LAW OFFICES
KELLER AND HECKMAN
1150 17TH STREET, N. W.
SUITE 1000
WASHINGTON, D. C. 20036

TELEPHONE
202 296-2700
CABLE ADDRESS "KELMAN"

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BORGHESANI, JR
ROBERT R TIERNAN
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DAVID L. HILL
MARTIN W BERCOVICI
MARC E SHAYE
LELAND J BLAIR
PETER M. NEMKOV

April 28, 1972

Mr. Robert M. Miller
Hercules, Inc.
Delaware Trust Building
Wilmington, Delaware 19899

Dear Bob:

Once again I am in the position of having to try to provide you and the other members of the Food, Drug and Cosmetics Packaging Materials Committee with what will amount to a sort of "catch up" report. Since we have been seeing each other quite frequently lately, I know that you understand why we are a bit behind in reporting on developments of great interest. My hope is that this letter will give the rest of the Committee some idea of what is "in the works."

Firstly, I want to direct your attention to the lead article which appeared in this week's issue of Food Chemical News. I am enclosing a copy of the one page story with the permission of the editors. Once again, however, I would like to urge that all members of the Committee who can possibly do so subscribe to the publication since I believe the "incidental additives," as well as many other situations of interest, are heating up to the point where it will be virtually impossible for us to keep everyone informed with as much currency as we would like on all of the items of interest.

Food Chemical News is actually leading the way with many of its stories in bringing possible future developments to light. Thus, and while we assure you that we have no pecuniary interest in the publication's present or future, we do believe that

all of you will benefit by having the information that appears in the publication. At the same time, and especially in light of some of the types of calls we receive so often, we should point out that you should not view FCN as an official Food and Drug Administration spokesman. Some of the predicting action type stories, such as the one enclosed, foretell only possibilities which may not come about for some time, if ever.

To return to the point, immediately after we saw the attached article which, incidentally, coined the new phrase "post-sanction" letters, we did a good bit of contacting of our sources at FDA. Among other things, a primary objective of making the contacts was to get a reading on what was meant by the statement in the Food Chemical News story to the effect that: "Current feeling at FDA is that substances fall into only three categories: (1) Prior sanctions; (2) 'Generally recognized as safe;' and (3) Regulated additives." Our main concern, of course, was what this might mean as regards substances we continue to consider "non-additives," i.e. substances which may not reasonably be expected to become components of food.

I spoke with Peter Hutt, the General Counsel of the Food and Drug Administration, on this subject yesterday and was pleased to be advised that, as he views it, "nothing has changed" as far as the content of the so-called "Tom Brown letter" of August 21, 1970 is concerned. This means that there still is and will be such a thing as "non-additive" status although there may ultimately have to be some system for listing substances which have been declared to be in this category under specified conditions, or for designated uses.

The one trouble with the advice we received from Peter Hutt is that we are not certain it has drifted down to the people working at the Bureau of Foods. For the moment, let me simply assure you that we plan to do everything we can to bring about a closing of this communications gap. Furthermore, we

are now attempting to set up some additional informal talks relative to the indicated intention of FDA to set up a new listing of "insignificant" levels of migrants, this being something like a plan we suggested to FDA during the ill-fated session we had some time ago to try to bring about definitive action on the Ramsey proposal.

Any progress we make in this connection will be reported to you as promptly as possible. I can tell you that we already have it on good authority that Dr. Wodicka, the Director of the Bureau of Foods; and Richard Ronk, the new Chief of the Petitions Processing Branch, advise that (1) FDA is now very eager to reduce significantly all time delays in its petition work, and (2) is anxious to develop a system to clear "insignificant" migrants on a rapid fire basis with "much less data" then heretofore demanded. Needless to say, we have advised Mr. Ronk that these are long cherished goals of ours--a fact he said he was well aware of--and would be willing to help in any way he can. At the same time, I should caution that all of our sources lead us to the conclusion that any new guidelines FDA may establish in this area are not to be expected momentarily, even though you might gather that something is imminent from the Food Chemical News article.

Let me turn now to two other subjects of great interest since I am sure some of you must be wondering where we are with respect to them.

Firstly, concerning the polychlorinated biphenyls rulemaking proposal, on which comments are due by May 17, you are aware that we have had a number of meetings and conversations with you and representatives of some of the other packaging industries. The only reason the Committee has not heard from us about the matter recently is that we have not completed a draft of proposed SPI Comments which we have been planning

to send to everyone for review prior to filing. We hope to have such a draft in reasonably good shape some time next week and will then send it for your reactions.

Generally speaking, the position we will enunciate in the draft is that the 5 ppm limitation should be applied only to foods, not packaging materials, and that, in any case, the new rules should not be made applicable to plastics packaging at this time because (1) the known test methodology for PCB analysis is not suitable where plastics are concerned, and (2) by FDA's own admission, PCB contamination of foods as a result of plastics packaging has not been the subject of concern. Again, we hope to have a draft in your hands within the next week or so which should allow sufficient time for you to review our attempt and advise us if you feel our approach is incorrect, or should be revised.

Finally, we also hope to send you, simultaneously with the PCB Comment draft, a proposed set of Comments on the new GRAS regulations change published in the March 25, 1972 edition of the Federal Register. In this instance, the comments we would propose to submit will be quite lengthy since our plan is to use this opportunity to press once more for special treatment of indirect additives along the lines originally contemplated by the Ramsey proposal. For the moment, I will simply ask for a little more of your patience while letting you know that we have no intention of passing up this opportunity to try in another way to bring about some general improvement in the entire incidental additives regulatory structure.

There are, of course, many other subjects of interest to the Committee which might well warrant further reporting here. However, perhaps the information we are conveying will serve to post you on the projects of most immediate concern, and let you know that you will be hearing from us again soon. If you

have any questions in the meantime, we trust you will not hesitate to call or write.

Cordially yours,

Jerome H. Heckman

Enclosure
cc: SPI Food, Drug and Cosmetics Packaging Materials Committee

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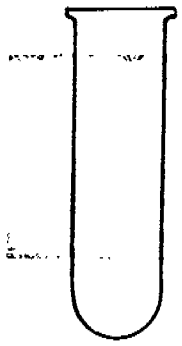

FDA DECIDES TO END USE OF "POST-SANCTION" LETTERS

The Food and Drug Administration has decided to eliminate the use of so-called "post-sanction" letters permitting minute levels of indirect additives in food from packaging uses.

The decision to discontinue the practice came as a result of an industry dispute in which a company challenged the legality of an informal approval held by another only to find out that the "post-sanction" letter was, in fact, valid.

The use of the letters has been in dispute at FDA for some time, but the new controversy resulted in a reappraisal of the practice. The letters, which are sometimes used to inform inquirers that they have "no food additive problem," based on the minute or trace levels of migration expected, will notbe revoked under the new policy.

A New Subpart under §121 to Be Used to List Minor Migrants

However, FDA-ers will now require a listing under a new §121 subpart for "insignificant" levels of migrants from food packaging materials. Data required for this type of listing are not expected to be as extensive as now expected from firms who go through the Food Additive Petition process to clear indirect additives with problems of toxicity.

FDA-ers are now attempting to establish guidelines for this type of procedure.

Current feeling at FDA is that substances fall into only three categories: (1) Prior sanctions; (2) "Generally recognized as safe;" and (3) Regulated additives.

The new listings will bring these indirect additives into regulated status, and, once published, unless protected by patents, like other Food Additives, can be manufactured by any company.

The current dispute erupted from a competitive battle. One firm held a letter; the other did not. FDA decided the "post-sanction" letter to one resulted in a competitive advantage.

The new approach is expected to put all companies on an equal footing.