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~~AK~~ FDA
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April 15, 1988

TO: SPI Food, Drug and Cosmetic Packaging Materials Committee

Re: Colorants for Polymers

Ladies and Gentlemen:

As you know from our last letter to you, the FEDERAL REGISTER for Wednesday, April 6, 1988, contained a Food and Drug Administration (FDA) Tentative Final Rule dealing with colorants for polymers. 53 Fed. Reg. 11402. Our initial shock and dismay about the wording of Section II of the Preamble for the Rule, which seemed to indicate an FDA intent to revise the definition of the term "food additive" set forth in Section 201(s) of the Federal Food, Drug and Cosmetic Act (Act) and to overrule the Court of Appeals' decision in Monsanto Co. v. Kennedy (613 F.2d 947 (1979)), have now been somewhat mitigated. In discussions I have had with ranking FDA'ers, including General Counsel Tom Scarlett, I have been assured that there is no intent to do anything other than stay closely within the confines of Monsanto and that if the Preamble conveys a different impression, they are prepared to make necessary clarifications in response to our Comments.

The purpose of this letter is to provide you with additional background information, our analysis of the Rule as it presently reads, and some suggestions for Comments to be filed with the Agency. In connection with this latter point,

we are hereby asking for information regarding the number of different colorants currently used in food-contact plastics which are not included in the Section 178.3297 list because we think the "Economic Impact" section of the document grossly underestimates the effect the regulation will have on small entities, including small businesses, if its Preamble (under FDA's rules, a binding Advisory Opinion) is not significantly amended.

Overview of the Rulemaking

In the Preamble to its Tentative Final Rule, FDA has provided an abbreviated history of the rulemaking in Section I, a response to the Comments filed on the 1972 proposal in Section II, a response to the Comments on the 1983 Final Rule establishing 21 C.F.R. § 178.3297 in Section III, and a discussion of the scope of the Tentative Final Rule in Section IV. This latter includes a discussion of the environmental and economic impacts of the rulemaking. The Preamble is followed by the codified amendments.

Overall, the Tentative Final Rule contains some good news and some very bad news. The good news, and it is tempered by a request for additional environmental information, is that the three colorants which the 1972 proposed regulation would have restricted to use in polyethylene only with maximum limits of migration are now eligible to be cleared for use with all polymers with no extraction limitations. The bad news to which much of the remainder of this letter is directed are (1) the Preamble statements that appear to amend the statutory definition of the term "food additive," (and ignore the teachings of Monsanto) and (2) the environmental data demands made in the rulemaking.

The Tentative Final Rule calls for environmental impact data on some of the colorants for polymers listed which FDA listed in its 1972 proposal but restricted to use with only certain polymers. FDA states it will remove these restrictions if it receives an environmental impact assessment that raises no important concerns. The colorants involved are chromium oxide green, cobalt aluminate, phthalocyanine green, quinacridone red, zinc carbonate and zinc oxide. As the still languishing polyvinyl chloride rulemaking has painfully taught us, satisfying the Agency's appetite for environmental data can be the most difficult and time-consuming aspect of the rulemaking process.

Section II - the 1972 Comments

Section II deals with Comments filed in response to the 1972 proposal; item 1 is directed to the Comments SPI filed. For your ready reference in following the discussion, we are enclosing a copy of our August 4 and November 13, 1972 filings. In our opinion, FDA misinterpreted these 1972 Comments, and in an effort to establish a strong defensive posture, has mistakenly created a seriously adverse draft Advisory Opinion which, if left uncorrected, could occasion our recommending the institution of Court of Appeals proceedings to you.

You will note that in the 1972 Comments SPI recommended that colorants for plastics generally should not be considered food additives because they were not reasonably expected to become components of food, and that, therefore, there was no need for FDA to proceed with the rulemaking. This was in line with the position advocated at the National Conference for Indirect Additives held in 1968 and the subsequent "Ramsey Proposal," which embodied FDA's first pass at putting in place a de minimis or threshold of regulation approach. However, the Comments then went on to state that if FDA insisted that a colorants regulation was necessary, the regulation "should provide explicit recognition of the 'no migration' concept where it is clearly applicable."

SPI requested that either in the Preamble or in the Order itself, FDA "specifically acknowledge that the colorants which do not migrate to foods may continue to be used under the Food Additive Regulations." Finally, the Comments proposed language for inclusion in the regulation that would (a) distinguish between colorants and color additives, (b) provide for a 50 ppb detection limit in deciding whether a colorant was or was not a food additive, and (c) amend the list of colorants in the regulation to delete those which were not food additives. SPI also asked FDA to provide for suitable extraction and analytical procedures to determine compliance with the recommended 50 ppb extraction limitations.

SPI never opposed promulgation of a regulation covering colorants for polymers in those situations where there is detectable migration of a colorant to food; such a regulation is required by the statute. Indeed, our 1983 Comments on FDA's Final Rule establishing a colorants for polymers regulation

also made it clear that we have no objection to such a colorants for polymers rulemaking in those cases where the colorants are food additives.

Nevertheless, for reasons that are difficult to understand, but which I now believe flowed from a mistaken sort of taking into account of Comments written some 16 years ago, FDA's response to our 1972 Comments focused exclusively on the question of whether a colorants regulation was needed at all. Ignoring the question of "how much," the Agency is now stating categorically, "colorants used in food-contact polymers do become components of food. Existing theory and data produced by industry demonstrate that, under normal conditions of use, colorants will migrate to food from all polymers." 53 Fed. Reg. at 11403. In support of this strangely unequivocal pronouncement, FDA notes that "the diffusion equations derived from Fick's Second Law always predict a finite migration of the colorant to food . . . provided that the diffusivity is not zero. Only if diffusivity is zero would no migration be likely." Id. The statement continues:

> FDA believes that the diffusivity of colorants in polymers will always be greater than zero, and that migration will occur whenever a colorant is present in the polymer. These . . . theoretical calculations are supported by actual extraction studies with food-simulating solvents that have either been included in petitions by industry to support the use of colorants in polymers . . . or submitted to the Agency in letters that have requested opinions from FDA. (Id.) (Emphasis supplied.)

In its explanation, FDA indicates its view that it is relying on Monsanto v. Kennedy, which, the Agency notes, states that for a substance to be deemed a food additive, "the Agency must determine with a fair degree of confidence that the substance . . . migrates into food in more than insignificant amounts. The court said that it is not necessary that the level of migration be significant with reference to the threshold of direct detectability, so long as the substance's presence in food can be predicted on the basis of a meaningful projection

from reliable data." Id. FDA considers that the citation of Fick's Laws, supplemented by its citation of experimental evidence that demonstrates migration, is sufficient to permit a meaningful projection (i.e., using Fick's Laws) from reliable data (i.e., the experimental evidence).

It is obvious that the Agency's citation of Fick's Laws to predict that (a) there will always be diffusion of any colorant from any polymer unless the diffusivity is zero; and (b) that the diffusivity is never zero is merely another variant on FDA's original argument advanced in the Monsanto case. There, FDA argued, relying on predictions derived from the Second Law of Thermodynamics, "there will be some migration of any two substances which come in contact." In response, the Monsanto court noted, "Congress did not intend that the component requirement of 'food additive' would be satisfied by a mere recitation of the diffusion principle, a mere finding of any contact whatever with food." 613 F.2d at 955.

Put another way, by stating that there will always be diffusion unless the diffusivity is zero and that the diffusivity is never zero, FDA is merely reciting the diffusion principle. The Agency is ignoring the Monsanto explication of the food additive definition. The Preamble overlooks the reality that for some colorants in some polymers under ordinary exposure conditions the amount of migration will only be molecular during the finite shelf-life of the packaged food. In short, the "meaningful projection" FDA claims to have made ignores the Monsanto court's requirement that the migration occur, or be predicted, "in more than insignificant amounts." (Our Comments will provide a technical discussion as to why some colorants will not -- cannot -- migrate in more than molecular amounts during a finite product shelf-life.)

Ironically, the Preamble's dogmatic reliance on diffusion theory also runs counter to the Agency's own current interpretation of Monsanto as expressed by FDA's General Counsel in the Public Citizen colorants case. Public Citizen v. Young, No. 86-1548 slip op. (D.C. Cir. Oct. 23, 1987).1/ In a March 18, 1988 brief opposing Supreme Court review of the case, FDA states that the Court in Monsanto held the Agency

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1/ The Court in Public Citizen struck down FDA's use of quantitative risk assessment and the de minimis doctrine to clear carcinogenic color additives, i.e., D&C Orange No. 17 and D&C Red No. 19, despite the Delaney Clause. However, as we

[Footnote continued on next page]

"has the authority to apply a de minimis exception to the definition of a food additive . . . and to ignore trace amounts of a substance that migrate from a container into food as long as the presence of those trace amounts does not pose a significant risk of injury to the public health." Brief for Federal Respondents at 6. In contrast, taken literally, the colorants for polymers Preamble puts presumed migration of a single molecule on the same regulatory plane as measured migration of, for example, 50 ppb of a colorant that has a molecular weight of 500 into 1 gram of food, i.e., $6x10^{17}$ molecules.

In an attempt to show that it is not relying solely on the theoretical teachings of Fick's Laws but rather on experimental confirming evidence, FDA cites data submitted in petitions to support its contention that all colorants will migrate from all plastics. Clearly, however, when migration is observed, a food additive petition is required as a matter of law. To cite evidence in such petitions as support for the conclusion that all colorants will migrate from all polymers is patently specious.

Indeed, as you may recall, in the case of Solvaperm Red G and Solvaperm Yellow (colorants produced by American Hoechst Corporation for use in polyethylene terephthalate bottles), Hoechst (and a customer) supplied FDA with data demonstrating no detectable migration with validated sensitivities in the range between 1 and 5 ppb when the plastics were exposed for times and temperatures far more severe than those recommended in FDA's guidelines.

FDA ultimately provided "no objection" letters on both these colorants. Although it did not explicitly acknowledge that the colorant did not migrate at some theoretical level, the FDA letter concerning Solvaperm Red G stated that the Agency "concluded that the present data form a sufficient basis for concluding that when Solvaperm Red G is used . . . to color PET polymers formulated for making bottles for packaging

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have previously reported, the decision distinguished the application of the Delaney Clause in the food additive context and upheld the teaching of Monsanto that the de minimis concept may be used to determine that even a carcinogenic substance that migrates into food in trivial amounts is not a food additive. For a full discussion of the Public Citizen decision, see our October 29, 1987 letter.

carbonated and alcoholic beverages, it need not be approved by the issuance of a food additive regulation." Letter from Gerad L. McCowin, FDA Center for Food Safety and Applied Nutrition, to Jerome H. Heckman, October 10, 1986. For an account of the Solvaperm Red G saga, see our October 17, 1986 letter to the Committee, which includes pertinent FDA letters and Food Chemical News reports.

We know that in commenting on such data, an FDA representative stated that the failure to detect migration only demonstrated that the analytical methodology was not sensitive enough, that there must have been some migration since this is predicted by Fick's Laws. The logical fallacy here is apparent: one cannot rely on measured data to validate Fick's Laws; use the Laws to predict migration beyond the range where it can be tested, and then cite the previously measured values to prove the Laws' applicability. We think it appropriate to point out that projecting physical laws beyond the range where they can be confirmed has often proven invalid. Even Newton's laws do not apply at very high velocities or in the realm of minute dimensions.

In our discussions with FDA personnel close to the writing of this Preamble, we were informed that they did not intend the quoted statements to be read as broadly as indicated above. Rather, they said FDA intends only to deal explicitly with the colorants listed in the proposed regulation and the others added as a result of post-1972 food additive petitions. If this is the intention, the Preamble is written in an unnecessarily broad and extreme manner. The Comments we plan to circulate for your review will ask that FDA revise the obviously broad, sweeping generalizations set forth in the Preamble so as to limit regulatory treatment to those colorants which are truly food additives.

Carbon Blacks and Benzidene Yellows and Other Specific Colors

Item 3 in Section II discusses the use of carbon blacks other than channel black as colorants. FDA notes that its concern with carbon black made by other than the channel process relates to the generally high level of polynuclear aromatic hydrocarbons made by the "furnace" process. The Agency notes that a Food Additive Petition with adequate analytical data could lead to a regulation explicitly permitting the use of other types of black.

With respect to the benzidene yellows, FDA states, "because no acceptable Food Additive Petitions were submitted, . . . there was no basis for FDA to include these colorants in the 1972 proposal." Here again, the Agency is inviting appropriate Food Additive Petitions.

Item 6 of this section discusses in some detail the maximum extraction limits set forth in the 1972 proposal for chromium oxide green, phthalocyanine green and quinacridone red. The Agency agrees that these extraction limits are not necessary. Furthermore, in item 7, FDA also agrees that the use of these colorants could be extended to all polymers; the same conclusion was also reached with respect to cobalt aluminate, zinc carbonate and zinc oxide. However, the Agency is requesting environmental impact information before it will agree to extend the usage of these colorants to other polymers.

Section III

Section III of the Preamble contains responses to the Comments received on the October 14, 1983 rulemaking. The SPI Comments on the rulemaking mainly addressed the over-broad definition of "colorant" set forth in paragraph A of section 178.3297. The Comments make it clear that SPI in response to FDA's 1972 proposal "urged FDA to explicitly note in the final rulemaking "that colorants need not be listed in the colorants regulation if they are not food additives in terms of section 201(s) of the Federal Food, Drug and Cosmetic Act," and that FDA had not responded to this in the 1983 rulemaking. The SPI Comments clearly acknowledged that colorants that are food additives are properly the subject of a colorants regulation; SPI requested once again that the regulation define a colorant so as to exclude substances that are not reasonably expected to become components of food under the intended conditions of use.

In our view, FDA ignored this SPI request; no mention of this Comment appears in section 3. Indeed, despite the assurances we were given that the broad language in section 2 was intended to apply only to the listed colorants, the failure to respond to SPI's 1983 Comments implies that the Agency does not recognize the statutory definition of the term "food additive," or, at the very best, that there will be a great deal of confusion about the status of "non-migrants" if corrections in the Preamble are not made.

Section 3 does discuss a tangential point SPI made to the effect that the original title of the regulation, Colorants for Plastics, was more appropriate than the new title, Colorants for Polymers, and affirmed FDA's intention to keep the new terminology. More significantly, the Agency, at item 10, makes it clear that the listed colorants are intended for use in resinous polymeric substances and not for use in paper and paperboard products, per se. The Agency also makes clear at item 13 that substances listed as color additives in foods, ingested drugs and ingested cosmetics can be used as colorants for plastics provided appropriate and acceptable environmental impact information is provided.

Section IV

In discussing the scope of the Tentative Final Rule in Section IV, FDA outlines the changes it is "tentatively" making on a section-by-section basis. Then, it provides a discussion of the environmental impact this regulation is expected to have.

Regarding environmental impact FDA, duly acknowledges that it has issued many opinion letters in the past twenty-four years permitting the use of the listed colorants and that consequently the action on the Tentative Final Rule will not affect the market volume or use level of these colorants. The Preamble notes:

> Based on this finding, the Agency has determined under 21 CFR 25.24(a)(9) that its action, to include in the tentative final rule those colorants listed in the 1972 proposal, is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required. (53 Fed. Reg. at 11408.)

The Agency then explains that it is prepared to expand the permitted uses of some of the listed colorants, as discussed above, but say these "expanded uses" can be codified only after interested parties file environmental assessments in the format specified in 21 C.F.R. § 25.31(a)(b)(1) within the comment period.

The Agency is, to the best of our knowledge, wrong in considering that the listed colorants have been used only for

the polymers originally designated in the earlier proposed regulation. Rather, following informal advice of FDA staff members and because for many of the colorants a sound no migration, hence no food additive position could be established, the colorants were and are being used in a large number of other polymers. For these, therefore, amending the Tentative Final Rule to explicitly show the additional permitted uses will not either individually or cumulatively have a significant effect on the human environment because neither the market volume nor use level of the colorants will be affected. This is another point we will develop in our Comments.

The final substantive portion of Section IV deals with the economic impact of the regulations. Assuming, as we must at this time, that FDA's Preamble means what it says, that all colorants used in all food packaging materials must be the subject of food additive regulations, the economic impact analysis is inadequate and misleading. The economic impact statement notes "the effect of this regulation is to maintain current known uses of colorants for polymers. This action merely formalizes the approvals FDA has been providing in informal advisory opinion letters during the past 25 years. Therefore, FDA certifies . . . that no significant economic impact on a substantial number of small entities will derive from this action."

If FDA had amended the colorant definition as we had requested, this statement would be correct. Since, however, FDA stated that all colorants used in all polymers must now be the subject of regulations, many new food additive regulations for colorants will be required. We anticipate that the cost of preparing and prosecuting food additive petitions for the non-migratory colorants now in use may well be significant.

To obtain sound data on this point, we are hereby requesting those of you who make or use colorants to identify the individual colorants (dyes or pigments) you currently employ on the basis of "no migration" and which are not now the subject of food additive regulations. To avoid double counting, we ask that you include the chemical or trade name of the colorant and the Color Index Number where applicable. We will use this information to estimate the number of food additive petitions that will be required and, in light of the costs involved, determine whether the economic impact will, as we suspect, be

quite severe on small entities. In this connection, please be assured that any information of this type provided to us will be kept strictly confidential.

* * * *

We are presently drafting proposed Comments which will deal with the scientific and legal deficiencies in the FDA Preamble. We will then circulate them to you for your review and recommendations. We hope that we will be able to obtain your final approval of the Comments during the full Committee meeting here in Washington. It may also be necessary to establish a Colorants Task Force, drawing upon the manufacturers of these products for technical input. Here, too, we hope that the establishment of such a group (if needed) can be accomplished during the semi-annual meeting.

We trust you will find that this letter provides a reasonably complete discussion of FDA's colorants rulemaking and the problems it has precipitated. If any of you have questions or comments about any aspect of the matter while you are waiting to see our draft comments, please do not hesitate to let us know.

Cordially yours,

Jerome H. Heckman

Enclosures