

JUL 23 1970

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July 20, 1970

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

Dear Bob:

Enclosed herewith, simply for your information, is a copy of a congratulatory letter I have now directed to Bill Randolph, formerly of the Division of Regulations and Petitions Control of the Office of Compliance of the Bureau of Foods, Pesticides and Product Safety; and now in the office of the Associate Commissioner for Compliance.

By way of a personal comment on this staff shift at FDA, let me simply note that I think it might prove a very worthwhile one for all concerned. This will depend, of course, on how well Bill Randolph is able to use the knowledge he has acquired to help with the solution of some of the problems of concern to all of us. I do know that Bill has been disenchanted with such concepts as the current FDA "no migration" policy, and was anything but pleased with the development, publication, and confusion created by the April 9 FDA Statement of Policy relating to GRAS and prior sanctioned substances. Perhaps he will now have a meaningful way to make his opinions known. In any event, we intend to maintain our close relationship with him so that we can obtain a better idea of where FDA's "front office" is going on some of these issues.

ASI-PR 0000827

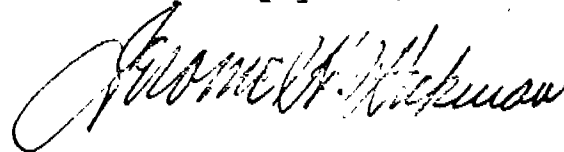
Mr. Robert M. Miller
July 20, 1970
Page 2

While writing to inform you and the other members of the Committee about this matter--and since I was away from my desk all of last week--I thought I might also direct everyone's attention to the Food Chemical News item that appeared on pages 21-23 of the July 13 edition. For the benefit of those who do not receive Food Chemical News, we have obtained permission to reproduce pages 21 through 23 so that copies of the same are enclosed.

Much of what is said in the FCN report is reflective of information we received during our recent meeting with Mr. Brown of the Office of Compliance. During the meeting, he noted that the staff is aware of the need for doing something to clarify the confusion created by the April 9 "Statement of Policy." I know that there will be more forthcoming in this connection. Meanwhile, the Food Chemical News material may be of interest to you although I doubt that it will do much more than let you know that the situation remains confused while FDA gropes with the problem of how to deal more effectively with the problems of misunderstanding it created when the Statement of Policy was released.

Obviously, we are continuing to work on all of these matters so we shall probably be reporting to you from time to time as developments take place. If anyone has any specific questions in the meantime, we trust he will not hesitate to let us know.

Cordially yours,



Enclosures

cc: SPI Food, Drug and Cosmetic
Packaging Materials Committee

ASI-PR 0000828

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July 20, 1970

Mr. William F. Randolph
Office of the Associate
Commissioner for Compliance
Food and Drug Administration
U.S. Department of Health,
Education and Welfare
Parklawn Building, Room 9-57
Rockville, Maryland

Dear Bill:

I have just returned from a full week away from the office on business trips so this is my first opportunity to congratulate you, and give you our best wishes for all success in your new post as assistant to Deputy Commissioner Duggan.

I am sure that we will miss you a great deal in the food additive petition handling area because I doubt that anyone is much more familiar than I am with the contributions you have made in this very difficult field. Nevertheless, it is good to know that you will now be operating at an even higher level where the experience you have obtained in the day-to-day processing of food additive petitions may be brought to bear to solve some of the serious procedural problems that exist. Your knowledge of these problems will undoubtedly prove invaluable to the Associate Commissioner's office.

I am looking forward to continuing the excellent relationships we have had over the years, and hope that you will thoroughly enjoy

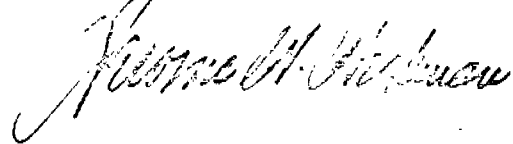
ASI-PR 0000829

Mr. William F. Randolph
July 20, 1970
Page 2

your new responsibilities, as well as your new
surroundings in "beautiful downtown Rockville."

With warmest regards.

Cordially yours,

A handwritten signature in cursive script, appearing to read "James M. McInerney". The signature is written in dark ink and is positioned below the typed name "James M. McInerney".

July 13, 1970

Regarding cyclamate table sweeteners, it is a possibility that FDA may ultimately place the products on Rx legend. Much more likely, however, is that they will be restricted to drug store sale. Such a move would probably satisfy Fountain and his colleagues.

If the boom is completely lowered on cyclamates, it still will be against the private wishes of a number of FDA-ers, who feel that the Delaney Clause has forced unnecessary restrictions on the product. Some other FDA-ers, of course, feel there should be a total ban.

At the earlier Fountain hearings, it was made clear that the switching of cyclamate-containing foods to the "drug" category was forced on FDA by HEW. It is understood that some at the HEW level feel they have been made the "goats" for a decision that was actually dictated by the White House.

GRAS STATUS OF SOME NON-DIRECT ADDITIVES REAFFIRMED

The Food and Drug Administration is reaffirming the "generally recognized as safe" status of a few, innocuous feed additives and indirect additives, but is not committing itself on direct food additives.

The agency on April 9 revoked letters which had issued in the past concurring in the GRAS status or prior sanction of substances - - although the status of the substances themselves was not revoked. FDA asked that copies of the original letters be submitted to the agency, stating that they would be replaced by "current and qualified" opinions.

Some of the prior sanction letters have been submitted to FDA. These prior sanctions - - of which FDA had no complete inventory - - are expected to be added to the list of GRAS items to be reviewed. The National Academy of Sciences, under contract, is firming up plans for the GRAS review.

In a few cases, firms submitting prior sanction letters for non-direct additives have received reaffirmation of GRAS status in about two weeks.

On the veterinary side, GRAS status is reaffirmed generally if the substance has been ruled by FDA to be safe for food use. In other words, if there is a question of residues in food or of safety to the animals, GRAS status is not reaffirmed. In these cases, FDA will review the substance.

In the area of indirect additives, GRAS status has been reaffirmed for a few substances, including some used in adhesives. However, these substances are either "foods" rather than "food additives," or have been cleared under FDA regulations. Some of them have been cleared under Food Additive Orders for other uses.

Regarding direct additives, FDA is acknowledging receipt of the prior sanction letters and describing the forthcoming review of GRAS and prior sanctioned substances. Pending this review, the agency is saying that "we do not propose to initiate regulatory action adverse to their continued use without prior notification."

Federal Register Document Prepared on Prior Sanction Review

FDA-ers are believed to be working on a regulation or statement of policy to clarify the agency's approach to exempt food additives and the review. This should be published in the Federal Register in the near future.

Among the questions to be considered by the agency is whether non-food additive status of substances should be reaffirmed by letter, or whether they should be made a matter of public record. There is some difference of opinion within the agency on this point, and those favoring the private approach note that some prior sanctions cover proprietary substances which are of use only to the individual firm to which the sanction was granted.

However, there is bound to be some political pressure to spread all approvals - - including exemptions from the clearance procedures - - on the record.

Another question to be tackled by FDA-ers involves decisions made by firms or trade associations that substances are GRAS. Under the Food Additive Law, a substance may be deemed to be GRAS when judged to be so by experts.

This approach has been effectively used by the Flavor and Extract Manufacturers' Association, which established a panel of experts to review use data and the literature on flavoring substances. On the basis of the findings of the expert panel, FEMA deemed a large number of flavoring substances to be GRAS.

FDA has never challenged FEMA on the status of these substances. However, some FDA-ers seem to believe that the exempt status of such substances should be subject to some kind of concurrence by the agency. A policy statement may be considered on this subject.

As a matter of fact, many of the substances on the FEMA GRAS list have been incorporated into Food Additive Orders by FDA. If any questions are raised, they probably would center on recent additions to the FEMA list of substances which were not in use prior to 1958 (See FOOD CHEMICAL NEWS, June 8, Page 13).

The FEMA approach developed because of the economic difficulties in requiring toxicity testing of substances produced and used in minute quantities. Manufacturers could not afford to do the work for many of them. FDA has gone along, in part because most of the substances are self-limiting and could not be used at toxicologically significant levels.

Those FDA-ers who indicate a belief that testing should be required for some of these substances concede that the Government might have to foot at least part of the bill for the testing.

July 13, 1970

Page 23
FOOD CHEMICAL NEWS

The review of GRAS and prior sanctioned substances - -which some FDA-ers have indicated might be extended to include substances which are cleared under Food Additive Orders - - would be greatly simplified by adoption by FDA of the principle of toxicological insignificance. This has been proposed specifically for indirect additives, and the principle has been endorsed by the NAS-NRC Food Protection Committee (See FOOD CHEMICAL NEWS, Feb. 3, 1969, Page 29).

It is understood that the principle of toxicological insignificance is still under serious consideration at FDA. Its progress had been all but halted because of the furor over food additives, and the agency topsiders may feel a blanket exemption from clearance procedures would be unwise in the current political climate. However, such a policy would ease the mammoth task of reviewing substances by washing out those that would obviously pose no hazard.

DELAY OF EFFECTIVE DATA FOR MIXED NUTS STANDARD URGED

The Peanut Butter Manufacturers and Nut Salters Association last week urged the Food and Drug Administration to change its Oct. 24 effective date for the new food standard for Mixed Nuts to Jan. 1 - - with the possibility of further time extensions for specific products (See FOOD CHEMICAL NEWS, June 29, Page 44).

Asking either such a change or a public hearing, the Association objected only to the effective date, saying, "It would not be feasible for the manufacturers of packaged nuts to dispose of all supplies of containers, wrappers, and labels in stock and on order or to obtain new supplies . . . by Oct. 24 . . ." This, the letter said, is a particular problem for metal lithographed cans, since there are only a limited number of container firms which manufacture them and these need "considerable lead time."

Noting that the peak season for mixed nuts is the Christmas holiday season, the Association said most manufacturers have already ordered the containers in which the nuts will be packaged for this season.

Asking the Jan. 1, 1971, effective date, the group urged "a provision that any company which cannot be in compliance by that time may submit in writing . . . information as to the reasons why it is not possible to comply by that date, with an application for an extension of time in which to comply."

The labeling difficulty also will delay compliance with the new standard of fill beyond Oct. 24, the letter said, because if manufacturers comply with the fill requirement, in many cases the actual fill will not be in compliance with the net quantity statement already lithographed or printed on the label or wrapper.

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