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July 11, 1972

Dr. Karl A. Hochschwender
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Dear Karl:

With the usual permission of the Editors of Food Chemical News, I am enclosing herewith reproductions of pages 24 through 30 of this week's edition since these pages contain a good summary report on some of the many comments filed in connection with the so-called "Freedom of Information" regulations rulemaking proposal. I think you and the other members of the Committee will see that just about every point one might imagine has been raised by the commenting parties. I can tell you from other contacts that even more in the way of comment of interest to our group was submitted, especially as regards preservation of confidentiality of data in New Drug Applications and Drug Master Files.

Actually, since I believe most of our Committee members now see Food Chemical News, I would suspect that my sending the reproductions may be a little redundant. Nevertheless, I thought it would be best to forward the material, especially since we were not instructed to file comments on behalf of SPI in this proceeding, nor do I think it was necessary for us to do so. The only thing I might add on this score is that every inquiry we received from our Committee members prior to the July 6 deadline date related to specific problems, all of which involved preserving the confidentiality of

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Drug Master File data. In every instance we advised the calling party that our suggestion was that they write to the Office of Scientific Evaluation of the Bureau of Drugs, reference their Drug Master File or files, and ask that a letter be placed in each file asserting that they consider the data in the file a "trade secret," the confidentiality of which should be preserved even if the rule making is adopted in the present form since it specifically states that trade secrets will continue to be kept confidential. Even Peter Hutt has publicly stated that such data relative to drug situations should be treated confidentially since drug regulation is of the licensing variety.

If any of you have not written such letters and feel you should do so, we might note that we believe one point you should include in your letter is the notation that the reason a Drug Master File was established in lieu of providing a prospective new or supplemental new drug applicant with the information (e.g. a formulation or process) is precisely because the data was considered a trade secret.

There is one other bit of information about this rule making which I would like to call to your attention. A number of members of the organized Bar here in Washington have been meeting in recent months to discuss various Food and Drug Administration problems. One of the ones on which we have been focusing has been the "Freedom of Information" question. A few weeks ago we discussed the possibility of either filing comments as a Bar group on the proposal, or sponsoring a small "Seminar" at which representatives of FDA, consumer activists, and private legal practitioners would be invited to speak and exchange views on interpretations relating to disclosures. At one point, we had set a tentative date for such a Seminar, having decided that this would be a better approach than the filing of comments.

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Larry Wood, the President of the Food and Drug Law Institute, with whom I have been working on establishing a more effective local Bar approach to FDA problems, has now talked with FDA about this concept. He has been advised informally that, even though the comment deadline date for the "Freedom of Information" rule making proceeding will not be formally extended, FDA will continue to receive comments for a time and does not believe it will finalize the proposal until late Fall, if then. Thus, the Seminar idea has not been cast aside but has been postponed. What we have been advised is that Peter Hutt and his associates would probably be willing to participate in such a session in September, and that holding it then will still be timely in light of FDA's preoccupation with a myriad of other rule makings now flowing like wine from the Agency.

I just thought I would pass this collateral information along since the timing question might be of considerable interest to the members of our group.

There is perhaps one other subject which I will mention briefly here since we have been receiving so many questions about it lately.

As you know, the Food and Drug Administration's "Proposal for use of Colorants for Plastics," published in the June 6 Federal Register has been the subject of much consternation, confusion, and correspondence. Among other things, we have good reason to believe that FDA misunderstood or misinterpreted much of the data previously submitted to it when it proposed the extraction criteria for chromium oxide green and phthalocyanine green. Some of the members of our Committee have been in direct contact with the FDA Staff in these and other respects.

We are presently preparing a set of draft comments which we would hope to be able to send to you by July 28, at the latest, the filing deadline

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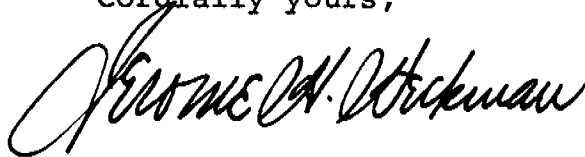
date being August 7. Actually, this is another case where we are certain that FDA will follow its new "policy" of receiving comments after the deadline if necessary so the deadline date need not be considered totally crucial.

I will not attempt to outline the form of the comments we propose to submit to you now. However, I might mention that we definitely intend to suggest strongly that the final rule making, or at least the preamble of the order adopting it, note that the applicability of the "no migration" policy enunciated in the Tom Brown letter and the FDA Regulations (Section 121.1(e)) be mentioned since the list of colorants in the June 6 proposal is by no means adequate vis-a-vis present industry practice and usage.

In any event, you will have ample time to review our draft in due course so I am merely letting you know by means of this letter that we have something in the works which you will ultimately receive. I might also take this opportunity to thank those who have written to us on this subject and thereby let them know that their comments are not being overlooked.

If you have any questions about any of the topics covered herein, please do not hesitate to let us know.

Cordially yours,



Enclosures

cc: SPI Food, Drug and Cosmetic Packaging Materials
Committee

In the new contracts, FDA also asked the States to place priority on manufacturers of food and cosmetics by volume of business, followed by repackers and private label distributors.

GUIDELINES FOR CONFIDENTIAL DATA IN PETITIONS URGED

Noting that data in Food Additive Petitions would be excluded from the disclosure provisions of the Food and Drug Administration's proposed freedom of information regulations (See FOOD CHEMICAL NEWS, July 3, Page 25) only under "extraordinary circumstances," Campbell Soup last week urged FDA to propose "guidelines" to establish these "extraordinary circumstances."

The firm said the guidelines should be "adequate to preclude public disclosure of such data." Campbell said that "by leaving open the meaning of 'extraordinary circumstances,' the FDA has proposed a regulation which must discourage further filings since companies uncertain as to what circumstances may be considered extraordinary by the FDA will, when appropriate, avoid the filing of any Petition."

The result of this, Campbell wrote, "would be less public disclosure and public awareness than under present regulations."

Campbell Soup noted that under the FDA proposals, protocols would be made available to the public, except where confidentiality or a trade secret is established. The firm said:

"The provision that the information must provide a competitive advantage to be regarded as confidential, while perhaps appropriate to research data on the safety, functionality and effectiveness of a wide variety of ingredients and products submitted to FDA, is not appropriate to other areas covered by the proposed regulation where the protection afforded by the exemption is important to the individual and disclosure is not necessary for the public interest."

The National Confectioners Association said a firm submitting a Food Additive Petition or Color Additive Petition should "not be under such a burden" of establishing confidentiality of the data. NCA said:

"The company may have submitted the information at various times and places, but which has not resulted in public disclosure and which as far as the public is concerned would not have come to its attention any more than if the information has been retained entirely within the company. If a company voluntarily submits information and data . . . and it classifies it as confidential, it should not be made public unless the company voluntarily changes its classification, which it might choose to do if requested by FDA."

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American Cyanamid urged FDA to delete the concepts of "good cause" or "extraordinary circumstances," saying that, "A document either is or is not a trade secret as defined."

Regarding data in New Animal Drug Applications, the company urged that FDA guard as "trade secrets" safety and effectiveness data, protocols, formulae, manufacturing methods or processes, quality control procedures and sales data, making public adverse reaction and complaint data, and product experience.

Ralston Purina said FDA's regulations should make it clear that even after a New Animal Drug is a "not new drug," is withdrawn, or is subject to abbreviated New Animal Drug Applications, the formula information and manufacturing and control procedures should remain confidential.

The Midwest Feed Manufacturers Association said placing on industry the "burden of proof" that data should not be made public is "harassment." MFMA said:

" . . . Even the most innocuous seeming data acquired by a manufacturer who pioneered in a product development can . . . represent a free gift to a would-be competitor who comes along later and does not have to invest in research facilities or time to acquire this basic information. . . . FDA does not possess the omniscience to evaluate scientific data for its commercial value."

National Starch and Chemical hit the proposal that Petition data which are "not the type of valuable commercial information" will be made public unless extraordinary circumstances are shown, saying, "Such data represent an investment by a company which should be protected."

As an example, the firm hypothesized that Company A filed a Petition, and an Order was issued. Saying that the Petitioner may want to market the additive in a foreign country, but wishes to wait until the time is right, National Starch and Chemical wrote: "In the past Company A knew that its investments in feeding studies, analytical studies, etc., were protected and were considered confidential by FDA." However, the firm said, under the proposed policy, Company B could have access to this information, and "could use it to clear and sell such an additive in other countries."

FDA's proposal appears to place "the onus . . . on the wrong party," National Starch said, explaining: "One who files a Food Additive Petition now has the burden . . . of arguing the confidentiality of his information. 'The public' apparently doesn't have to justify any compelling need or cogent reason for requesting the information."

Taking the opposite viewpoint, the Environmental Defense Fund said FDA should have flatly made data in Petitions open to the public "rather than making it appear to be a determination of fact subject to contradiction in extraordinary circumstances."

The National Flexible Packaging Association urged that FDA should "make it clear that the list of ingredients or any one or more of the ingredients shall not be disclosed if marked confidential and if good cause is shown to justify the confidentiality."

NFPA said this is needed to resolve an inconsistency between a section that says a "particular ingredient" may be excluded from the list of disclosed ingredients upon a showing that it is a trade secret, and a section which provides that all data submitted voluntarily and marked confidential will not be disclosed if good cause is shown to justify confidentiality.

A number of the comments raised questions about a proposed provision that data may be claimed to be confidential only if it has been disclosed to no one other than employees of a firm or paid consultants of that firm.

BASF noted that "confidentiality is lost when information has in any way previously been furnished to anyone other than an employee or paid consultant in an authorized manner by any person," saying "this would also exclude information from confidentiality that has been given to health authorities outside the U.S.A. with the understanding that it was to be kept strictly secret."

Badische Anilin & Soda-Fabrik explained that it usually presents a new product to German authorities, and if they say there is no hazard the additive is then presented for clearance in the U.S. BASF said, "Incalculable damage would be caused if such absolutely confidential information were excluded from confidential treatment by the FDA."

American Cyanamid said the provision that disclosure could be made only to employees and consultants is "too narrow and unrealistic." Ralston Purina said, "There are others to whom confidential information may be given without its being considered as public," giving as examples the supplying of formulation and processing methods to contract manufacturers. The company also noted that "many of the regulatory agencies require the submission of confidential information."

Suggesting a competitive disadvantage for firms required by law to obtain agency approval of a product or ingredient prior to marketing, National Starch and Chemical said:

"What about information that has been submitted on a confidential basis to the food and drug officials of other countries? Does this mean that if the information has been disclosed on a confidential basis to these official agencies, FDA will not keep the information confidential? Also, on occasion information may be disclosed to a customer or some other company under a secrecy or confidentiality agreement. This should not give FDA grounds to disallow confidentiality of information submitted . . ."

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The opposite viewpoint was taken by EDF, which said it is "dismayed that the more liberal policy expressed in parts of the new regulations is not more clearly articulated." The Fund hit the exemption for confidential information because "there is no justification in the Freedom of Information Act for an exemption which enshrouds in secrecy any information which is not protected by the 'trade secret' exemption."

Urging public release of all assay methods and protocols, EDF said FDA should provide that "no trade secret or confidential information justification is sufficient to overcome the public interest in disclosure."

Cyanamid asked for "a definition of trade secret addressed to knowledge, not use, recognizing the criteria of whether the data are valuable and not normally disclosed or published openly."

Campbell Soup said the agency's proposal would "affect information currently in the possession of the FDA that has been submitted voluntarily," protesting that the proposal offers "no outer time limit as to previously filed data. . . ."

The company urged that the disclosure provisions "should not apply to material filed more than two to three years ago," saying that without such a cut-off date "it will be necessary to review filings with the FDA for a period far longer than is practical for reasonable public disclosure." If there is a cut-off time, Campbell said, "In special cases, upon adequate showing of need and after notice and opportunity to review given to the party involved, these files, too, could be made available for public scrutiny."

Cyanamid said that if no claims of trade secret status have to be made with respect to data already on file, neither FDA nor industry will have to review the files.

The company asked that demands for data be forwarded to whoever supplied that data, giving the firm 30 days to identify what it considers to be trade secrets, or to furnish the documents to the person requesting them. FDA would furnish copies of everything not claimed as trade secrets and not furnished by the firm. Under the American Cyanamid proposal, the person requesting the information and the firm could present arguments to FDA's General Counsel, and the General Counsel's decision could be appealed in a Freedom of Information Act lawsuit or injunction request.

National Starch and Chemical said old Food Additive Petitions are "water over the dam, since they are protected under §121.51(h) of the food additive administrative regulations. The company explained:

"Petitions having been submitted and accepted on this basis, we do not recognize the right of FDA to unilaterally decide that this information will no longer be held as confidential unless past Petitioners go to considerable time and expense to justify confidentiality. If, and when, an issue is raised concerning the availability of some specific information, the

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question of releasing the information can be considered at that time. In such a case, the person seeking the information should justify why the data should be made available."

A number of letters noted that the final decision on whether a piece of information is made public rests with FDA's Assistant Commissioner for Public Affairs. Comments contained suggestions that (1) decision of the Assistant Commissioner be applicable to the courts, with time allowed for such appeals, and/or (2) firms be permitted to withdraw Petitions if the Assistant Commissioner rules for public disclosure.

The National Flexible Packaging Association said that "some Petitioners would prefer not to file a Petition rather than risk disclosing confidential information." The group asked for a provision "that a Petitioner may withdraw the Petition (and avoid disclosure) if the Assistant Commissioner decides against confidentiality."

Ralston Purina urged that provision be made for appeals from decisions by the Assistant Commissioner, and Mead Johnson urged that a reasonable time be allowed for court appeal before the information is disclosed to the public. National Starch and Chemical asked if, after a decision by the Assistant Commissioner, the Petitioner may "withdraw his Petition and have all copies of the Petition returned to him to protect his information?"

Campbell Soup questioned public disclosure of FDA investigatory files, saying that "the very fact that an investigation is contemplated or commenced would be disclosed to the public without regard to the ultimate outcome of such investigation." The company wrote:

"Such disclosure could easily result in a substantial disservice to the company involved if allegations which may or may not be established in the future as fact are published. It is manifestly clear that all such files should be made available only upon a showing that enforcement action is necessary. Even then, disclosures should only be made upon termination of the proceedings. If this precaution is not taken, a premature leak of mere allegations can result in undue pressure placed on the FDA for a given outcome of the investigation."

The National Confectioners Association asked, "After a file has been 'closed' or after the statute of limitations has run, then should the file be made public or 'reopened' if the FDA has investigated the matter and decided not to institute legal action?" Asking "Why should the information it assembled which it decided does not justify legal actions be released to the public?" The Association commented: "To do so would encourage a 'trial by press' with its possibly equally or greater penalizing than a trial by law which the FDA has decided could not be maintained."

Also questioned were proposals to make public records of all informal enforcement actions, including letters to and responses from companies following inspections, recall or detention requests, and letters to companies requesting corrective measures.

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Campbell Soup said that if these are to be made available, FDA should require them to "contain a section providing for an overall description of the premises in question," adding: "In this manner, the public is afforded an opportunity to draw accurate conclusions as to the overall conditions that exist." Campbell commented:

" . . . By making available to the public records of even minor or routine administrative actions, the proposal offers an opportunity to obtain and publish, out of context, critical material. Observations made by FDA inspectors at food processing plants may comment on a number of relatively inconsequential and minor situations. As minimal as these adverse findings may be, they can lend themselves to irresponsible exaggeration by the media and/or special interest groups looking for a sensational report."

National Confectioners Association said it would be "both unfair and self-defeating" to make public informal enforcement actions, explaining that most companies now cooperate with FDA. Under the proposal, NCA said, "a company may well decide that if it should comply it would constitute an admission of guilt when such would not be the case but merely a desire to cooperate." Therefore, the group wrote, "As a result the company may feel that it is placed in a position where it cannot cooperate."

Ralston Purina, discussing correspondence following an inspection, said many such letters contain confidential information regarding processing, formulations and controls. "We believe that it would be detrimental both to the regulatory agency and to the industry should this information be made public," the company said.

There were also criticisms of the proposal to make public summaries of memos, letters, phone calls and meetings. This section would exempt intra-agency materials, but would make public factual information. Campbell Soup commented:

"The regulation seems to imply that the content of intra-agency or inter-agency memoranda are accurate, appropriate or even true. Before such memoranda are made available to public scrutiny, the FDA should at least provide the parties involved with an opportunity to question and contest, where appropriate, the ex parte conclusions reached by the FDA or other agencies.

"By the same reasoning that we find the unchecked release of intra-agency or inter-agency memoranda unacceptable, so do we reject the position that a summary of a telephone call or meeting involving any person who is not a government employee or special government employee is available to public disclosure. . . . Without review by such companies or persons, the available material may include misquotations, inaccurate transcriptions and one-sided interpretations."

Ralston Purina said, "With particular reference to telephone conversations, we would compare this to wiretapping," adding: "Evidence of this nature is not even permissible in a court of law so that we seriously question why notes taken on a telephone conversation or a personal communication should be made available to the public. This will have an extremely detrimental effect upon the exchange of information between industry and the agency."

Campbell urged that the regulations "should make clear that requests for confidential treatment are, themselves confidential," saying that "disclosure of the request might well be tantamount to disclosure of the data."

National Confectioners Association said "the product complained of would be identified, but the person complaining would not be identified," inviting "malicious and evil intended comments that would not need to be justified . . ."

Ralston Purina discussed the proposal to make public complaint information, saying, "It is well known that many of the complaints which are received . . . are not based on fact." The firm said a complaint should only be made public if it "has been confirmed by investigation to be legitimate and product-related." Ralston wrote, "Neither the general public nor the press have the capability and resources to determine whether or not a complaint is justified."

The National Flexible Packaging Association asked that FDA provide that information contained in a pending patent application is "prima facie confidential and not subject to disclosure."

The Greenhouse Association, representing producers of organic foods, endorsed the FDA proposals. EDF asked FDA to "make explicit what recommendations it has made on the many occasions it has urged a Congressional review of the statutory provisions denying public access to information contained in its files."

The National Confectioners Association said that "it seems definite that if a proposed regulation becomes effective, industry policy necessarily will have to change considerably to one of giving to the FDA only that information which is required by law."

Many of the other comments submitted on the proposals centered on New Drug Applications and Investigational NDAs. Among those who commented recently were Burroughs Wellcome, Beacham, Lederle Laboratories, The Regulatory Authorities for Pharmaceutical Products in Switzerland, Merck, Ciba-Geigy, Sandoz-Warner, the American Pharmaceutical Association, and Sinclair-Koppers.

FDA INVITES CONSULTANTS TO WORK ON ANTIBIOTIC PROTOCOLS

The Food and Drug Administration has invited a number of academic experts to serve as consultants in working out model protocols for studies of low-level antibiotics in animal and poultry feed (See FOOD CHEMICAL NEWS, April 24, Page 50).