FDA Proof Source

Direct Food Contact and the Functional Barrier Concept Defined
Position Letters from the Food & Drug Administration

NS26
(09/14)

April 21, 1989

Fred Bichaylo sent a letter to Mary Lipien, Consumer Safety Officer, at the FDA's Center for Food Safety and Applied Nutrition (CFSAN). He was seeking her opinion on printing inks in direct contact with dry cereal.

June 1, 1989
Mary responded and agreed with Fred's assessment on the proper ingredients to use for food contact but added if a resinous coating was used the ink ingredients would not need to be approved.

July 17, 1989
Fred wanted Mary to define resinous coating as being an effective functional barrier given the fact that most printing methods would only deposit thin film thicknesses. Therefore it would be difficult to ensure a continuous film with no pinholing.

July 31, 1989
Marvin Mack, Consumer Safety Officer, agreed with Fred and defined a functional barrier: "Even though a resinous coating is acceptable on the basis of its containing components approved under the food additive regulations for their use, it must be applied in such a manner that forms an effective functional barrier; that is, it must be of sufficient thickness and continuity that it prevents the ink from passing through the coating and migrating to food. The manufacturer must employ good manufacturing practices to ensure that the coating has formed a continuous coating over the ink and substrate so that no "pinholing" is present and/or the coating is of sufficient thickness to prevent migration of ink through it."

October 4, 2001
Jerry Napiecek sent a letter to Joseph Levitt, Director, CFSAN, requesting that they look at previous letters between Colorcon and the FDA to reaffirm what was understood by us.

December 6, 2001
Dr. Anna Shanklin responded to Jerry stating the "agency has not changed its standards and the opinions offered in those letters are still valid". Dr. Shanklin restated the definition of functional barrier concept adding: "If the coating does not provide a functional barrier and if the components of your ink are not regulated for their intended use, GRAS, or prior sanctioned, you would need to submit a food contact notification following the procedure outlined in the proposal that published July 13, 2000, in the Federal Register, etc….."

Additional Note:
September 1, 1999
The National Association of Printing Ink Manufacturers (NAPIM) published a White Paper titled, "Printing Ink and Food Packaging Regulations". The contents included the same wording and regulatory statements which were referenced in our exchange of information with the FDA. The degree to which a printing ink or coating may be reasonably expected to migrate to food is its migration potential. The burden of proof regarding no migration is the responsibility of the food packager.

For more information, contact your Colorcon representative or call 1-800-724-0624
You can also visit our website at http://www.colorcon.com/notox

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A DIVISION OF BERWIND PHARMACEUTICAL SERVICES, INC
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April 21, 1989

Ms. Mary W. Lipien
Consumer Safety Officer
CENTER FOR FOOD SAFETY & APPLIED NUTRITION
(HFF-335)
FOOD & DRUG ADMINISTRATION
200 "C" Street
Washington, D.C. 20204

Dear Ms. Lipien,

We have recently had a difference of opinion with a potential customer regarding the regulatory acceptability of inks used to print coupons or similar items on paper or paperboard which are inserted into a package of dry cereal.

Since the coupon will be in direct contact with the cereal, it is our contention that some of the components of the ink could become a part of the food due to migration, diffusion or abrasion by the product. Therefore, the inks must be formulated entirely from ingredients permitted for direct contact with food in accordance with all applicable sections of 21 CFR 170-189.

In addition, the colorants used in these inks must be selected from those color additives permitted for direct addition to food generally, or those regulated for direct contact with foods, namely: those color additives for food use exempt from certification listed in 21 CFR, Part 73, Subpart A; those FD&C certified colors subject to certification listed in 21 CFR, Part 74, Subpart A; those color additives provisionally listed for food use in 21 CFR 81.1(a); or those colorants permitted for direct contact with foods listed in 21 CFR 175.300(b)(3)(xxvi).

Our customer, on the other hand, believes that since the cereal is a dry food product, migration is unlikely to occur. Therefore, the inks on the coupon are not food additives and need not comply with the food additive regulations, or, at best they would have to be acceptable only for "minimal" contact with foods. In either case, neither the colorants nor any other components of the ink would have to conform to the food contact regulations described in the previous paragraphs.

We would appreciate your opinion and comments to help clarify this issue at your earliest convenience.

Thank you for your continued cooperation.

Very truly yours,

Frederick E. Bichaylo
Manager
Industrial Products Div.
Technical Services

FEB:mac

cc: J.D.Flanagan
M.F.Gettis
E.J.Furmanek
G.L.Napiecek

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

JUN 1 1989

Mr. Frederick Bichaylo
Colorcon
415 Moyer Boulevard
West Point, PA 19486

Re: Printing inks

Dear Mr. Bichaylo:

This is in reference to your letter of April 21, 1989, concerning the regulatory acceptability of inks used for printing on paper or paperboard coupons to be inserted into a package of dry cereal.

The Food Additives Amendment of the Federal Food, Drug and Cosmetic Act requires that a food additive be tested for safety and approved by the Food and Drug Administration (FDA) before permitting its use in food. A food additive is defined as a substance the intended use of which results or may reasonably be expected to result, directly or indirectly, either in its becoming a component of food or otherwise affecting the characteristics of food (21 CFR 170.3(e)). Because the printing ink on a paper coupon inserted into a package of dry food (e.g., cereal, rice, pasta, bread, etc.) will have direct contact with the food, there is a reasonable expectation that the ingredients of the printing ink will become components of the packaged food, and they are therefore subject to the provisions and requirements of the FD&C Act.

As stated in your letter, printing inks used on paper or paperboard in direct contact with food must be formulated from ingredients approved by FDA for food-contact use. Substances approved for use as components of paper and paperboard in contact with dry food are listed in Section 176.180 of 21 CFR (copy enclosed). This regulation also allows, by cross-reference, the use of other substances listed in Parts 170 through 189, subject to any provisions or limitations of such listings.

As a final note, we would mention that if there is a food-contact approved functional barrier (e.g., resinous coating, protective film, transparent cover, etc.) separating the printed coupon from the food, then we would not consider such use of printing ink to be a food additive situation, and the printing ink ingredients would not need to be approved.

If you have further questions on this subject, please feel free to contact us.

Sincerely yours,

Mary W. Lipien

Mary W. Lipien
Indirect Additives Branch
Division of Food and Color Additives
Center for Food Safety
and Applied Nutrition

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July 17, 1989

Ms. Mary W. Lipien
INDIRECT ADDITIVES BRANCH
DIVISION OF FOOD AND COLOR ADDITIVES
CENTER FOR FOOD SAFETY
AND APPLIED NUTRITION (HFF-335)
FOOD & DRUG ADMINISTRATION
200 "C" Street
Washington, D.C. 20204

Dear Ms. Lipien,

Thank you for your letter of June 1, 1989, concerning the regulatory acceptability of printing inks in direct contact with dry food products. Your comments have been most helpful.

However, a question has now arisen regarding the use of approved functional barriers, as described in the last pararaph on page one of your letter (copy enclosed). I hope you can provide us with your detailed opinion concerning this issue.

If by "protective film, transparent cover, etc.", you mean an approved plastic film or paper sheet used as an overwrap or as a liner placed between the printed insert and the food, then there is complete agreement as to such materials and methods constituting an effective functional barrier.

The difference in opinion with some of our customers relates to the use of "resinous coatings". They feel that an overprint varnish or coating formulated from approved ingredients listed in the appropriate sections of 21 CFR 170-189, and applied over an ink(s) by one of the normal printing processes (letterpress, offset lithography, gravure, flexography, etc.) would constitute a functional barrier. Therefore, the ink(s) used under the overprint coating need not be formulated from ingredients approved for direct contact with foods.

Our position is that even though the resinous coating or overprint is acceptable from an ingredient standpoint, it must also possess suitable resistance to the food product, and be applied in such a manner, that it forms an <u>effective</u> functional barrier; that is, it must be of sufficient thickness and continuity that it prevents any of the ink components from passing through the coating and migrating to the food.

It is our opinion that a resinous coating or overprint applied by one of the conventional printing processes described above <u>may not</u> constitute an <u>effective</u> functional barrier because of the

Ms. Mary Lipien
FOOD & DRUG ADMINISTRATION

thin film thicknesses of overprint deposited by most of these printing methods. As a result, it would be difficult to insure that the coating has formed a completely continuous film over the ink and substrate so that no "pinholing" is present and/or that the coating is of sufficient and uniform thickness so as to prevent any migration of ink through it.

We would appreciate your opinion and comments regarding this issue at your earliest convenience.

Thank you, again, for your continued cooperation and assistance.

Sincerely,

Frederick E. Bichaylo
Manager
Industrial Products Div.
Technical Services

FEB:mac

cc: J.D.Flanagan
M.F.Gettis
E.J.Furmanek
G.L.Napiecek

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

JUL 31 1989

Mr. Frederick E. Bichaylo
Manager, Industrial Products Div.
Colorcon
415 Moyer Boulevard
West Point, PA 19486

Dear Mr. Bichaylo:

This is in response to your letter of July 17, 1989 referencing Mrs. Lipien's letter of June 1, 1989 in response to your inquiry concerning the food additive regulatory acceptability of printing inks in direct contact with dry food products.

As referenced in your letter, Mrs. Lipien commented that if there is a food-contact approved functional barrier (e.g., resinous coating, protective film, transparent cover, etc.) separating the printed coupon from the food, then we would not consider such use of a printing ink to be a food additive situation, and the printing ink ingredients would not need to be FDA approved.

This is in response to your request for confirmation of FDA's opinion as to the characteristics of a functional barrier. Even though a resinous coating is acceptable on the basis of its containing components approved under the food additive regulations for their use, it must be applied in such a manner that forms an effective functional barrier; that is, it must be of sufficient thickness and continuity that it prevents the ink from passing through the coating and migrating to food. The manufacturer must employ good manufacturing practices to ensure that the coating has formed a continuous coating over the ink and substrate so that no "pinholing" is present and/or the coating is of sufficient thickness to prevent migration of ink through it. When these conditions of application of a coating are met, a functional barrier is formed.

If we can be of further assistance please feel free to contact us.

Sincerely yours,

Marvin D. Mack

Marvin D. Mack, J.D.
Indirect Additives Branch, HFF-335
Division of Food and Color Additives
Center for Food Safety
and Applied Nutrition

Colorcon
A DIVISION OF BERWIND PHARMACEUTICAL SERVICES, INC

October 4, 2001

Mr. Joseph A. Levitt
Director
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
(CFSAN)
FOOD AND DRUG ADMINISTRATION
200 "C" Street
Washington, DC 20204

Dear Mr. Levitt:

I have recently been reviewing several "position" letters which we had received from the Center For Food Safety and Applied Nutrition, Indirect Additives Branch over a decade ago dealing with the components of printing inks and varnishes used on direct food contact surfaces. One of the letters also included a position on the use of "resinous coatings" (i.e. varnishes) as effective functional barriers over surfaces composed of non-food additive materials.

I am enclosing copies of two position letters received from CFSAN (6/1/89 from Mary Lipien and 7/31/89 from Marvin Mack) along with our letters which led to these responses. I would like to ask you to review the letters and respond as to whether the positions stated are still indeed the position of FDA on these matters. Should you have any questions or would like to discuss this request in greater detail, please feel free to contact me directly by telephone at (215) 661-2561 or by e-mail at jnapiecek@colorcon.com .

Thank you for your attention to this matter. We look forward to your comments at your earliest convenience.

Sincerely,

Gerald L. Napiecek
Manager, No-Tox Technical Services and Regulatory Affairs
Colorcon

c: M.Gettis
B.Kinsey

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

December 6, 2001

Gerald L. Napiecek
Manager, No-Tox Technical Services and Regulatory Affairs
Colorcon
415 Moyer Blvd.
P.O. Box 24
West Point, Pennsylvania 19486

Dear Mr. Napiecek:

This responds to your inquiry of October 4, 2001, requesting our current regulatory opinions on the use of components of printing inks and varnishes intended for use in contact with food. More specifically, you wanted our current opinion on the use of resinous coatings (i.e. varnishes) as effective functional barriers over surfaces composed of non-food additive materials. You attached two letters previously sent from our agency for our current opinion on these matters.

Our agency has not changed it's standards for stipulating conditions of safe use for chemicals intended for use in contact with food, so the opinions offered in those letters are still valid. If there is a reasonable expectation that the ingredients of materials will become components of the food from their use in inks, then each component would be required to comply with the Federal Food, Drug, and Cosmetic Act (the Act). Generally speaking, inks that are expected to come in direct contact with food should be composed of either substances approved for use in contact with food under the proposed conditions of use, substances that are the subject of an effective food contact substance notification for such use, or substances that are generally recognized as safe (GRAS). If a substance listed under 21 CFR 175.300, *Resinous and polymeric coatings*, is used over the ink it may form a functional barrier so that components of the ink would not be considered food contact substances and thus would not be subject to the premarket approval requirements. However, a functional barrier is formed only when there is sufficient thickness and continuity of the coating to prevent any of the components from migrating into the food and that this process employs good manufacturing practices

If the coating does not provide a functional barrier and if the components of your ink are not regulated for their intended use, GRAS, or prior sanctioned, you would need to submit a food contact notification following the procedure outlined in the proposal that published July 13, 2000, in the Federal Register (65 FR 43269), at least 120 days prior to marketing your ink in the United States. This Federal Register document may be accessed on the internet at http://www.cfsan.fda.gov/~dms/opa-noti.html. In addition, you may also access FDA's current guidelines for the preparation and submission of a food contact notification at that same internet site.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Anna P. Shanklin

Anna P. Shanklin, Ph.D.
Division of Food Contact Substance
Notification Review, HFS-215
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition