



August 25, 2003

Mr. Larry R. Pilot
McKenna, Long, & Aldridge, L.L.P.
1900 K Street, NW
Washington, DC 20006

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Dear Mr. Pilot:

This responds to your letter of July 21, 2003, to the Dockets Management Branch of the Food and Drug Administration (FDA), objecting to the withdrawal of a proposed rule in Docket No. 02N-0434. That docket serves as a repository of information regarding a notice of intent, which FDA published in the *Federal Register* of April 22, 2003 (68 FR 19766), to withdraw certain advance notice of proposed rulemakings (ANPRMs), proposed rules, and other proposed actions that published in the *Federal Register* more than 5 years ago. As discussed in that notice of intent, these rules are no longer considered viable candidates for final action at this time; withdrawing the rules will enable FDA to reduce its regulatory backlog and focus its resources on current public health issues. The notice of intent is part of an overall regulatory reform strategy initiated by the Secretary of the Department of Health and Human Services, Tommy G. Thompson.

In your letter, you specifically objected to the withdrawal of "Shellac and Shellac Wax; Proposed Affirmation of GRAS Status With Specific Limitations as Direct Human Food Ingredients" (Docket No. 89N-0106; the proposed affirmation). The uses of shellac provided for in the proposed affirmation are as a surface finishing agent in cakes, cones, and fruit cakes; confections and frostings; fresh vegetables; fresh fruits; and soft candy and as a color and color adjunct in inks for marking shell eggs. The uses of shellac wax provided for in the proposed affirmation are as a surface finishing agent in chewing gum and as a stabilizer or thickener in cakes.

Because a substance that is GRAS for its intended use is excluded from the definition of food additive and, thus, is not subject to premarket review and approval by FDA, that substance may be marketed without affirmation by FDA that the intended use of the substance is GRAS. Therefore, a withdrawal by FDA of these GRAS affirmation petitions would not impact their use in food on the basis of the GRAS provision. Because shellac and shellac wax are not approved as food additives, it would still be appropriate to identify the use of these substances as GRAS.

FDA has published decisions on the GRAS status of some uses of food substances in parts 182, 184, and 186 of title 21 of the Code of Federal Regulations (21 CFR 182, 184, and 186), but the use of a substance need not appear in FDA's GRAS regulations in order to be considered GRAS. A company may choose to make its own GRAS determination without notifying FDA or a company may voluntarily notify FDA of its GRAS determination through submission of a GRAS notice. The criteria for eligibility for GRAS status are set forth in 21 CFR 170.30. If you have determined that shellac and/or shellac wax is GRAS for a specified food use, and you would like

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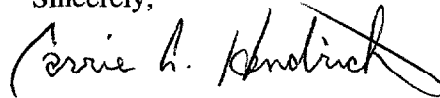
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the Agency to evaluate your independent determination, you can submit a GRAS notice in accordance with the GRAS notification program. Information and guidance on submitting a GRAS notice to FDA can be found on the world wide web at <http://www.cfsan.fda.gov/~lrd/foodadd.html>. We encourage you to review the Agency's discussion of the scientific, legal, and regulatory aspects that are essential in making a valid GRAS determination.

Please note that the withdrawal of the proposed affirmation *will not change* the regulation of shellac as a food additive for use as a component of adhesives used in food packaging (21 CFR 175.105); as a component of resinous and polymeric coatings for food contact surfaces (21 CFR 175.300); as a component of paper and paperboard used in contact with aqueous and fatty foods (21 CFR 175.170); and as a diluent in color additive mixtures for marking food supplements in tablet form, gum, and confectionary (21 CFR 73.1(b)(1)(i)).

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

Sincerely,



Carrie A. Hendrickson, Ph.D.
Division of Biotechnology
And GRAS Notice Review,
Office of Food Additive Safety
Center for Food Additive Safety
And Applied Nutrition

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