of the many papers given on the subject by Arthur A. Checchi, then Assistant to Deputy Commissioner Harvey, it was stated:

> "Let's take a look at what can be done. To establish the status of a food package under the Amendment, one should undertake immediately to conduct extraction studies on it to determine what, if anything, migrates from it to food under the intended conditions of use. There is little point in trying to establish the status of packaging materials under the Amendment without first having developed the extraction data. Unless you have gone over these

procedures with the Food and Drug Administration in the past, we suggest you get together the technical information regarding the composition, production and proposed use of the material to be tested; then, come to Washington and discuss extraction methods. We may be able to save you both time and money.

"Once the extraction studies are completed, you will find yourself confronted with one of two possibilities. There may be no expected migration of any substance to food. If so, you're home free. The packaging material you have tested is not subject to the Amendment, except in the unlikely event that it otherwise affects the characteristics of the food contained in it."5/ (Emphasis supplied.)



It should be noted that, even to this day, FDA public pronouncements advise industry companies to perform extraction studies first to determine whether or not they really have a food additives problem before they undertake the acquisition of much more time consuming and expensive

5/ Cf. Food Packaging Under the Food Additives Amendment--What Needs to be Done, pp. 2, 3. paper presented by Mr. Checchi at 14th Annual Paper and Plastics Conference, Chicago, Illinois, September 22, 1959. Papers such as the one cited do constitute official statements of FDA policy under the general operating practices followed by the agency. We are advised that Mr. Checchi's comments in the referenced paper were pre-cleared in the Commissioner's office under the normal procedure.

In passing it might also be noted here that we do not submit to the view that policies of continuing day-to-day cruciality should be announced and treated only in speeches by FDA staff members. This practice precludes efficient communication of vital concepts to the scientific and legal community because such papers as those given by Mr. Checchi are not made part of any permanent regulatory codification. All too often they become unavailable and are forgotten.

toxicological work, or undertake to file a Food Additive Petition.[6/]

There can be no real question but that the thrust of FDA's advice to industry, as exemplified by the above quotation of Mr. Checchi, was tantamount to saying to food packaging materials interests:

> "Deal with your threshold question first. Test for extraction under the methodology we deem adequately sensitive and give us the results. If the results are essentially negative, i.e. if you show no simulating solvent extraction within the sensitivity limits of our regulatory test methods, we will concur in non-additive status and you can assure your customers that your product is legally satisfactory for use as intended. You will then be 'home free.'"

This, in fact, is precisely the way such matters were handled until 1960, as indicated by then Assistant to the Commissioner, J. Kenneth Kirk, in the following preliminary explanation of how FDA had been treating the jurisdictional inquiries:

6/ Cf. Synthetic Polymers and the Federal Food, Drug and Cosmetic Act, by E. B. Detwiler, SPE Journal, January 1966, pp. 61-64

"I spoke earlier of the correspondence we have had in this field of food additives. A substantial part of this has involved inquiries dealing with the status of various packaging and equipment items. It will be recalled that we have recommended that if there is any question of whether or not components of a particular package may migrate to specific foods with which they are in contact, such questions may be resolved through the extraction and abrasion studies following the program devised by Mr. Ramsey of our Division of Food as announced in the spring of 1959.

"We remain convinced that the results of these extraction tests are valid for determining whether or not a particular packaging material, made up of one or more substances not generally recognized as safe, may be considered adequate criteria for a conclusion that the article is safe. We have repeatedly advised inquirers that under this food-additives amendment they are at liberty to make their own decisions on the question of status of items and that there is no requirement that they clear these decisions with the Food and Drug Administration. It is our view that if such a decision by a manufacturer is based on sound scientific data, there should be no occasion for any concern on his or our part. We did, however, announce--and, in fact, make a part of our regulations--our willingness to comment on any material where a food additive question may be involved if a manufacturer desires we do so. In this particular category, some manufacturers have submitted their data to us inviting our concurrence in their conclusions that their data demonstrated no food additive problem. In some instances a study of the data convinced us that the conclusion was correct, and we so notified the inquirers by letter."7/ /Emphasis supplied./

7/ Cf. Food Additive Developments, J. Kenneth Kirk, Food Drug Cosmetic Law Journal, December, 1960 pp. 757-758.

This straightforward concurrence procedure was in every sense appropriate, and in accord with FDA's responsibility to pass on product status under the law and the provisions of Section 121.3(c) of the Administration's own procedural regulations. FDA was actually doing nothing more than dealing forthrightly with wholly proper and crucial industry inquiries about its jurisdiction. At the same time it was avoiding the handling of extra-statutory petitions and the adoption of meaningless regulations.[8/]

Securing such FDA concurrence in no migration, therefore "non-additive," status was often a very satisfactory means of obtaining the type of customer assurance indication needed to do business with food processing companies. Unfortunately, FDA suddenly came to the conclusion that providing the no-migration concurrence letters was creating allegedly difficult administrative problems for it so that in his talk at the aforementioned FDA-Food Law Institute (FLI) Conference in 1960, Mr. Kirk

8/ It may not be contended in good faith that a policy of simply refusing to pass with candor on such jurisdictional questions, even while taking no enforcement action, is responsible agency conduct in a field where it is well known that food industry customers will use nothing without some FDA imprimatur. (Cf. Paper delivered by Kenneth E. Mulford at a 1960 American Bar Association meeting, entitled The Effect of the Food-Additives Amendment on Ingredient Suppliers, reported in the October, 1960 Food, Drug, Cosmetic Law Journal at Page 632. Note particularly Mr. Mulford's remarks on pages 632 and 633.). (cont.)

indicated that, henceforth, FDA would find it necessary to make its concurrence letters a bit less unequivocal.

The way in which the new policy was developed and presently stands is perhaps best and most briefly summarized by quoting from a response to a question given by Mr. Kirk in the 1961 FDA-FLI Conference panel discussion.

> "Mr. Kirk: The situation has not changed since last year's meeting. At that time, we discussed the very situation where we had been receiving reports of extraction studies which did not show any migration to the food. We wrote letters stating that we agreed that these items were not food additives. After many of these had issued, we found they were being used as sales promotion pieces, often to the detriment of other firms who had the same items, and had properly made up their minds without consulting us that the Food Additives Amendment did not involve their items. As a result, we concluded that we could no longer issue that kind of letter. Additionally, there were instances where small amounts of migratory substances were, in our opinion, properly classed as food additives. As a result of our reconsideration of the situation, we stated that we would, if requested, review data submitted to us and if this represented the right kind of work, I say right, as recommended by Mr. Ramsey's article, for example, and showed no migration, we would issue a letter which, unfortunately, would not be a

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8/ (cont.) Furthermore, firm FDA statements regarding substance status in this country are virtual sine qua non's to obtaining needed clearances in foreign countries.

> letter suitable for advertising. Essentially, the letter would say: 'You made your mind up. You have a perfect right to do so and even though you didn't give us any reason to say that you're wrong, we still have no facts of our own on which to agree.'
>
> "The other alternative is that if you want a 'letter,' the way to get it is to submit a petition for a Food Additive Regulation. If we can find that the product and the use involved are safe, then we can issue a regulation which will be there for all to see and will apply to everyone who has the same product for the same use."9/

Obviously, the thrust of this statement was to the effect that, regardless of the type of data FDA might be given, it would no longer provide any statement as to non-additive status based on "no migration" which would be helpful in allaying customers' questions.

To complete this brief history of the no-migration concept, it should be noted that there were immediate objections to the newly announced "no migration" doctrine from the legal community. It was pointed out at various Bar Association and other meetings that, in the opinion of food and drug lawyers, FDA had an obligation under Section 121.3(d) of its procedural regulations to provide industry with

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9/ "Panel Discussion of Questions Submitted to the 1961 FDA-FLI Conference", 17 Food Drug Cosmetic Law Journal 79 (Jan. 1962).

sound and clear-cut advice as to the Food Additives Amendment status of products upon request.

Upon the advancing of this legal argument, a helpless industrial community was met with some most unusual counter-reasoning. The legal justification advanced for the FDA policy--that is as far as its refusal to concur in non-additive status for "non-migrants"--boils down to FDA avowal of the theory that it has a right to refuse to concur in proof of such an exempt status. Why? Because it can reason that if a company goes to the trouble of conducting extraction studies it must believe that some or all of its product "may reasonably be expected to become a component of food" and, hence, the product and/or its components are legally "food additives"! Under this theory, there really is no such thing as an exemption from the law for non-migrants as a practical matter because no manufacturer of integrity would conclude that his product is a non-food additive <u>without performing extraction studies</u>. Yet FDA takes the view that once such studies are undertaken, regardless of the results, food additive status is established and official clearance can be given only upon the filing of a Food Additive Petition.

The FDA legal theory was first explained in a documented form in an address given by the then Deputy Commissioner of the FDA, John L. Harvey, at Rutgers University on January 18, 1962. In pertinent part, Commissioner Harvey's explanation was as follows:

> "We came to the conclusion that we had opened Pandora's box and had better find a way to close it before the situation got completely out of hand. We therefore reevaluated our position after consultation with our legal counsel and came to the conclusion that basically, if there was enough reason to run extraction studies on packaging or equipment materials, why shouldn't it be concluded that it would be reasonable to expect that the substances involved would, in fact, become a part of the food? Since the law refers to 'reasonably to be expected' we then began to advise those who asked that we were not in a position to give them a letter which would absolve their product from any responsibility from under the Food Additives Amendment but instead suggested that they file petitions. That is the present status of this item."10/ (Emphasis supplied.)

And, indeed, this remains the present status of this item.

FDA's Present Policy of Refusing to Meet Its Section 121.3 Obligations in Dealing with the Jurisdictional Question Inherent in "No-Migration" Cases has led to Extra-Statutory Regulation and a Variety of Complications Which Make Current Indirect Additive Procedures Sheer Chaos; Unless and Until this and the Consequential Problems that have Arisen are Completely Reevaluated and Rationally Handled, There can be no Meaningful Progress in Petition Processing

In reviewing the history of the current "no-migration" policy several legal facts seem most striking. At no time prior

10/ Harvey, Food Additives and Regulations, 17 Food Drug Cosmetic Law Journal 275 (April 1962).

to the fall of 1960, nor since, has it ever been contended that the Food and Drug Administration lacks the expertise to review extraction data and, on the basis thereof, to pass very directly on whether or not a substance to be used in a so-called food contact application may or may not reasonably be expected to become a component of food under specified intended conditions of use. At no time has it ever been contended by anyone that FDA lacks the power to voice its approval, by rulemaking or otherwise, for reasonable extraction test criteria and methodology on the basis of which it could be routinely concluded in all but the unusual cases that a component of a food packaging material, or of food processing equipment, may not reasonably be expected to become a component of food. The methodology described by Dr. Lehman in some of the earlier work in this field seems to us as satisfactory as ever for general regulatory purposes, no occasion ever having arisen for doubting the efficacy of this approach in protecting the public health. Nor, indeed, has FDA ever formally disavowed the validity for regulatory purposes of the extraction tests lauded so generously by Administration spokesmen in 1960 and earlier (see p. 13, supra.)

It most certainly seems safe to assume that Congress intended FDA to bring its expertise to bear in all good faith in making reasonable judgments and establishing interpretative rules or policies relating to the "no-migration" concept. If not, it would have performed this function itself by setting threshold limits of some sort for FDA's packaging materials jurisdiction.

Even more certainly, it cannot even be conceived that Congress would anticipate FDA's present legal position, as enumerated by Mr. Harvey, since this position makes a nullity of the statutory language. Under it, anything in a food contact surface is a food additive (despite the statutory language which limits the definition of food additive to substances reasonably expected to become components of food) unless a producer evidences the ultimate in irresponsibility by refusing to test for possible migration. 11/

11/ The implied suggestion of Mr. Harvey that a food packaging material supplier might be best advised to make an educated guess that his product is not likely to become a component of food, rather than to test it scientifically before reaching such a conclusion, flies in the face of a good deal of FDA importuning of industry by other FDA officials. On innumerable occasions, in the public addresses which constitute FDA expressions of policy, manufacturers were advised in no uncertain terms that failing to test a substance to be used in a food contact surface for potential migration would seem to constitute a severe form of irresponsibility. For example, in one of his series of 1959 papers, Mr. Arthur Checchi, then Assistant to

FDA could have dealt with the immediate problem cited as a reason for its policy change by Messrs. Kirk and Harvey, i.e. misuse of FDA status letters, under available procedures which permit government action to block advertising misrepresentations implying "FDA approvals."[12] This would have constituted use of a proper "rifle" approach which would have given appropriate results.

11/ (cont.) the Deputy Commissioner of the Food and Drug Administration states as follows:

> "Thus, whenever a new wrapping material is developed, even though it be composed entirely of substances which have been tested and found to be safe individually or in other combinations, extraction studies should be made and the extractables looked at from the standpoint of the Food Additives Amendment. Unless the substances which may migrate to food are generally recognized as safe for their intended use or their presence conforms with a pre-existing approval or order under the Amendment, then a petition seeking an order authorizing their addition to food is necessary."

Developments under the National Pure Food Law Affecting the Packaging Industry, Paper given at January 20, 1959 meeting of National Flexible Packaging Institute, New York City.

Similar expressions about the absolute necessity of conducting extraction studies were made by Mr. Checchi and other FDA officials on many occasions. See, for example, the following additional Checchi papers: Food Packaging Under the Food Additives Amendment--What Needs to be Done, 14th Annual Paper and Plastics Conference, Edgewater Beach Hotel, Chicago, Illinois, September 22, 1959; The Application of Food Additives Amendment to Packaging Materials, Industry Conference on the Safety of Packaging Materials Sponsored by the Packaging Institute, Statler Hilton Hotel, New York, New York, March 3, 1959.

12/ Advertising which so much as implies government approval of a product without such express approval constitutes an "unfair (cont.)

in every sense. All too many of them serve only to mislead the uninformed--especially those in foreign countries--in a number of ways, the following listing being exemplary:

1. A great many of the regulations imply that the materials listed therein are the only ones suitable for the intended application, even where all or almost all of the ingredients in the regulation have been included on a "no-migration anticipated" assumption. These "laundry list" regulations imply that anything not included may not be safely used and practical experience proves that marketing unlisted products is impossible even with the strongest evidence that they may not be expected to become food components.

2. Many of the regulations contain extraction limitations which are in no way intended to be indicative of what is expected to become a component of foods. These

limitations are not "tolerances" in the accepted sense, but, rather, are only intended to identify the substance being regulated so as to characterize it with a set of specifications. This approach would be understandable as a pragmatic alternative to meeting the often impossible requirement for developing a "practical analytical method" for determining actual presence of a packaging material component in foods but the regulations should make it entirely clear that the specification approach was being used. Since the regulations, with characteristic lack of clarity, do not so indicate, however, foreign governments, as well as industry personnel here, have misunderstood the regulations as prescribing a sort of limit on the degree to which a packaging material will be allowed to "contaminate" foods.

Thus, at the present time, we are advised that the Dutch government is proposing to employ

Rather than move under these principles, and despite a total lack of any adverse scientific experience with its pre-1960 approach, FDA embarked on its present course in the fall of that year. And how was this done? How did FDA go about changing a long standing procedure and "enacting" one of its first and most far reaching reinterpretations of how to proceed under the 1958 law?

No rulemaking proceeding was announced or instituted. No hearing was held. No public health or safety basis was even alleged to justify the institution of a new policy which has led to the filing of an immense number of food additive petitions covering all sorts of substances in almost as many inconceivably different ways.

This critical policy change--really a substantive change of enormous impact on the law--was brought to the attention of the business world in speeches given at FDA-Food Law Institute meetings in 1960 and 1961, and the legal rationale for it was not explained until a year and one-half later in another speech given to an even more exclusive group at Rutgers University.

12/ (cont.) trade practice" prosecutable by the Federal Trade Commission under Section 5 of the FTC Act (15 U.S.C.A. § 45). (With particular regard to misrepresentations of "FDA approval", see CCH Trade Regulation Reporter, Par. 7673.48.)

In this way industry was brought to the present intolerable situation without any effective opportunity to make its views known, with no hearing of any type, and without so much as an official FDA policy statement or change in the Food Additives Procedural Regulations. At the very least one would think FDA should have proposed a change in Section 121.3 of the Regulations so that no one would be misled about the type of response that might be expected in answer to a status inquiry based on data tending to show no reasonable expectation of migration.[13/]

And what has the policy change brought about? A mass of regulations covering a conglomerate of substances, within and without the statutory purview. The net result is a set of superficially imposing regulations--"paper tigers"

13/ The courts have always strictly construed and applied administrative agencies' procedural regulations. In a 1966 decision involving the Federal Trade Commission, Pacific Molasses Co. v. FTC, 356 F2d 386, the U. S. Court of Appeals for the Fifth Circuit summarized several Supreme Court and Appellate Court decisions (Service v. Dulles, 354 U.S. 363; U.S. ex rel. Accardi v. Shaughnessy, 347 U.S. 260; and Sangamon Valley Television Corp. v. U.S., 269 F2d 221, Cert. denied (1964) 376 U.S. 915) stating that "(W)hen an administrative agency promulgates rules to govern its proceedings, these rules must be scrupulously observed. *** For once an agency exercises its discretion and creates the procedural rules under which it desires to have its actions judged, it denies itself the right to violate these rules. If an agency in its proceedings violates its rules and prejudice results, any action taken as a result of the proceedings cannot stand."

the test methods used in some of the FDA regulations on polymers but, since it has apparently misunderstood the intent of these regulations, will now demand that a polymer like polyethylene meet a much lower extraction limit than is allowed in this country.

It is hoped that the Dutch government can be made to understand the true nature of the specification approach used here and will not employ test methods designed to identify materials on the theory that they actually govern extraction into foods. If this cannot be accomplished, all of Europe may become a closed area for American materials since it is expected that the Dutch regulations will serve as a model for the Common Market.

3. The regulations now include a vast number of prior sanctioned, "GRAS", and otherwise exempt materials. The reason for this is that, since 1960, the Food and Drug Administration has steadfastly refused to add to its prior sanction or GRAS listings, has also refused

to concur in "non-additive" status on the basis of reasonable extraction criteria such as those employed before 1960 (except in two special circumstances with even one of these now being open to new question)[15], and has, instead, in effect, insisted that anyone who requires an indication of some sort of FDA agreement about compliance with the law to sell his products obtain it by going through the tortuous petition-regulation process.

4. The way in which the handling of petitions has developed, with an increasingly unreasonable insistence on the most sophisticated type of scientific data to justify the issuance of a Food Additive Regulation has, without

15/ Heretofore, it was generally believed that there were two relatively well defined exceptions to the general FDA policy on no migration situations. Useful letter responses could be obtained in cases where inquiries were made requesting concurrence in non-additive status for components used in so-called "barrier" or "repeated use" applications. Thus, for example, FDA has concurred in the non-additive status of printing materials for use on the outside of wrappers where data showed that the wrapper presents an effective "functional barrier" between the food and the substance. Likewise, FDA has agreed to non-additive status for components of processing equipment intended for repeated use where it is reasonably clear that anything that might be expected to migrate from such equipment will be "washed out," or otherwise exhausted, during pre-use cleaning or flushing. (cont.)

question, led many small businessmen, and even larger ones, to forego any attempt to market perfectly safe products in the food packaging and food processing equipment areas.[16/]

The scientific information now required for a successful Food Additive Petition has reached such proportions that only a few companies can justify the expense. The end of this imbalanced imposition of the scientific mystique on industry seems nowhere in sight.

Extraction studies revealing no detectible extraction in accepted simulating solvents at a level higher than 1 ppm were deemed satisfactory in all but a few special cases to sustain

15/ (cont.) In the past few weeks, FDA has proposed a new Food Additive Regulation which purports to regulate certain colorants for paper and paper products. One criterion for acceptable status set forth in this proposal is that a functional barrier exists between the alleged food additive-colorant and the food to be packaged. This would seem to constitute another step in the direction of wholesale disregard for the reasonably-to-be-expected-to-become-a-component-of-food statutory standard.

16/ Cf. October 4, 1967 Comments filed by Rubber Manufacturers Association with Hearing Clerk, United States Department of Health, Education, and Welfare re "Proposed Changes in Procedural Food Additive Regulations."

non-additive status before 1960. Despite the fact that there is no known instance of any material "cleared" under this criteria having given rise to any public health problem (or even a remote implication of one), in preparing to file a petition for a "virtual" non-migrant at the current time, data must be supplied using extraction methods sensitive to a level of 0.01 ppm. Furthermore, toxicological information requiring at least ninety-day, two species studies are considered minimal and are demanded in many situations where extraction is detectible at any level above 0.01 ppm.[17/]

Advances in analytical techniques need not and should not be unreasoningly used as a basis for constantly changing regulatory criteria in an area where all available expertise, and all experience, indicates that it is simply wasteful of scarce scientific and administrative talent to insist on very costly, time

17/ Cf. "FDA Guidelines for Chemistry and Technology Requirements of Food Additive Petitions" Section II, D, 1 (Extraction Data). The concluding paragraph of this section states that

consuming studies for no purpose rationally related to the public health.

In summary here, we respectfully submit that a reevaluation of basic substantive principles in light of the statutory mandate, with a view towards adopting a more sensible interpretation of what is reasonably expected to become a component of food, is an absolute necessity. This may be accomplished by the compilation of a hearing record wherein expert scientific personnel could provide their opinions as a basis for adoption and publication of reasonable and valid Food and Drug Administration incidental additives jurisdictional rules so that the matter could be covered in a way that all would understand. 18/

17/ (cont.) "(I)f computations show that no more than 0.01 ppm of a substance would be added to food assuming it all migrated, the extracts usually need not be tested for such substance." As a practical matter what this phrase also implies is that the 0.01 ppm level has been informally adopted by the Food and Drug Administration as a type of "rule-of-thumb" no-effect level. Thus, if a Petitioner can demonstrate that his particular substance yields migration into food simulating solvents at a level below 0.01 ppm, his "burden of proof" to establish safety may be considerably lessened--perhaps nothing more than so-called LD-50 tests will be necessary--but FDA will still insist that the substance is a "food additive". If migration is detectible above 0.01 ppm, some toxicology work will almost always be required. The usual minimal studies are of the ninety-day, two species variety costing between $15,000 and $25,000. Where extraction is at slightly higher levels, e.g. more than 1 or 2 ppm, two year, two species toxicological studies at a cost of up to $100,000 are often demanded.

18/ One rule change which would do much to aid this end has already been recommended by Dr. Frawley in his October 23, 1967 Comments in this proceeding.

If the legislative, fact finding hearing approach does not appeal to FDA, then we urge the appointment of an industry-government advisory committee to deal with this subject rationally and recommend suitable rules and guidelines, with an opportunity provided in due course for comment by all interested parties on any recommendations made.

In any case, the present situation should not be permitted to continue, nor should the real problem areas be obscured by the adoption of the "Procedural Regulations" proposed here. Due process calls for nothing less than a full investigation of the root problems in petition handling.

III
SPECIFIC COMMENTS ON INSTANT RULE-MAKING PROPOSAL

General

Obviously, it is our position that commenting on the specifics of the proposed Procedural Regulations presents a number of severe difficulties because of the current lack of consistent policies in substantive areas. Indeed, many of the proposed provisions of the new Section 121.50 bespeak some misunderstanding of the underlying facts which have an immediate bearing on those situations which presently require the filing of Food Additive Petitions relating to packaging materials or processing equipment--or more properly, components for such applications.

The fact that there is little understanding of operative marketplace facts is apparent from a review of the present incidental additive regulations. These vital regulatory operating authorities for the packaging industries are characterized by a complete lack of consistency of approach that defies rationalization.

For example, many of the regulations purport to be of the so-called "omnibus" variety whereby lists of components are set forth and the regulatory criteria are in the nature of gross extraction limitations, regardless of how much of any one component in the list is used in making a finished package. Typical of this type of regulation are those covering components of paper and paperboard, coatings for metal substrates, rubber articles, and adhesives.

Even within this category, there is gross inconsistency. Two of the regulatory schemes, i.e. those for paper and metal substrate coatings, include gross extraction tests. Those for rubber articles and adhesives are obviously based on the unstated assumption that nothing may reasonably be expected to become a component of food because of its use in rubber articles for repeated use, or in adhesives; thus, the only specified enforcement criteria in these regulations is that they be made and used in accordance with "good manufacturing practices."

We take no issue with the Food and Drug Administration for adopting regulations of this type provided it is recognized that they really accomplish nothing more than the setting forth of a sort of "laundry list" of items that may be used in manufacturing the end products involved. The real function of some of these Regulations is only to provide suppliers of listed products with a customer assurance device because, in truth, the products are conceded to present no health hazard so no real regulatory controls are needed.

The unfortunate fact about the adoption of such regulations for such reasons is that they tend to confuse the regulatory picture and multiply petition filing by those who know their products "must be on the list" or will become unsaleable. That this is what takes place is made more apparent when one notes that the so-called "omnibus regulations" routinely include substances conceded to be "prior sanctioned", "generally recognized as safe (GRAS)", and not reasonably expected to become components of food. As a matter of law, the Food and Drug Administration has clearly exceeded its statutory jurisdiction in purporting to regulate such items but this is not to be criticized so long as the agency continues to refuse to carve out the jurisdictional coverage of the Food Additives Amendment in a

careful, consistent and rational way. So long as refusal to meet this obligation persists, it is only fair that FDA add all safe substances to its "laundry list" regulations, the statutory exclusions for certain classes of substances notwithstanding.

To compound the confusion, there are many other types of regulations. In some cases they cover only components used in finished packaging materials, and include such a wide variety of alleged means for practical enforcement as to make categorizing almost impossible. There are regulations which approve the use of some materials in unlimited quantities, subject only to the usual "good manufacturing practices" criterion; others seek to limit utilization and assure safety by the imposition of input restrictions; still others contain solvent extraction criteria. The differences in the regulatory approaches are due in part to the approach preferences of a variety of FDA administrative personnel as experience with the new law developed, and in part to sound pragmatic considerations. The point is that virtual chaos now exists and makes it impossible for even the most informed persons to rationalize the regulatory scheme, and glean some understanding of how a given new material or component should be regulated.

The instant proposals will do nothing to correct this situation. Thus, while the status quo prevails, the Food Additive Regulations covering incidental additives can only become more and more meaningless, as the listings and divergences of regulatory criteria become increasingly profuse.

What is needed first is (1) a much clearer definition of what needs to be regulated, (2) a sensible means for obtaining FDA concurrence on an informal basis that some materials simply do not require a formal regulation, (3) an understanding and taking into account of the commercial facts of life which make it impossible for manufacturers of components, as distinguished from finished packages or machines, to submit data which only the food processor or final package fabricator could possibly have, and (4) a new regulatory scheme, including but not limited to reasonable procedural regulations, which takes into account in some rational way the differences between regulations looking towards the coverage of components, and regulations covering end packaging or processing equipment products.

The urgent need for basic consideration of the actual facts which are so very operative along these lines is what makes it almost impossible to comment intelligently

on the instant regulations. Nevertheless, the following section-by-section comments are submitted for the record:

Re Section 121.9 Food Additive Master Files

In general, the Society agrees with the basic objectives involved in the establishment of "Food Additives Master Files" to the extent that the procedure contemplates a means whereby industry may set up permanent reference data for the convenience of the government, and perhaps other petitioners.

We do deem it relatively important that the Food and Drug Administration continually refer to such files as "Food Additive Master Files" because there is considerable confusion in the use of the term "Master File" by FDA. For example, many parties understandably are of the impression that establishing a "Master File" for reference in connection with packaging materials used in New Drug applications is the same as establishing such a file for reference in connection with Food Additive Petitions. Practical experience indicates that a Master File established for drug purposes is not readily available for reference for other purposes. Indeed, in handling the establishment of such files the Food and Drug Administration normally advises industry that

separate "Master Files" are being established. Although this is admittedly a minor point, it is recommended that FDA employ the distinguishing terminology as a regular procedure hereafter so as to eliminate unnecessary confusion.

Section 121.9(c), as presently written, is subject to considerable misunderstanding, especially when this Section is read in conjunction with the proposed Section 121.50(f) and the regulations adopted by the Department of Health, Education, and Welfare under the so-called "Freedom of Information Act" (P.L. 89-487). The HEW Regulations, published at 32 Fed. Reg. 126, pp. 9315 through 9319, included a listing of "examples of kinds of exempt records" which, under Item No. 11, describes as exempt ". . . data (submitted) in support of petitions relating to pesticide chemicals, food standards, food additives, and color additives, and master files relating thereto." (Emphasis supplied.)

Obviously, the HEW Regulations purport to exempt from disclosure analytical and toxicological data submitted in support of Food Additive Petitions. Furthermore, it has always heretofore been the general understanding that such basic data in petitions are treated as confidential and are only released with the permission of the party responsible for the filing.

We suspect that the language used by the Food and Drug Administration in Section 121.9(c) and 121.50(f) is actually intended only to make it clear that FDA will understandably treat as non-confidential the analytical methods relied upon for enforcement of a regulation, and the broad general conclusions reached as to so-called "no effect levels" where toxicology is concerned. If this is what is intended by the present language in 121.9(c) and 121.50(f), no objection of substance is lodged here but it is recommended strongly that the present language be changed to read as follows:

> "(c) The analytical methods relied upon for enforcement of a regulation and petitioners conclusion as to the toxicological basis on which a food additive regulation is based are not considered confidential or entitled to protection as trade secrets." (New language underlined.)

Re Section 121.50(a)

The third sentence of this Section, if applied strictly, will require that "Any published information used in support of /a/ petition shall be submitted in reprint form." Certain references are so well known, and so readily avilable to the Food and Drug Administration, as well as to anyone else in the scientific-technical community, that requiring reprints will do nothing more than add unnecessarily to the bulk of petitions. Furthermore, it

should be recognized that, even in its Food Additive Regulations, FDA avoids unnecessary verbiage by referencing accepted scientific material such as ASTM Standards. For these reasons, it is recommended that the third sentence of Section 121.50(a) be revised to read as follows:

> "Any published information used in support of the petition, and not readily available in recognized scientific or technical manuals (such as ASTM Standards publications) shall be submitted in reprint, or other legible form."

The penultimate sentence of subparagraph (a) of this Section requires that petitions include ". . . identification of the scientists who did the work and their pertinent qualifications." In this regard, we respectfully submit that there is no statutory basis nor indeed demonstrated need for such a requirement. To the best of our knowledge, such information has never been required in the past in connection with Food Additive Petitions, nor has this led to any known administrative or legal problem.

It has been the practice since the inception of the Food Additives Amendment for petitioners to properly identify by name any outside laboratory retained to do scientific work on a particular petition. Where no outside laboratory is used, the Petitioner obviously accepts full responsibility

for all data submitted after its preparation by company personnel.

At the very most, the Food and Drug Administration need only require information of the type requested here in special circumstances where it has doubt as to the scientific capabilities, or company reliability of a given Petitioner, or an outside laboratory employed to prepare data. This will be the rare, not the usual case. Furthermore, even in such instances, the only valid question should be one as to the qualifications of the personnel directly responsible for any data submitted. Supplying this type of information for all bench technicians and staff personnel who may have played some role in the preparation of data is patently unreasonable and unnecessary.

For these reasons, it is recommended that the penultimate sentence of Section 121.50(a) be deleted entirely or, if some such statement is deemed absolutely essential, that the following be substituted:

> "All original, unpublished scientific studies supplied in the petition shall include identification of the laboratory responsible for the work. Where it is deemed necessary, the Food and Drug Administration may request a brief

statement concerning the pertinent qualifications of any scientist or laboratory."19/

Re Section 121.50(b)

This section deals with incorporation by reference of previous submissions, and would permit the same where the previous submission ". . . is in a Food Additive Master File kept current by the petitioner, or is in another form of submission not over ten years old." Aside from the fact that we are unable to comprehend the need for the ten-year limitation, we respectfully submit that, unless it is deleted, it could result in the imposition of serious and unnecessary new hardships for both the government and industry.

Among other things, the provision as now written leaves at least one important question unanswered. Is the proposed rule to be applied only prospectively, or is it to be applied retroactively as well? If, in all fairness, it is to be applied prospectively only, its net effect and result will be that all future food additive petitioners with any degree of foresight will hereafter submit an

19/ Cf. Section 130.4(c) of the FDA Regulations which make clear the fact that, even in New Drug Applications, only those "responsible" for data need be identified and qualified.

extra copy of every Food Additive Petition, and will request that such extra copy be incorporated in a new "Food Additive Master File." Obviously this will mean that the Food and Drug Administration will have a duplicate set of files for every Food Additive Petition submitted so that it will in no event be in a position to "retire" Food Additive Petitions on a practical basis after a ten year period. A new paper handling process will have been established which will lead to nothing more than the receipt and cataloguing of wholly duplicative filings.

If the proposal contemplates retroactive application of the ten-year limitation, many petitioners will be saddled with an unforeseeable and inequitable burden, (i.e. the burden of refiling data already in the Food and Drug Administration's hands as numbered and catalogued Food Additive Petitions) simply so that they will not be placed in the position of being unable to refer to extensive data heretofore supplied. It is impossible to understand what useful purpose the imposition of such a burden on industry could possibly accomplish.

In short, all that the ten-year limitation can lead to here is some type of unjustifiable duplication of effort, either immediately or in the future. The administrative

process, as well as industry, can do nothing but suffer unnecessarily if the Food and Drug Administration adopts this proposal. For this reason, we respectfully submit that the clause of the first sentence of Section 121.50(b) which reads "and provided that the submission is in a Food Additive Master File kept current by the petitioner, or is in another form of submission not over 10 years old." should be deleted entirely.

Re Section 121.50(c)

A great deal has already been said by many other commenting parties regarding the unreasonableness of the FDA proposal to require the use of 8 x 10½ inch pages for all Food Additive Petition filings. Suffice it to say that we endorse the comments submitted by other parties in this regard and recommend that the Food and Drug Administration drop its proposal entirely or, at the very least, revise it so that it will do nothing more than make clear the assumed intention to steer petitioners away from the use of documentation on other than "standard sized", as distinguished from "legal sized", or other unusual forms of paper.

We are not entirely unsympathetic with the administrative problems that can arise where submissions are received in peculiar forms. However, the Food and Drug

Administration must be aware of the fact that the standard size stationery used throughout the country for almost all purposes is not the government 8 x 10½ inch paper, but is 8½ x 11 inch stock. To require that all of industry use government standard paper is to require the stocking of special materials for Food Additive Petitions for no sound purpose. Furthermore, stringent paper size limitations of the type the Food and Drug Administration proposes here would present intolerable difficulties in some instances where petitions must include data reproductions, or technical information printed on book size paper.

For these reasons, we recommend that the first two sentences of Section 121.50(c) be revised to read as follows:

> "(c) Petitions shall be assembled in the manner prescribed in paragraph (e) of this Section and submitted in a form suitable for binding, with all texts double spaced <u>on standard size pages (as distinguished from legal size)</u> with a lefthand margin of approximately 1½ inches and a righthand margin of approximately 1 inch. <u>Data submitted or reproduced from other publications shall be included in the petition in such a way as to facilitate filing with all possible recognition and consideration for the fact that standard size files are employed by the Food and Drug Administration</u>."

It is to be noted that we are recommending the complete deletion of the requirement for punching of the lefthand

margin of all pages submitted in a petition since it is our belief that this simple manual operation can best be handled by filing personnel at the Food and Drug Administration when filing is being accomplished. Practical experience indicates that slight deviations in such prepunching, or in ring binders, can create unnecessary inconvenience.

Re Section 121.50(e)I.B.2.

Under this section, the Food and Drug Administration proposes to make mandatory the providing of "an estimate of the maximum as well as the average quantity of the food additive to be expected in the total daily diet of the consumer. . .".

This requirement might have some validity in connection with direct additives where a food processor can reasonably estimate the consumption of the food product, and can know how much of the additive is proposed for use. As regards incidental additives, even a finished package fabricator would be hard pressed to make any sort of guess at how widely his package might be employed, and for which foods, unless he is asking for exceptionally limited coverage for the use of his product. To require such information from a relatively small company which

produces only a component to be used in a food packaging material, or in food processing equipment, is to make it totally impossible for him to comply with the mandatory demands of the proposed regulations.

The failure to distinguish between the different types of suppliers of products, and their consequent limitations in providing data, is a fatal defect in the conception of this proposal. This points up one of our basic problems with the entire FDA approach here and emphasizes the need for the in-depth reevaluation called for by these comments.

Re Section 121.50(e)I.B.3.

Under this section, and the more detailed version of it hereinafter discussed, FDA would propose to require that every petitioner, including those who manufacture nothing more than a food packaging material, or processing equipment component, develop and supply data to show that it will accomplish some technical effect, and that the amount proposed for use is the minimum necessary to accomplish this effect.

We submit that the proposal bespeaks an underlying substantive misconception of its statutory authority by the Food and Drug Administration. Speaking practically,

this could impose a virtual bar to the filing of a successful Food Additive Petition by any small component supplier. Such a supplier simply cannot demonstrate the exact effect his product will have in a package manufactured by another over whom he has no control and, further, cannot predict with accuracy the minimum amount of the material necessary to accomplish this effect in every possible application by fabricator customers.

Since this section is actually only a general prelude to the requirements detailed in the proposed Section 121.50(e)II.C.4.b., we are hereinafter discussing the entire "technical effects" problem (including statutory considerations), as it relates to incidental additives, more fully in our comments on the latter section. Suffice it to say at this point that we recommend such revisions of Section 121.50(e)I.B.3. as may be required to comport with our comments on Section 121.50(e)II.C.4.b.

Re Sections 121.50(e)I.B.5. and 121.50(e)II.A.2.

These sections again bring into the spotlight our most basic difficulty with the instant proposed regulations as they reflect current FDA policy under the Food Additives Amendment.

At the very end of the Section 121.50(e)I.B.5. "Toxicology" paragraph, it is revealed, albeit indirectly, that FDA will accept and act on petitions depending "upon virtual lack of migration" and will require from all petitioners a mass of data, including toxicology, much of which has no real relationship to safety, and cannot be supplied within the limits of practicality by producers of components of food packaging materials.

The second cited section (121.50(e)II A.2.) looks quite incredibly to an expansion of the statutory definition of indirect additives to cover "substances incidentally present in a final product because of addition for functional use elsewhere in the production operation," whether or not such substances may reasonably be expected to become a component of food.

Other considerations aside, the language used in Section 121.50(e)II.A.2. is ill conceived. As it now reads, an "indirect additive", as FDA proposes to redefine it, would not only include what the Statute contemplates, i.e. those substances reasonably expected to become components of food, but also materials "<u>incidentally</u>" present in a final package, regardless of whether such a component might be expected to become a component of food. Furthermore, the semantics are even more peculiar because they imply that

components intentionally present in a final package are not indirect additives unless they meet the further requirement of being substances "that may reasonably be expected to become a component of food because of /its/ presence in food contact surfaces," while those not intentionally present in the final package are "indirect additives" in any case. This distinction is somewhat difficult to explain because it is, in fact, incomprehensible.

The only way to summarize our position on the above-referenced sections is to urge the Food and Drug Administration to conduct the type of searching reevaluation of the entire incidental additives problem called for throughout this filing. To the extent that specific recommendations can be made outside this framework, we recommend that:

1. The last sentence in Section 121.50 (e) I.B.5. be deleted entirely as bespeaking an extra-statutory extension of FDA power. It is further recommended that, for greater clarity and accuracy, the second sentence of Section 121.50(e)I.B.5. be revised to read:

"The highlights shall include the no-effect levels, if any, found in the several species of the test animals and the maximum safe level in the daily diet of the consumer." (New words underlined.)

2. Section 121.50(e)II.A.2. be completely rewritten so as to eliminate any language whereby the Food and Drug Administration arrogates authority over any substance in the absence of a rational threshold finding that such a substance may reasonably be expected to become a component of food. We would certainly agree that the term "incidental additives" requires and should be given a more significant meaning for regulatory purposes. However, this should be done within the bounds of the statutory language, and Congressional intent. This means, of course, that the term should be given more limited, not broader, significance. Until such time as the Food and Drug Administration can develop reasonable jurisdictional boundaries

and use them to define the term in a sound way, it will serve no useful purpose to go beyond the statutory definition.

Re Section 121.50(e)II.A.2.a.vi.

The proposed requirement for data bearing on "molecular weight distribution in the basic resin" is in many instances most difficult to meet. For many materials, there is no established method for determining molecular weight distribution and the relatively few techniques that have been developed for this purpose are not only complex, but present difficulty as far as providing reproducible data is concerned.

Actually, the essential safety factor where incidental additives are involved is the total safe extractive limit for any particular packaging or processing material, or component thereof, established in a regulation. Thus, even assuming that molecular weight variations may effect solubility and total extractives, a regulated product is still controlled by the extractives or solubility limits set, not by molecular weight. As a practical matter variations in molecular weight distribution which might

result in a product having higher extractive or solubility limits would also effectively bar such product from the marketplace.

Generally speaking, we are inclined to recommend that this section dealing with molecular weight be deleted completely. However, it being recognized that, on occasion, because given incidental additives regulations actually depend more on product specifications than on extractability limitations (such limits being difficult or impossible to set especially where extraction is de minimis), we can understand the desire of the Food and Drug Administration to have as many additive identifying characteristics included in petition data as possible. This purpose can be served by a more flexible requirement than is proposed as FDA has duly realized on the many occasions in the past when it has understood the difficulty or irrelevance of supplying molecular weight data, and has accepted information of a related nature to accomplish the same purpose.

With this in mind, and believing that quite often such data as intrinsic viscosity, reduced specific viscosity, melting point range or various ratios of melt flow, for example, could be the proper criteria to use in lieu of

molecular weight, we recommend that the following be substituted for the presently proposed language in Section 121.50(e)II.A.2.a.vi.:

> "Molecular weight. For polymeric substances include the average molecular weight and the molecular weight distribution in the basic resin, where possible; otherwise submit data concerning other properties which provide indications of the nature and degree of resin extractability with suitable explanations and the methodology used to make relative determinations.

Re Section 121.50(e)II.A.2.b.iii.

This section would require the filing of a description of the manufacturing process for an additive, including a list of all substances used together with their specifications, regardless of whether this would have any bearing at all on safety or extractability.

We respectfully submit that, even assuming such proprietary information regarding manufacturing processes is afforded the utmost confidentiality, requiring it is unnecessary, and beyond the intent of the law. All normally pertinent information regarding the character and composition of an indirect additive is proposed to be

required by the other subsections of the protocol for indirect additives.

Section 409(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 348(a)), which details the statutory requirements for a food additive petition, clearly supports the argument that production process information should be required only in special situations and not as a matter of routine. More specifically, subsections A through E of Section 409(b)(2) of the Act list the basic statutory requirements of data that must be included in a petition and no reference whatsoever is made in this Section to production process information.

It is recognized, of course, that a separate subsection of Section 409(b), namely (b)(3), deals with the problem of supplying, upon request of the Secretary, "a full description of the methods used in and the facilities and controls used for the production of such additive." Indeed, the fact that this proviso appears in a separate section of the law is persuasive to the view that the intent of Congress was simply to give the Secretary the power to require such information where relevant because

of special circumstances, not merely as a matter of routine in every petition. Otherwise, section (b)(3) would be meaningless since the requirement of production process information could have been listed in subsection (b)(2) of 409.

Another difficulty with the proposal in this Section is that it could easily be read to imply that a company petitioning for a new regulation will be obliged to continue to use the particular method of manufacture described in its petition after the regulation has been promulgated. Such, we are reasonably certain, is not the intention of this subsection but, taken to its logical conclusion, this sort of interpretation would create great inequity. Among other considerations, companies other than the petitioner could manufacture the same indirect additive following the issuance of a regulation even though they would not be obliged to furnish information bearing on their particular manufacturing processes. They would thus have a "flexibility windfall."

As a practical matter, most petitioners do, of course, include general descriptions of their respective manufacturing processes in indirect additives petitions. This, we submit, should continue to suffice so we recommend

that this proposed Section be completely revised to read as follows:

> "iii. Manufacturing process. A general description of the manufacturing process, including any relevant production controls employed to assure a reproducible product."

Re Section 121.50(e)II.A.2.b.iv.

Inasmuch as "production batch" data is, as a practical matter, almost impossible to obtain before an additive can be sold for food contact use (i.e. until an additive is cleared, no package producer will employ it on a "production batch" basis), the proposal here is unrealistic and unreasonable. The same purpose should be served if the third sentence of this section is revised to read:

> "Data from a suitable number of representative production batches or, where no such batches are available, developmental or experimental samples, of the food contact surface . . . etc." (New language underlined.)

Re Section 121.50(e)II.B.2.

The requirements which would be imposed on a petitioner under this section are so broad in scope that they might well make it wholly impossible for a component

supplier to file a Food Additive Petition. They would truly present a massive obstacle for even the largest of companies much less small businessmen.

It is often impossible for a supplier of a particular prospective component of food packaging material to know, or to be able to control, the conditions under which a final food contact material will be used. The mere fact that a petitioner is only a component supplier makes it obvious that such petitioners cannot clearly foresee all of the immediate end uses which will be made of their substances, much less the long range uses. Furthermore, even in cases where a final food contact material is the subject matter of a petition, it is virtually impossible to detail the ultimately possible end-uses of a new product in a dynamic food market.

We do not contend that a petitioner cannot define broadly the expected conditions of use of a particular end product (e.g., temperature limitations under which a particular component or material may be utilized in or as a food package), nor the generic categories of food products for which he believes a particular material will be safe. <u>This can and should be done</u>. Even those who make only components for finished packages can provide data in this connection.

On the other hand, we respectfully submit that it is impractical to expect an indirect additive petitioner to be able to list specific foods, predict the precise range of temperatures under which a particular product will be stored, or the "weight of food" that will be packaged in a particular container, particularly in view of the fact that he may have little or nothing to do with the manufacture of the final food package.

The practice in filing indirect additive petitions heretofore has been to specify in the petition the general types of uses intended for a particular material or component (i.e. film, molded containers or bottles for use in packaging dry, aqueous or fatty foods, etc.). This has adequately served the purposes of the Food and Drug Administration in evaluating the safety of a particular indirect additive under the proposed conditions of use. We know of no incident where such general type of information bearing on proposed applications has hindered FDA in evaluating the safety of a particular additive and, therefore, we can see no useful purpose for requiring such detailed information as is requested by means of proposed Section II, B, 2. Therefore, we urge that Section II, B, 2 be modified to read as follows:

> "2. Indirect additives. If transfer to food results or may be reasonably expected to result

from the use of a food additive in processing, in packaging material, or in food processing and handling equipment, the petitioner shall describe the conditions of use by listing the generic food categories, i.e. fruits, vegetables, meats, etc. to be packaged, as well as temperature limitations (e.g. maximum temperature at which package may be filled, stored or cooled), and, when a petition is submitted by the manufacturer of the food contact surface, area and mil thickness (including weight) of film or other container such as a bottle or coating exposed to food in the minimum size package. The petitioner shall furnish an estimate of the maximum as well as the average quantity of the food additive and, where appropriate, its conversion products to be expected in the generic categories of foods for which coverage is sought. This estimate shall be based on experimental migration data using the food itself or on extraction data using solvents that simulate various types of food. These data shall reflect the most severe conditions, as well as the more usual conditions of the proposed usage. The food or the extracts are to be analyzed by methods of adequate sensitivity and reliability for the food additive components of the food-contact surface. Details of the analytical procedure must be furnished including sufficient data to verify the claimed sensitivity and reliability of the methods."

Re Section 121.50(e)II.C.4.b.

By means of this section, the Food and Drug Administration proposes to require the filing of so-called "intended technical effect data" in connection with indirect Food Additive Petitions.

We have heretofore had occasion to comment extensively on the matter of when such data must be supplied, have vigorously challenged FDA's statutory authority to require these data, and have protested indiscriminate demands for them. For a complete statement of the position of the Society in this regard, including a comprehensive discussion of the legal aspects of the problem, FDA is referred to our "Guidelines Comments", previously mentioned in Note 2 above, and attached to this statement as Exhibit A.

With reference to the precise language used by FDA in the instant proposal, we have observed that, if our reading of the language is correct, Section 121.50(e)II.C.4.b. will not require a petitioner to provide details about the intended technical effect of an indirect additive unless (1) migration of the additive will be a function of the concentration of the component in a food contact article, (2) a tolerance will be required in the regulation, and (3) assurance must be given that only the minimal amount of the additive necessary to accomplish the technical effect will be used so as to avoid excessive use of a substance for which a tolerance is necessary.

If this is indeed what is intended, assuming arguendo, that FDA has the statutory authority to require such information, we have no substantial objection to the provision. However, we respectfully recommend that the Food and Drug Administration

take appropriate steps to revise its "FDA Guidelines for Chemistry and Technology Requirements of Food Additive Petitions" and, if necessary, the proposed Section 121.50 (e)IIC.4.b. so that it can be made clear to FDA staff members, as well as to industry, that FDA will no longer demand technical effect data except where the three conditions listed above exist. In other words, and with reference to the lengthy analysis which appears on Pages 12 through 18 of our Exhibit A, the Food and Drug Administration is urged to clarify both the aforesaid Guidelines and the instant proposed Section of the "Procedural Regulations" so that they will leave no doubt but that indirect food additive petitioners need only supply "minimum-necessary-to-accomplish-the-intended-technical-effect" data where (1) a true "tolerance" is required for the substance in question to assure safety, (2) migration to foods is a function of additive concentration in a food contact surface, and (3) a minimization of the amount of the additive used in a food contact surface is necessary to stay within the in-foods tolerances prescribed.

Re Section 121.50(e)II.E.4.

A minor clarifying addition in this section, which proposes to require ". . . full reports of adequate tests

reasonably applicable to establish whether or not the food additive is safe for its intended use," is recommended so that it will provide for the possibility that no new animal or biological studies might be required for some petitions. This is the case, for example, in situations where FDA already has adequate toxicological data in its files demonstrating the safety of a particular substance, and a petitioner merely wishes to make reference to such studies in his petition. It might also be the case where a petitioner needs only to reference data in a "Food Additives Master File", as suggested in the proposed Section 121.9.

We therefore urge that the following sentence be included at the conclusion of this subsection:

> "In cases where a petitioner is relying on safety data already on file with the Food and Drug Administration, a statement to this effect and otherwise clearly identifying such data shall be sufficient for purposes of this subsection."

Re Section 121.50(f)

For the same reasons set forth in our comments under Section 121.9(c), it is recommended that Section 121.50(f) be revised to read as follows:

> "(f) Data in a petition regarding any method or process entitled to protection as a trade secret will be held confidential

and will not be revealed unless it is necessary to do so in a regulation, or in an administrative hearing preliminary to any judicial proceedings under the Act. The scientific bases of safety on which any food additive regulation rests including food additive analytical methods relied upon for enforcement of a regulation and the petitioner's conclusions of the toxicological basis on which a food additive regulation is based are not considered confidential." (New language underlined.)

IV

IN ADDITION TO CONDUCTING A BASIC REEVALUATION OF THE ENTIRE INCIDENTAL ADDITIVES REGULATORY PLAN, THE FOOD AND DRUG ADMINISTRATION SHOULD PROMULGATE REGULATIONS AND ADOPT NEW PROCEDURES AIMED AT MAKING ITS POLICIES MORE EFFECTIVE AND MORE WIDELY UNDERSTANDABLE

Throughout these comments we have attempted to point up the many reasons which militate in favor of a comprehensive review and reorientation of the incidental additives regulatory pattern. We sincerely hope that the Food and Drug Administration will heed this request and will move immediately, with the help of industry, to pursue such a program. The Society of the Plastics Industry pledges its willingness, indeed eagerness, to participate in such a program to the fullest possible extent. We will spare no effort to work cooperatively with the Food and Drug Administration staff towards achieving a more satisfactory regulatory program.

Whether the government sees fit to bring about such a reevaluation by means of a legislative type hearing, some other investigatory process, or by use of a government-industry advisory committee, is properly the subject for FDA determination, but we cannot urge too strongly that some means of this type be used so that the present problem will not be compounded by a continuation of the policies and procedures now operative.

Aside from this principal recommendation, the following specific suggestions for improvement in current practices are respectfully submitted:

1. We have now had occasion to review the comments in this proceeding submitted by Dr. John P. Frawley of Hercules Incorporated on October 23. On the basis of our evaluation of Dr. Frawley's comments and his excellently reasoned paper submitted simultaneously, the Society of the Plastics Industry hereby endorses the recommendation that Section 121.2500 of the Food Additive Regulations be amended to include a new paragraph 2(d)(5) to read as follows:

"(5) Substances used at a level of no more than 0.2% by weight of the container or no more than 0.2% by weight of the coating or other surface treatment, provided these substances are not heavy metals, as defined in Food Chemicals Codex, or pesticides, as defined in the Federal Insecticide, Rodenticide and Fungicide Act."

Dr. Frawley's proposal, based as it is on firm toxicological conclusions widely supported by experts in the field, is worthy of all due consideration by the Food and Drug Administration. We respectfully submit that it can be adopted within the scope of FDA's broad rulemaking power which allows, and, indeed, even orders the adoption of regulations consistent with the law which will advance the administration of the Food Additives Amendment of 1958.

2. While Dr. Frawley's recommendation might well go a long way towards eliminating many present regulatory problems by setting one of the types of jurisdictional boundaries we have called for herein, we would further recommend that FDA promulgate a new regulation--or publicly announce a new interpretation of Section 121.3 of the present Regulations--which will make it clear

that any party may submit data about a substance intended to be used in a food package, or in food processing equipment, and may thereby obtain a direct and unequivocal response from FDA indicating whether or not it believes such a substance in the intended use described would constitute a food additive or not, within the meaning of the Food Additives Amendment of 1958.

If it is deemed necessary, any such new regulation or interpretation could preclude the misuse of an FDA opinion in this regard in advertising by making it clear (as FDA has in correspondence on occasion in the past) that it is a violation of federal law to advertise that a product is "FDA approved" when, in fact, FDA does not approve products but merely advises on their status in light of applicable regulations.

3. So that many of the very important policy determinations made by the Food and Drug Administration in the course of its day-to-day correspondence, as well as by means

of papers given by FDA officials, will no longer be known only to the well informed few, we strongly recommend that the Food and Drug Administration adopt some procedure similar to the one now in use by the Federal Trade Commission whereby the general public can be advised of advisory opinions or similar pronouncements which have a continuing and significant effect. Whatever formal process is used, such opinions or policy statements should be issued in a way that will permit ready reference and a degree of regulatory permanence. The use of numerical or similar designations for advisory opinions is one way in which this could be done easily.

By way of providing FDA with examples of the type of opinion it should make known through this sort of distribution, a copy of one letter issued by an FDA Staff member in 1963 is attached hereto as Exhibit F. Had this letter been released under the sort of procedure described, the FDA Staff would undoubtedly have been saved the trouble of

writing innumerable additional letters dealing with the same subjects of "mixtures" of cleared substances, and the use of the phrase "FDA approved."

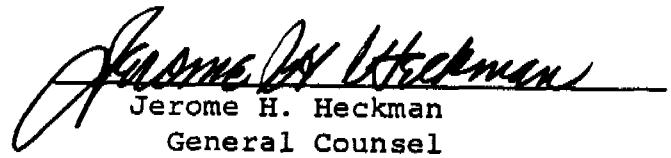
For the administration's further convenience in evaluating the institution of a program similar to that employed by the Federal Trade Commission, we are herewith attaching as Exhibit G, the regulatory provisions governing the FTC's Advisory Opinion activity. As Exhibit H, we are attaching a few samples of typical FTC Advisory Opinions released to the public under the current procedures. It should be noted that, in all cases, confidentiality is to be preserved as regards the identity of, and details about, any party who asks for such a broad interpretation of the law.

* * *

We respectfully request that due consideration be given to all of the foregoing recommendations and that the instantly proposed "Procedural Regulations" be set aside

or withdrawn until such time as the complete reevaluation called for has been undertaken.

Respectfully submitted,



Jerome H. Heckman
General Counsel
The Society of the Plastics Industry, Inc.

DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20201

EXHIBIT F

August 23, 1963

This replies to your letter of August 9, 1963, in which you ask the question: "If polymer A is FDA approved and polymer B is FDA approved, is a blend of polymer A and polymer B FDA approved?" As a specific example you refer to a blend of 0-20% polystyrene and 100-80% high density polyethylene. However, you stated that polymer blends are becoming more and more important in the plastics industry and that you were interested in a general rather than a specific answer. You further stated in your letter that in all cases to be considered, there would be no additives in addition to those approved for polymer A or polymer B and also that the temperature of mixing would be lower than the normal processing temperature for either polymer A or B.

If the polymer blends to which you refer are physical mixtures rather than reaction products, we can provide the following general answer: Where we have declared that substance A is safe for a specified use and that substance B is safe for the same use, then we would agree that a physical mixture of substance A and B would also be safe for such use provided that each individual substance complies with any limitations of its respective regulation. However, if there is a reaction between substance A and substance B which results in the formation of substance C then, unless specifically defined by an appropriate regulation, substance C would not be authorized for use in contact with food and would require a petition proposing a regulation which would prescribe conditions of safe use.

We have taken exception to the phrase "FDA approved" in connection with the marketing of a product which is the subject of a food additive regulation or a prior sanction. We have no objection to statements that a product conforms with any applicable food additive regulations.

Sincerely yours,

William F. Randolph

William F. Randolph
Staff Assistant

AUG 26 1963

ASI 00000267

EXHIBIT C

TITLE 16—COMMERCIAL PRACTICES

Chapter I—Federal Trade Commission

SUBCHAPTER A—PROCEDURES AND RULES OF PRACTICE

PART 1—GENERAL PROCEDURES

PART 2—NONADJUDICATIVE PROCEDURES

PART 3—RULES OF PRACTICE FOR ADJUDICATIVE PROCEDURES

PART 4—MISCELLANEOUS RULES

The following revised general procedures and rules of practice of the Federal Trade Commission shall become effective July 1, 1967:

PART 1—GENERAL PROCEDURES

Subpart A—Industry Guidance

ADVISORY OPINIONS

AUTHORITY: The provisions of this Part 1 issued under sec. 6, 38 Stat. 721; 15 U.S.C. 46.

Subpart A—Industry Guidance

ADVISORY OPINIONS

§ 1.1 Policy.

Any person, partnership, or corporation may request advice from the Commission with respect to a course of action which the requesting party proposes to pursue. It is the Commission's policy to consider requests for such advice and, where practicable, to inform the requesting party of the Commission's views. A request ordinarily will be considered inappropriate for such advice: (a) Where the course of action is already being followed by the requesting party; (b) where the same or substantially the same course of action is under investigation or is or has been the subject of a current proceeding, order, or decree initiated or obtained by the Commission or another governmental agency; or (c) where the proposed course of action or its effects may be such that an informed decision thereon cannot be made or could be made only after extensive investigation, clinical study, testing, or collateral inquiry.

§ 1.2 Procedure.

The request for advice should be submitted in writing to the Secretary of the Commission and should include full and complete information regarding the proposed course of action. Conferences with members of the Commission's staff may be held before or after submittal of the request. Submittals of additional information may be required. The original submittal should affirmatively show that the proposed course of action is not currently being followed by the requesting party and is not the subject of a pending investigation or other proceeding by the Commission or any other governmental agency. If the request is for advice as to whether the proposed course of action may violate an outstanding order to cease and desist issued by the Commission, such request will be considered as provided for in § 3.61 of this chapter.

§ 1.3 Advice.

(a) On the basis of the facts submitted, as well as other information available to the Commission, and if practicable, the Commission will inform the requesting party of its views and may take such other action as may be appropriate.

(b) Any advice given is without prejudice to the right of the Commission to reconsider the questions involved and, where the public interest requires, to rescind or revoke the advice. Notice of such rescission or revocation will be given to the requesting party so that he may discontinue the course of action taken pursuant to the Commission's advice. The Commission will not proceed against the requesting party with respect to any action taken in good faith reliance upon the Commission's advice under this section, where all relevant facts were fully, completely, and accurately presented to the Commission and where such action was promptly discontinued upon notification of rescission or revocation of the Commission's approval.

§ 1.4 Publication.

Texts or digests of advisory opinions of general interest will be published by the Commission, subject to statutory restrictions against disclosure of trade secrets and names of customers and to considerations of the confidentiality of commercial, financial, and other facts involved and of meritorious objections made by the requesting party to such publication.

INDUSTRY GUIDES

§ 1.5 Purpose.

Industry guides are administrative interpretations of laws administered by the Commission for the guidance of the public in conducting its affairs in conformity with legal requirements. They provide the basis for voluntary and simultaneous abandonment of unlawful practices by members of industry. Failure to comply with the guides may result in corrective action by the Commission under applicable statutory provisions. Guides may relate to a practice common to many industries or to specific practices of a particular industry.

§ 1.6 How promulgated.

Industry guides[1] are promulgated by the Commission on its own initiative or pursuant to petition filed with the Secretary or upon informal application therefor, by any interested person or group, when it appears to the Commission that guidance as to the legal requirements applicable to particular practices would be beneficial in the public interest and would serve to bring about more widespread and equitable observance of laws administered by the Commission. In connection with the promulgation of industry guides, the Commission at any time may conduct such investigations, make such studies, and hold such conferences or hearings as it may deem appropriate. All or any part of any such investigation, study, conference, or hearing may be conducted under the provisions of Subpart A of Part 2 of this chapter.

Subpart B—Rules and Rulemaking

§ 1.11 Scope of the rules in this subpart.

The rules in this subpart apply to and govern procedure for the promulgation of trade regulation rules, quantity limit rules, rules authorized under the Wool Products Labeling Act of 1939, the Fur Products Labeling Act, the Flammable Fabrics Act, and the Textile Fiber Products Identification Act, and rules under the Fair Packaging and Labeling Act except to the extent that objections to orders relating to the issuance, amendment, or repeal of rules under the latter Act are required by statute to be determined on the record after opportunity for an agency hearing. The rules in this sub-

[1] In the past, certain of these have been promulgated and referred to as trade practice rules.

EXHIBIT H-2

FEDERAL TRADE COMMISSION

Washington, D.C. 20580

OFFICE OF INFORMATION 393-6800 Ext. 197

For RELEASE: A.M. Wednesday, August 30, 1967

ADVISORY OPINION DIGEST
NO. 139

PERSONAL DEODORANT SPRAY

The Commission announced today it had rendered an advisory opinion in regard to some proposed advertising claims for a personal deodorant spray.

Specifically, the Commission considered the propriety of the following two claims: (1) that the product meets the U.S. Government requirements for safety and effectiveness and (2) that no other medicated personal deodorant spray equals its safety and effectiveness.

In regard to the first claim, the Commission said there were no specific standards or requirements officially recognized by the U. S. Government relating to the safety and effectiveness of personal deodorant sprays. Under these circumstances, therefore, the Commission said it would be improper to claim that such requirements exist and that the product meets those requirements.

With respect to the second claim, the Commission said that opinion evidence indicated there are other medicated deodorant sprays on the market which are equally as safe and effective as the product in question. In view of this opinion evidence, and in the absence of reports of properly controlled studies establishing the validity of the claim, the Commission said that it could not give its approval to the second claim.

NOTE: In conformity with Commission policy concerning publication of digests of advisory opinions, this news release is the only material of public record. The advisory opinion itself and all background papers are confidential and are not available to the public.

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EXHIBIT H-3

NEWS RELEASE

FEDERAL TRADE COMMISSION

Washington, D.C. 20580

OFFICE OF INFORMATION 393-6800 Ext. 197

For RELEASE: A.M., Friday, September 29, 1967

ADVISORY OPINION DIGEST
NO. 144

PROPOSED LICENSE AGREEMENT
FOR PROCESS PATENT

The Commission recently rendered an advisory opinion in which it informed the owner of patented process for preparing food that it could see no objection to the form of a proposed licensing agreement with the food processing industry.

The proposed agreement, which was the only form of agreement to be used, was described as nonexclusive in nature and provided for the licensees to use the process and machinery at one uniform rental rate regardless of the physical location of the licensee. Although the process patent contemplates the use of the machinery and the agreement contemplates use by the licensees of that machinery, there is no absolute requirement that the licensees use any particular machinery in connection with the process.

The hourly rental to be charged all licensees was to be measured by a meter attached to the machine and the licensor reserved the right to cancel the license if the annual rental due from operation of the machinery fell below a stated minimum amount, unless the licensee paid the difference between the actual rental due and the required minimum. The duration of the agreement was to be for a period of five years.

The Commission advised that while it did not purport to pass upon the purely contractual aspects of the agreement, it could see no objection to the form of the agreement from the standpoint of the laws it administered, as distinguished from matters pertaining to the implementation thereof.

NOTE: In conformity with Commission policy concerning publication of digests of advisory opinions, this news release is the only material of public record. The advisory opinion itself and all background papers are confidential and are not available to the public.

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EXHIBIT H-1

NEWS RELEASE

FEDERAL TRADE COMMISSION

Washington, D.C. 20580

OFFICE OF INFORMATION 393-6800 Ext. 197

For RELEASE: A.M., Thursday, July 13, 1967

ADVISORY OPINION DIGEST
NO. 133

AGREEMENT AMONG MEMBERS OF TRADE ASSOCIATION TO COMPLY WITH GOVERNMENT RULING.

A trade association recently requested an advisory opinion as to its proposal to hold joint discussions among its members as to the proper description of the industry's product looking toward a possible agreement among all concerned to comply with ruling of a government agency as to how the product should be labeled. The Association assured the Commission that the discussion would be for this limited purpose only and that there would be no price fixing, monopoly or other antitrust question involved.

The Commission advised that there could be no objection to a discussion among the members looking toward a limited agreement to comply with this ruling on a voluntary basis. The members were further advised, however, that nothing in this opinion was to be construed as approval of any steps which might be taken by the members, acting in their private capacity, to enforce this ruling themselves as to any members who might be inclined to agree. Such approval as was given was limited to the simple agreement in principle to comply with the ruling, with enforcement being left to the properly constituted government authorities.

Note: In conformity with Commission policy concerning publication of digests of advisory opinions, this news release is the only material of public record. The advisory opinion itself and all background papers are confidential and are not available to the public.

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EXHIBIT H-4

FEDERAL TRADE COMMISSION

Washington, D.C. 20580

OFFICE OF INFORMATION 393-6800 Ext. 197

For RELEASE: A.M., Tuesday, October 24, 1967

ADVISORY OPINION DIGEST
NO. 146

REQUEST FOR REVISION OF ADVISORY OPINION PERTAINING TO USE OF THE WORD "NEW"

The Commission was recently requested to reconsider and revise its advisory opinion as to the permissible period of time during which an advertiser may continue to describe a new product as being "new." The opinion in question was announced in Advisory Opinion Digest No. 120 and took the position that until such time as later developments may show the need for a different rule, the Commission would be inclined to question use of any claim that a product was new for a longer period of time than six months.

The request was that the Commission revise this opinion to omit specifying any time limit or, in the alternative, to specify a period of at least one year, with the same proviso as was written into the present opinion that exceptional circumstances may warrant a longer or shorter period. In response to this request, the Commission stated its basic conclusion that the general rule announced in the opinion, which was announced as the rule which would be followed until later developments might show the need for a different rule, has not been in existence long enough for the accumulation of any additional experience which would indicate the need for a change at this time.

However, the Commission did take note of the argument that six months is not adequate time for test marketing new products, which are usually tested in areas representing between 1% and 15% of the population and run for an average of six months to two years. In this regard, the Commission advised that the six months rule announced in its previous opinion does not apply to the bona fide test marketing of a new product. So long as the test marketing program does not cover more than 15% of the population, so long as the test period does not exceed six months in duration and so long as it is being conducted in good faith for test purposes only, the Commission stated that it did not intend to apply the six months rule until the test period had ended and the product had been introduced to the general market.

The requesting party had further contended that the time selected was not long enough to cover the average life of packaging materials and advertising literature and thus would necessitate scrapping such materials after the time had expired. With respect to this point, the Commission stated that while it was always anxious to minimize such losses to advertisers whenever it could do so consistently with its duty to protect the public from deception, it would seem that here the advertiser is peculiarly in control of the situation and able to protect himself against being caught with a large inventory of such materials on hand.

When an advertiser introduces a new product to the market he is at that time on notice that the claim "new" can remain valid for only a temporary period of time and he is at that time charged with the responsibility of preparing only so much material containing the word as can be used within the period of time during which the product can accurately be described as new. Even granting that one cannot predict with mathematical accuracy how fast the inventory will be consumed, still one experienced in such matters should be able to predict with reasonable accuracy how much will be needed for six months use and be prepared to discontinue use of such material at the end of that time without the loss of significant amounts.

Finally, the Commission stated that it had announced in its first advisory opinion on this subject (Advisory Opinion No. 120) that shorter or longer periods of time would be considered for particular products upon a showing that such different period was more appropriate for the product in question. No such showing had been made on this application warranting the Commission to make any change in its announced time period.

NOTE: In conformity with Commission policy concerning publication of digests of advisory opinions, this news release is the only material of public record. The advisory opinion itself and all background papers are confidential and are not available to the public.

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