

December 28, 1970

MEMORANDUM

TO: Dr. Buzard
 Dr. Onien
 Dr. Jenkins
 Dr. Moe
 Mr. O'Bleness

VOLUNTARY SUBMISSION
 CONFIDENTIAL - Trade Secret
 Information

FROM: Mr. Helling

SUBJ: Food and Drug Sweetener Strategy

These are thoughts on the matter of sweetener strategy. As I see it, our objective is to obtain approval from the Food and Drug Administration for SC-18362 for enough uses to permit consumption (and hence production) at a level that will meet the economic requirements. With that in mind, we have to say what we need to do, know, or accomplish in order to bring about this objective.

We must determine which application of the sweetener seems possible and then select from these those that seem most likely to be approved. We must do this on a food category by food category basis for reasons which will become obvious as you read on. We must then estimate the consumption potential and what portion of this we think we could get for each of these uses to get a projected consumption level; this will allow us to estimate selling price at each aggregate level of consumption (production).

We must decide what factors Food & Drug would be most concerned about and determine which of these food items would present the least serious concerns (after ranking the concerns in order of our difficulty to meet at this time).

We should arrange an early informal meeting with Dr. Wodike and Dr. Blumenthal. At this meeting, the basic philosophy of our approach to Food and Drug should be to try to get them to say "yes." and to rank the things that we are going to ask for so that we are putting first those questions that we are likely to get "yes" to, even if we have to throw some in that have no significance to us other than putting them into a yes-saying habit. We must create an affirmative atmosphere in our dealing with them. It would also help if we can get them or get the people involved to do us any sort of favor as this would also help bring them into a subconscious spirit of participation.

My prime concern at this time is with the production of the DKP and our lack of complete toxicological data on DKP if SC-18362 went -- out completely to DKP. If we select foods that have their storage in dry form particularly if they are formulated so there is an acid ingredient, then we would

have confidence that the SC-18362 would not break down measurably during the usual maximum storage periods. We then must consider how much DKP could be formed from the time the system is converted to a wet system to the time of consumption allowing for maximum likely abuse. In this way, I would say that the first category of items for which we should seek approval would be these applications where the sweetener is used and held in dry form and consumed within an hour of solution, where no heat is involved. All illustration of this is a pre-sweetened cereal product that's consumed cold. A second category would be where the sweetener containing composition is held dry and consumed within about an hour, but heat is involved. An example of that is a mix that is pre-sweetened such as a chocolate drink or tablets for table use; I exclude from this the table-top sweetener. The next category would be where the acid food is kept cold but for periods of more than a few hours and no heat is used in its preparation. For example here would be a Kool Aid product that would have a maximum likely exposure of about one day unrefrigerated and have a maximum likely exposure of about one day unrefrigerated and perhaps as long as a week refrigerated. For this, as an acid product, we would expect good stability, but we must be prepared to have actual data on DKP formation during one week's refrigeration storage of 24 hours at say 30°C before we proceed to Food and Drug. The next category that I would think would be worth looking at would be a non-acid product stored cold that involved heat such as a non-instant dietetic pudding or a pre-sweetened hot cereal. Somewhere in here we would be also trying to fit in such things as a non-dry, but still essentially non-aqueous system such as bacon and the products that are stored frozen that are heated and consumed immediately and then the products that are stored frozen that are cooked and not consumed immediately and so on.

In effect then, I would first ask for an informal, but not necessarily off the record meeting. As a basis for this meeting, we would present a series of assumptions. These assumptions will be specifically stated and any informal non-binding opinions would be predicated on the basis that we can, do the right thing, convince them that the assumptions are true. I would first make the assumption that the material is stable in dry form and that therefore the DKP exposure is limited to about 2-, which is the normal contamination level in the sweetener. I would not at this time raise the question of restrictions on essential and non-essential amino acids, but I would be prepared to respond if they raised it at this time and would certainly want to

VOLUNTARY SUBMISSION
CONFIDENTIAL - Trade Secret Information

raise it before the day was out. Once we've gotten this far, I would want to establish that with the level of sweetener, as it's normally composed including the DKP, and with the toxicity data that we have in the feeding studies, we expect to get approvals now on the basis of the data on hand. We would have to be prepared with the average intakes of the sweetener that might be involved and maximum likely intake involved in the presweetened cereal type use. I would proceed to the next food category, and take these food categories one at a time to see which we begin to meet resistance. Where we meet resistance, having the data on average and maximum likely exposure for each of the uses that would bring up, then I would want to explore the nature of the resistance and what we would have to do to overcome it, particularly in relation to studies that are going on.

I think that it's vital to point out to the Food and Drug people at this meeting that the sweetener is not suitable for all applications for artificial sweeteners and at best would only be functional in part of the market that we held by cyclamate or sacharin. The approach from the meeting standpoint must be made to or thru Virgil Wodicka, Head of the Bureau of Foods, who is from an industrial back-ground and whom Dr. Scott feels is quite good.

With the spoon-for-spoon, we have no way of estimating maximum likely abuse and hence need to utilize data based on almost complete conversion to DKP. If we include this use in the original FAP, we stand a good chance of ending up with nothing in the short run and nothing in the long run whereas the other approach would give us something in the short run and, quite likely as much as we would ever get in the long run. I think it becomes very important for us to start to get our sweetener into commercial channels as soon as possible to minimize the incentive that people now have to work on other sweeteners. Actions in the U.S. will tend to influence the actions in other countries as well.

Herbert Helling

HH:jad

VOLUNTARY SUBMISSION
CONFIDENTIAL - Trade Secret Information