

December 22, 1966

Mr. O. J. Britton
Technical Development Department
The Pfaudler Company
Rochester, New York 14603

Dear Mr. Britton:

I hasten to answer your letter without delay, since I shall be going to San Francisco on January 3rd, to be there for three months. (I shall receive from the Laboratory the items of mail that require my attention, and I shall return for several days during each month, but there will be some delay, no doubt. I shall indicate my address and telephone number, below, so that I can be reached if necessary.)

I am sorry, indeed, to have to take a pessimistic view of the prospects of your Company's exploitation of the use of its product as a coating for receptacles for food. Nevertheless, on the evidence before us, I consider the product to be entirely unsatisfactory for its intended purpose, and I am sure that the approval of the F.D.A. could not be obtained for its use, both because of their public position and because of the law of the land. I shall explain my position, and also predict their action.

1. (a) I am told that stainless steel tanks can be used - and in fact, are being used - for purposes similar to that which you have in mind, and that such tanks pose no problem of contamination. If this is the case, it would seem that there is no compelling reason for resort to other metal tanks supplied with such a coating as you have in mind. This is merely point number one.

Now I may be wrong in this, or I may be partially in error, in that certain advantages of the product may be involved in the use of a metal coating. If there are intrinsic advantages in the use of the coating (beyond the cost of equipment and its maintenance), they should be made clear to me so as not to continue in error.

2. (a) I think it wise, and even necessary, to discourage the use of any product or equipment, in connection with the storage, processing or distribution of food materials that contributes to the lead content of such food materials. If one item makes a certain small contribution, and another and another make additional small contributions, the lead content of the food of the country increases. Ultimately it approaches and exceeds the limit of tolerance. Twice the present level of the composite food of the country is as far as we dare go with public safety, and the actual level now ranges between 0.2 and 0.4 mg. per day, averaging about 0.3 per day. Thus, you see, a few micrograms here and there become of considerable quantitative importance. Because of the multiplicity of opportunities for contamination of food materials with lead, every increase that can be avoided readily, should be. Hardly a week goes by ^{but} that some issue of this sort comes to my attention, and it is apparent, therefore, that the

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opportunities are legion.

3. (a) The analytical evidence now available, instead of being negligible in significance, is clearly indicative of the occurrence of a degree of contamination that should not be permitted to occur. Accordingly, I should advise you, even if there were no governmental agency to which to apply for approval, not to proceed with this project, until and unless you can develop a coating that does not yield such evidence of the extractability of lead therefrom. If the direct result of such tests as have been made cannot be reduced to the second decimal place, i.e., to the point at which 0.02 (at the maximum) is found instead of 0.15 to 0.26 (under the conditions of the test), your product, in my opinion, is unsatisfactory. This may be hard to do, technically, but it is, I believe, necessary. If you think I am being unduly severe, just consider what the addition of 0.1 mg. of lead in one liter of beer per day will do to the average intake of lead in the food and beverages of the average man in the U.S.A., without even considering what the "unusual" man may do.

Turning now to the attitude of F.D.A., which I have explored carefully, the position is this:

1. (a) The food of the country is vulnerable to contamination ^{with} lead, in addition to that which occurs normally or unavoidably, because of the nature of the general environment of our time.

(b) Their job, in this specific matter, is to see that no contamination beyond that which is normal or unavoidable is permitted to occur, so far as they have knowledge or power under the laws of the land.

(c) The statutes under which they operate define any unnecessary or unavoidable contamination of food and beverages (excepting meat, over which they have no present power of control) in industrial processing as "adulteration," and declare it to be a violation of the law. F.D.A., therefore, have no authority, even if they desired, to sanction such contamination if it can be identified as such.

On account of this situation, I think it would be unwise for me or yourselves, or for either of us alone, to approach F.D.A. for further discussion of this matter. I am not refusing to do so, if your people differ from my opinion, but you can see that with my view of the matter I can hardly be of help to you.

I should say, on the contrary, that if you think it necessary to continue in this direction, that you should return to the laboratory and develop a process, with or without lead, that will not result, demonstrably, in the contamination of beer or other food materials.

Again, may I say that I deeply regret having to take this position, but I am sure that you expect to obtain my opinion, and not my compliance with your purposes. This is not a Christmas message, but, I would like to express to you my best wishes for the holiday season.

Cordially,

RAK:wp

Robert A. Kehoe, M.D.

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