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RESEARCH AND DEVELOPMENT
LABORATORIES

October 6, 1967

Mr. Jerome H. Heckman
Keller and Heckman
1712 N Street, N. W.
Washington, D. C. 20038

Re: Proposed Food Additives Procedural Regulations
(32 Fed. Reg. 152, p. 11443)

Dear Jerry:

With respect to your letter of September 27 to the members of the SPI Food Packaging Materials Committee, my main objection is that there is not sufficient differentiation between classes of food additives; and the Procedural Regulations may be interpreted too strictly with respect to petitions where no real question of safety is involved.

Although hinted at in a few places, I think it would be helpful to have a statement concerning a "test of reasonableness" so that the reader would know that the main consideration is a well organized, readable document (in the stipulated format) that presents a logical and scientific proof to substantiate the clearance of a substance or material. The extent to which full compliance to all aspects of the Procedural Regulations would be required would depend on the toxicity of the food additive, the intended uses, and the amount that would get into food.

Unless this is recognized, money may be wasted in senseless testing, or a petition may be reviewed administratively and rejected even though the information therein is entirely adequate to support the requested regulation or clearance.

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My comments concerning specific sections are as follows:

121.50 (a)

What constitutes a "scientific study"? We assume that data accumulated thr ugh

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standard test procedures of analysis, extraction, etc., would not be included. An entirely new test method would. In the case of feeding studies conducted by recognized outside laboratories, will the name and address of the laboratory and the signature of the responsible director suffice?

121.50 (c)

We have checked local stationers. 8" x 10½" sheets would have to be cut to size. This page size would also pose problems in reproducing copies of reports and letters which are usually on standard 8½" x 11" pages.

121.50 (e) I.B.3. Technical effect

We believe this provision has to be considered with some regard for appropriateness. What about clearing a solvent for use in applying coatings? The amount required would vary depending on the solubility of the material being dissolved, the desired viscosity, the desired solids, etc.

121.50 II A
1.b.v.,1.b.vi.,2.b.iv. and 2.b.v.

In some instances, particularly in the case of direct food additives, a manufacturer will not get into full size production batches until a material has been cleared and a market is assured. The evaluations may be done on pilot plant material. In any event, if a manufacturer gives specifications, these are controlling and will determine the suitability of production material.

With particular reference to indirect food additives, there should be some obligation on the part of both manufacturers and FDA to limit specifications, reproducibility controls, etc. to what is reasonably required to insure safety. If this is not done, FDA may be in the position of restricting trade by imposing unnecessarily severe or unrealistic requirements for many uses.

Such situations sometimes arise in Subpart F with respect to a substance covered by a specific regulation. A substance may be cleared under several different "application" regulations, taking into consideration degree of food contract and good manufacturing practice, and be used for several years. Then a specific substance regulation issues including very tight specifications designed to cover direct food contact situations. The inclusion of the paragraph, "Provided however, that any substance named in this subparagraph and covered by a specific regulation in this Subpart, must meet any specifications in subject regulation". , in the various "application" regulations makes all uses (even those involving only incidental contact) subject to the same tight specifications.

Manufacturers who 5 or 6 years earlier received assurance from a supplier that a substance was cleared under "application" regulation may now be in technical

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violation because of the unnecessarily restrictive requirements of a specific substance regulation.

121.50 II B

Except for direct food additives with highly specific and limited uses, we do not see how maximum and average quantity in the diet could be stated. It should be recognized that any such estimate usually would be very approximate.

121.50 C.4.b.

See the comments above on Technical effect.

121.50 D.2. and D.4.

These two paragraphs could be written more clearly to bring out the fact that in some instances tests on foods will be required whereas in other instances the tests will be made on food packaging materials or components of food packaging materials.

I suspect that FDA uses the term "tolerance" almost exclusively with respect to levels occurring in foods (for example, insecticides) but the reader might interpret this less specifically.

With reference to D.4. - if a specification of not over 0.5% residual monomer for a plastic were set, this would, in effect, be a tolerance also.

Therefore, we suggest that the first sentence in D.2. state:

"If usage of the food additive requires a tolerance in food for the food additive . . . . . ".

The use of the phrase "food-contact surface" in D.4. seems unnecessarily limited. Many substances which are cleared under Subpart F are not food-contact surfaces as such. However, the same principles for clearance would apply.

We hope that these comments will be helpful to you in drawing up the consolidated comments for submission to FDA. If there are any questions, please let us know.

Very truly yours,

W. W. Sederlund

W. W. Sederlund
Manager for Product Assurance

WWS:bb