CPMA
COLOR PIGMENTS
MANUFACTURERS
ASSOCIATION, INC.

June 26, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
Attn: Docket Numbers 02N-0277 and 02N-0275

Re: Comments of the Color Pigments Manufacturers Association, Inc. on the Food and Drug Administration Proposed Rules for Establishment and Maintenance of Records for Food Facilities, 68 Fed. Reg. 25188, Docket Number 02N-0277 and Administrative Detention of Food, 68 Fed. Reg. 25242, Docket Number 02N-0275, Under the Public Health Security and Bioterrorism Preparedness and Response Act

Dear Sir or Madam:

I am writing on behalf of the Color Pigments Manufacturers Association, Inc. ("CPMA") in response to the Food and Drug Administration Proposed Rules for Establishment and Maintenance of Records for Food Facilities, 68 Fed. Reg. 25188, Docket Number 02N-0277 (the "Proposed Record Rule") and Administrative Detention of Food, 68 Fed. Reg. 25242, Docket Number 02N-0275, (the "Detention Rule"), proposed under the Public Health Security and Bioterrorism Preparedness and Response Act (collectively, the "Proposed Rules").

02N-0275 C25

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The CPMA is an industry trade association representing color pigment companies in Canada, Mexico and the United States. CPMA also represents small, medium and large color pigment manufacturers throughout Canada, Mexico and the United States, accounting for 95% of the production of color pigments in these countries. Color pigment manufacturers located in other countries with sales in Canada, Mexico and the United States, and suppliers of intermediates, other chemicals and other products used by North American manufacturers of color pigments are also members of the Association. Color pigments are widely used in product compositions of all kinds, including paints, inks, plastics, glass, synthetic fibers, ceramics, color cement products, textiles, cosmetics and artists' colors.

INTRODUCTION

Our members are aware of the need to protect our nations security, and we support the initiative FDA is taking under the Public Health Security and Bioterrorism Act of 2002 (Public Law 107-188) to increase security and prevent the possible intentional or unintentional contamination of foods. However, as discussed in more detail below, based on our members' review of the Proposed Rules, we find little, if any, benefit to the application of these Proposed Rules to the manufacture and import of regulated indirect food contact color pigments which may be used in the manufacture of packaging for food.

These comments are not aimed at the manufacture and use of direct food colorants. Direct food colorants are regulated for the coloring of foods and food additives. To the contrary, these comments are aimed at indirect food colors, which are used in the manufacture plastics, polymers and coatings used in packaging, which may, in turn, come in contact with foods.

These comments will first discuss the general requirements of the Proposed Rules. After which, the basis of our concern, namely that the Proposed Rules will unnecessarily burden suppliers of color pigments to the packaging industry without any discernable security benefit, will be discussed in detail.

REQUIREMENTS OF THE PROPOSED RULES

Under these Proposed Rules, "food" will be defined to include food and feed and additives, including substances that migrate into food from food packaging and other articles. 68 Fed. Reg. 25193 This would include all substances which can migrate into food from any food packaging in contact with food. Indirect food contact color pigments could therefore be regulated under the Proposed Rules.

The Proposed Recordkeeping Rule would require that each facility, including foreign facilities, create and maintain detailed records including sources for each ingredient in each batch of product produced.

The Proposed Detention Rule would allow the FDA to detain foods where credible evidence indicates the food presents a threat of adverse health consequences or death to humans or animals. As discussed in more detail below, while we see little benefit to either of the Proposed Rules as they may be applied to indirect food additives, the primary focus of these comments will be the Proposed Recordkeeping Rule.

The records required by the Proposed Rule include:

- The firm's name, and the responsible individual representative of the firm that was the immediate previous source or the immediate subsequent recipient of the food
- The address, telephone and fax numbers, and e-mail address of that person, if available
- The type of food, including brand name and specific variety
- The date received or release
- Lot number or other identifier number, if available
- The quantity and type of packaging
- The name, address, telephone number--and, if available, fax number and e-mail address--of the transporter who transported the food

These Proposed Rules would establish a considerable record keeping burden on many companies which produce or market color

pigments which may be used in food contact applications. As discussed below, manufacturers with no actual knowledge that imported pigments will be used in contact with food, will be required to create and maintain these extensive records with no discernable security benefit for the FDA. Since food is defined to include all food contact substances, the impact of the Proposed Rules will go well beyond only those facilities which produce food colors used as direct food additives.

BACKGROUND, CPMA INDIRECT FOOD CONTACT COLOR PIGMENT PRODUCTS

The CPMA represents the following classes of organic and inorganic color pigments. Individual members of these pigment classes are used, or regulated for use, in indirect food contact applications. All of the pigments used in indirect food contact applications have been shown to the FDA to be safe in food contact applications.

Phthalocyanine Pigments

The phthalocyanine pigment class is characterized by a unique ring system which all of its members share. These pigments vary in color from blue to green depending on their chemical substituents and crystal structure.

Quinacridone Pigments

Quinacridones are pigments characterized by their linear, pentacyclic molecules manufactured either by oxidation of dihydroquinacridones, or by cyclization of 2,5-diarylaminoterephthlic acids. They are either opaque or transparent, high-tint strength pigments with high degrees of light fastness, chemical resistance, heat stability and bleed resistance.[1],[2]

Monoazo Pigments

Monoazo pigments are characterized by a single azo group. Many members of this class are small in volume and used for special applications. The major volume monoazo pigments are reds made by coupling diazotized sulfonated aromatic amines to beta-naphthol or beta-oxynaphthoic acid followed by conversion to insoluble metal salts with, for example, calcium chloride.

Complex Inorganic Color Pigments

Nickel titanium yellow, chrome titanium, copper chromite and chrome oxide greens are in this group.

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[1] Lewis, P.A., Editor, Pigment Handbook, Second Edition, John Wiley & Sons, 1987, pp. 601-607.

[2] Ehrich, F.F., "Pigments (Organic)," Encyclopedia of Chemical Technology, 2nd Edition, Volume 15, Wiley, New York, 1968, pp. 535-589.

Nickel titanium yellow and chrome titanium yellow are mixed phase pigments based in titanium dioxide. The rutile lattice of titanium dioxide absorbs nickel oxide or chromium oxide as coloring components and antimony oxide for equalization of valency. The incorporated oxides completely lose their original chemical, physical and physiological properties since they no longer exist as chemical individuals in the mixed phase. Many of these pigments are used in indirect food contact polymers and packaging.

All these pigments are produced by a calcining process in which metal oxides are fused at temperatures at or above 1000° C.

THE UTILITY OF THE PROPOSED RULES FOR INDIRECT FOOD COLOR PIGMENTS

There would appear to be no discernable security benefit to requiring that manufacturers of indirect food contact pigments maintain the extensive records required by the Proposed Rules. This is particularly true for colorants in food contact polymers where migration of the colorant to food is often immeasurable by the best of analytical equipment.

In order to be regulated as an indirect food contact color pigment, the pigment must be proven safe and cannot migrate into the food in more than de minimis quantities (generally measured in part per billion concentrations). Color pigments must be proven safe and stable, both in the medium of use (such as a polymer) and the food the packaging may contain at the migration level

anticipated. This proof must be established for listing in the Code of Federal Regulations as a regulated food contact substance. Alternatively, manufacturers must provide FDA with proof of non-migration pursuant to the Food Contact Notification Process in order to establish that color pigments proposed for indirect food contact pigments are not regulated, since these pigments do not become part of the enclosed food.

The point of the long-standing FDA regulatory process in this area is that the essential proof required by FDA for a product to be marketed as an indirect food contact color is that the product does not become a significant part of the enclosed food. If indirect food colors are not part of the food because they do not migrate to food, it does not appear reasonable for FDA to now regulate these color pigments as food for purposes of security, because it is highly unlikely that such a route could be utilized to impact the food stream.

Furthermore, the chemistry and function of color pigments is such that, if these products were, or could be, sufficiently adulterated to pose a threat by migration into foods from packaging, the pigment would not function correctly in the packaging, polymer or coating systems. Since color pigments must be almost completely insoluble in the medium in which they are used, particularly for food packaging, the amount of contaminants which would be required to pose a threat to food by migration from

polymers and coatings is such that the basic stable coloration function of the pigment would almost certainly be compromised.

It must be kept in mind that color pigments are almost always used in polymer and coating systems at very low loading concentrations, often no more than one or two percent. The color pigment must have sufficient color strength to provide stable uniform color at these low loading concentrations. A color pigment which is sufficiently adulterated to pose a threat by migration to food through the barrier of the polymer or coating could not provide the stable and completely insoluble specific color intended for the application. FDA has information available on the insolubility and use of color pigments in food contact applications. This information may be found in FDA petition and food contact notice records.

Additionally, food contact colors are several steps removed from the preparation and packaging of actual foods moving through commerce. The chain of commerce for color pigments which might be used in indirect food contact applications is a complex one. Ordinarily, a manufactured color pigment which can be used under the regulations for indirect food contact applications can also be used for many other purposes unrelated to food and food packaging. Color pigments are often used first by dispersion or concentrate producers which prepare colored plastics, coatings or inks in a concentrated form for use by others. The concentrated product is then sold to other manufacturers that produce plastic articles, or

coatings and inks using dilution of the concentrate product. These products, in turn, are sold to finished product manufacturers or packaging manufacturers and then users that would actually place food in the package. As a result, there are always several steps in commerce before these products are even used in food packaging. Therefore, the decision to use a color pigment in food packaging may not be made until well after the product is sold in commerce to manufacturers of dispersions and concentrates.

FDA already mandates a comprehensive system of Current Good Manufacturing Practice ("CGMP"). The CGMP regulations cover all manufacture, processing, packing or holding of food, food ingredients and regulated food additives. These regulations assure that all foods related manufacturers meet the requirements for safety in food preparation. 21 CFR §110. All manufacturers and importers of foods and food packaging are required, therefore, to ensure that no adulterated ingredients enter the food supply. Since food and food packaging manufacturers are tasked with compliance under this comprehensive system of regulation and since regulated indirect food contact color pigments are supplied to these manufacturers in intermediate products for use in regulated packaging, a system whereby purity in ingredients is required already exists. FDA's resources should be directed toward those manufacturers with some direct connection to the food supply.

ECONOMIC ANALYSIS

Benefits of the Proposed Rules

FDA indicates that an overall goal of the Proposed Recordkeeping Rule is to allow FDA personnel to be ready to respond to shipments that appear to be adulterated, whether through intentional or accidental means, as well as when FDA receives credible evidence that an entry represents a serious threat to human or animal health. The regulation of color pigments that, in a small percentage of cases, could be used for indirect food contact will only drain away FDA and industry resources that could be used to achieve that goal. Since only a small portion of those color pigments regulated for food contact by FDA are actually used in food contact applications, the Proposed Rule will have an unintended impact on many other non-food products and processes.

FDA indicated in earlier bioterrorism response rules that "historical evidence suggests that a terrorist or other intentional strike on the food supply is a low probability, but potentially high-cost event." 68 Fed. Reg. 5454. This statement is largely repeated in the Proposed Recordkeeping Rule, in which FDA states, "While the probability of a deliberate attack on the food supply may be low, the potential cost of a deliberate contamination of the food supply may be high." 68 Fed. Reg. 25225

Since intentional or unintentional contamination of the food supply using indirect food contact color pigments is nearly impossible, there would appear to be no likely benefit from FDA's expansion of the definition of "food" to include indirect food contact pigments.

The FDA states that:

> "Persons required to establish and maintain records on foods will also keep records on the food contact substances they use because these substances meet the definition of food. Moreover, we believe that a large portion of outer packaging materials used by persons required to establish records is shipped to that person along with the food contact substances." 68 Fed. Reg. 25212

This statement appears to ignore the realities of the marketplace. Indirect food contact additives are manufactured and processed by many users before these products come in contact with food. The assumption that these facilities are the same is incorrect and certainly unsubstantiated in the Proposed Rules. Many suppliers of products, such as color pigments, will be required to maintain these records. These facilities do not now keep such records or reports. Since there is no apparent benefit to color pigment suppliers preparing and maintaining these records, the cost of the Proposed Rules is disproportionate with the benefit.

FDA supports its analysis of the benefits of the Proposed Rules with examples of harm and costs incurred in reacting to food born illnesses. There has never been a food born illness, that we are aware of, attributed to a contaminant migrating from a color pigment used in food packaging. It would appear highly unlikely that there will be such an event in the future. We are aware of no biological contaminants which are likely to, or could, occur in food and also survive in the harsh environment of bulk commercial color pigments or the severe environment which occurs in the manufacturing formulation of plastics, inks and coatings.

Small Business

The FDA indicates in describing the costs of the Proposed Recorkeeping Rule that 1,230,000 facilities owned by 960,000 businesses will be impacted. This includes all firms which manufacture process, transport, distribute, pack, receive, hold or import food or food packaging, and foreign facilities performing any of these activities on food or food packaging. 68 Fed. Reg. 25201 Of this number, FDA indicates that more than 98% of these businesses are small, having less than 500 employees. FDA goes on to indicate that the cost of compliance with the Proposed Recorkeeping Rule will be approximately $3200.00 per firm for both startup and recurring costs. 68 Fed. Reg. 25232. This very brief and apparently inadequate analysis does not account for batch

manufacturing processes involving hundreds of color pigment products and thousands of ingredients, many of which are not actually used in food contact applications.

The analysis makes no effort to differentiate those businesses which produce indirect food contact color pigments for purposes other than food contact packaging. Many, if not the vast majority, of these products are used in other commercial colored products which have no relationship to food or food packaging. As an example, the same colored plastic which is used for specific food packaging applications may also be used for plastic furniture or automotive applications. The burden on small businesses to differentiate these possible uses for the FDA and maintain records when and where appropriate is not considered in the Proposed Rules. FDA also appears to assume that sufficient employees trained in the necessary research and record keeping techniques required by the Proposed Rules will be available to small businesses to comply with the regulation. Many, if not most, of the importers, manufacturers and users of color pigments that will be impacted are very small businesses including brokerage or import businesses with no actual manufacturing plant or storage in North America. There is no reason to assume that these businesses will have the resources required to make and maintain records for FDA inspection for every color pigment produced or imported which might, if downstream customers request, use specific portions of the purchased products for indirect food contact purposes.

CONCLUSION

FDA indicates that the hypothetical case in which someone would impact the food supply by adulterating food has a very low probability. 68 Fed. Reg. 25225. The possibility of adulterating food using food contact color pigments is a far more remote possibility. The Proposed Rules will require that the regulated community maintain a massive amount of information for the FDA on a continual basis. Since the FDA and other concerned Federal agencies have limited resources with which to monitor all of the possible scenarios which could conceivably pose a threat to security, regulation of indirect food contact colors would appear to be an added burden which does not achieve the goals of the proposed regulatory structure. The limited resources of the FDA would be better used to monitor those processes and products which may pose a more realistic threat.

Therefore, the Proposed Rules appear to be over broad in their scope and application. There is no apparent benefit to the Proposed Rules as applied to manufacturers of color pigments. As applied to food contact color pigments, the costs of the Proposed Rules are, therefore, disproportionate to any potential benefit derived from the Proposed Rules.

Indirect food contact color pigments should not be regulated with the same information requirements intended for actual food and direct food additives. The inclusion of indirect food contact

color pigments in this Proposed Rule when finalized would be a mistake and an unnecessary burden on an already overtaxed FDA. We therefore urge strongly that FDA remove indirect food contact colors from this proposed regulation and consider these products in a separate measure, if needed, which would more accurately address the remote risk posed by these products.

Please call if there is any further information that we can provide.

Sincerely,

J. Lawrence Robinson
President

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