Cleveland Research Admin.

Cleveland

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E. C. Baldwin

FDA Proposes Regulation of Lead and Certain Other Heavy Metals

The proposed FDA regulations, as published in The Federal Register on November 2 and as reviewed by Mr. Montgomery in his November 5 Legal Bulletin, contain several requirements that are different from what has been our prior understanding.

1). Lead levels are reduced to ¼% of the non-volatile on both interior and exterior surfaces accessible to children.

2). The effective date as now projected - July 1, 1972 - is considerably earlier than the recommendations made by the Executive Committee at their October 8 meeting. At that meeting a date of January 1, 1973 was suggested to meet a 1% limit on exterior paints.

3). The regulations as published would prohibit manufacture and interstate shipments after the effective date. This could be disastrous to us. Montgomery indicates that a request will be made to restrict only manufacture to the effective date.

Other than the manpower demands, we see no particular technical problems in meeting the dead-line on interiors. Meeting the July 1, 1972 date on exteriors is going to take some real doing, and considering the probable need for label changes, etc., it may be unattainable. Costs on deep colors will increase 8-10¢/gallon - $8-10,000 based on our 1970-71 volume.

Our greatest problem will not be the lead regulation, but meeting the 250.1 heavy metal restrictions of .05%. Antimony is included without qualification. Most of our popular yellows are made with nickel titanate pigment which contains 8-12% antimony. Antimony in this form has previously been considered insoluble and non-toxic. Our Chemicals Group has had rat feeding tests made, and in these tests at least there was no indication of toxicity.

Chemicals is working toward presenting an industry-wide appeal to FDA to exempt nickel titanate pigments.

Some expensive organic pigments might be useful replacements, but at substantial cost increases. Also, existing color systems would have to be redone in the yellow areas.

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This matter - nickel titanate - was discussed at the Product Sub-committee Meeting this morning. It was the opinion of the group that it is not feasible to meet this limitation. The committee recommends that if an exemption cannot be obtained, we proceed to label nickel titanate paints as hazardous substances.

To the best of our knowledge we are in full compliance with all existing and proposed mercury product regulations.

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cc WOS RSB WWG ADC RAM JJL

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