Atlanta
Denver
Los Angeles
Philadelphia

McKenna Long & Aldridge LLP
Attorneys at Law

1900 K Street, NW • Washington, DC 20006
202.496.7500 • Fax: 202.496.7756
www.mckennalong.com

San Diego
San Francisco
Washington, DC
Brussels

July 21, 2003

Larry R. Pilot
202-496-7561
lpilot@mckennalong.com

VIA MESSENGER

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane (HFA-305)
Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0434
Withdrawal of Certain Proposed Rules and Other Proposed Actions; Notice of Intent

Dear Recipient:

The undersigned submits these comments in opposition to the withdrawal of the proposed rule identified in Docket No. 89N-0106 and titled as follows:

> Shellac and Shellac Wax; Proposed Affirmation of GRAS Status With Specific Limitations as Direct Human Food Ingredients.

Additionally, the undersigned requests that the proposed rule be finalized as expressed on July 26, 1989 in Vol. 54, No. 142 of the Federal Register ("F.R.") at page 31059 (*i.e.*, 1989 Shellac Proposal).

The desire of HHS Secretary Tommy G. Thompson to accomplish regulatory reform is appropriate and welcome. It is possible that many of the advance notice of proposed rulemakings (ANPRMs), proposed rules, and other proposed actions published in the F.R. are appropriate for withdrawal. However, the above referenced affirmation of the Generally Recognized as Safe ("GRAS") status of Shellac and Shellac wax is appropriate for publication of a final rule rather than a summary withdrawal.

02N-0434

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The 1989 Shellac Proposal was initiated by the Food and Drug Administration ("FDA") in accordance with section 170.35 of Title 21 of the Code of Federal Regulations ("C.F.R."). Specifically 21 C.F.R. § 170.35(a) and (b) authorize the Commissioner "on his initiative" to affirm the GRAS status of substances and provide a 60-day period for review and/or comment on the data and information relied on by the Commissioner to affirm the GRAS status of the named substance(s). The preamble to the 1989 Shellac Proposal and supporting data/information clearly justify recognition of Shellac and Shellac wax as GRAS for the identified uses. Rather than repeat this carefully considered, conscientious, and credible justification expressed by the Commissioner, a copy of this 1989 Shellac Proposal is attached as an exhibit to these comments.

It was timely, appropriate, and scientifically sound for the FDA Commissioner to recognize and affirm the GRAS status of shellac in the 1989 Shellac Proposal. There has been no credible evidence since publication of the 1989 Shellac Proposal to suggest that the wise decision of the Commissioner should be altered. Rather, the record of this initiative justifies completion of the final rule and contradicts the notion of a withdrawal. In the absence of an explicit explanation of the justification for withdrawal of the 1989 Shellac Proposal supported by scientific evidence, such withdrawal of the 1989 Shellac Proposal would be arbitrary and capricious contrary to the purpose and function of the Administrative Procedure Act. Because of the safe use of Shellac and Shellac wax before and after the 1989 Shellac Proposal, the use of FDA resources to finalize the rule would be minimal and certainly less than the resources that would need to be applied by the FDA if a withdrawal is to be challenged.

In the interest of supporting the 2001 initiative of Secretary Thompson and the 1989 initiative of the FDA Commissioner, the undersigned respectfully requests that the objective of each of these public servants will be accomplished through the

publication of a simple and supportable final rule recognizing the GRAS status of Shellac and Shellac wax as expressed in the 1989 Shellac Proposal.

Sincerely,

Larry R. Pilot

LRP/clb
cc: Dockets Management Branch
Docket No. 89N-106

fact that they must be paid by the consumer in addition to the advertised price.

PART 399—[AMENDED]

3. The authority citation for Part 399 continues to read as follows:

Authority: 49 U.S.C. 1301, 1302, 1305, 1324, 1371, 1372, 1373, 1374, 1375, 1376, 1377, 1378, 1379, 1381, 1382, 1384, 1386, 1461, 1481, 1482, 1502 and 1504, unless otherwise noted.

4. Section 399.84 is revised to read as follows:

§ 399.84 Price advertising.

The Department considers any advertising or solicitation by a direct air carrier, indirect air carrier, or an agent of either, for passenger air transportation and ground accommodations), or a tour component (e.g., a hotel stay) that states a price for such air transportation, tour, or tour component to be an unfair or deceptive prictice, unelss the price stated is the entire price to be paid by the customer to the air carrier, or agent, for such air transportation, tour, or tour component, except:

(a) One-way fares that are available as part of a round-trip purchase may be advertised separately, provided that the advertisement indicate clearly that round-trip purchase is required.

(b) U.S. and foreign departure taxes, security charges, customs fees, immigration fees, tourism surcharges, and any other surcharges that may be imposed by the federal or a state, local, or foreign government may be stated separately in advertisements and promotional materials, provided they are levied on a per-passenger basis by the governmental entity and are remitted directly to the levying government, subject to the conditions in paragraph (d) of this section.

(c) Any other carrier fee or surcharge that may be approved by the U.S. government for separate imposition on individual passengers may be stated separately in advertisements and promotional materials, subject to the conditions in paragraph (d) of this section.

(d) All advertisements and promotional materials in which the charges described in paragraphs (c) and (d) of this section are stated separately must clearly and conspicuously state elsewhere in the advertisement the amount of such charges, the services they cover, and the fact that they must be paid by the consumer in addition to the advertised price.

Issued on: July 18, 1989.

Jeffrey N. Shane,

Assistant Secretary for Policy and International Affairs.

[FR Doc. 89-17201 Filed 7-25-89; 8:45 am]

BILLING CODE 4910-62-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 89N-0106]

Shellac and Shellac Wax; Proposed Affirmation of GRAS Status with Specific Limitations as Direct Human Food Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to affirm that shellac and shellac wax are generally recognized as safe (GRAS) with specific limitations, for use as direct human food ingredients. The safety of these ingredients has been evaluated under a comprehensive safety review conducted by the agency.

DATES: Comments by September 25, 1989.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Copies of the scientific literature review of shellac and shellac wax and the report of the Select Committee on GRAS Substances are available for review at the Dockets Management Branch and may be purchased from the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161.

FOR FURTHER INFORMATION CONTACT: John W. Gordon, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-5487.

SUPPLEMENTARY INFORMATION:

I. Background

Shellac and shellac wax are resinous materials derived from the hardened secretion of the lac insect, species *Lucifer (Tachardia) lacca Kerr* (family *Coccidae*) (Ref. 1), also known as *Kerria lacca* (Kerr) (Ref. 2). India and Thailand are the primary sources of shellac (Ref. 3). Food-grade shellac is refined from the crude lac secretion by a process that may include sieving, water washing, multiple filtration, solvent refining, dissolution in mild soda solutions, bleaching with sodium hypochlorite solution, and decolorizing with activated carbon (Ref. 2).

The items of commerce are food-grade bleached shellac, bleached shellac (wax-free), orange shellac, orange shellac (wax-free), and bleached shellac wax (Refs. 2 and 11). The exact nomenclature applied to the final product generally reflects the extent of refining (Ref. 2).

Orange shellac is unbleached and is produced either by a process of filtration in the molten state or by a hot solvent process. It may retain most of its wax or be dewaxed.

Bleached shellac is obtained by dissolving the lac in aqueous sodium carbonate followed by bleaching with sodium hypochlorite. The bleached lac is either precipitated with a diluted sulfuric acid solution or passed through a filter press to remove the wax, and then precipitated with a dilute sulfuric acid solution. The precipitate forms an off-white amorphous shellac resin upon drying. Removal of the wax during processing results in bleached shellac (wax-free). Shellac wax, as noted above, is a bleached byproduct of the processing of bleached shellac (Ref. 4).

II. Regulatory History

The agency has issued numerous opinion letters stating that shellac is GRAS for use in candy coatings, resinous glaze coatings for food, and coatings on apples, avocados, and tomatoes and as a coating for metal foil that contacts food. One letter (Ref. 14) sanctioning the use of shellac in coating candy predates the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act (the act).

Shellac is regulated as a food additive for use as a component of adhesives used in food packaging under 21 CFR 175.105; as a component of resinous and polymeric coatings for food-contact surfaces under 21 CFR 175.300; as a component of paper and paperboard used in contact with aqueous and fatty foods under 21 CFR 175.170; and as a diluent in color additive mixtures for marking food supplements in tablet form, gum, and confectionery under 21 CFR 73.1(b)(1)(i).

III. Consumers' Exposure to Shellac and Shellac Wax in Food

In 1971 and 1975, the National Academy of Sciences/National Research Council (NAS/NRC) reported to FDA on its survey of a cross-section of food manufacturers on the use of GRAS ingredients. The surveys contained the entry "wax, shellac" but

no separate listing for shellac. In 1971, 14 companies reported the use of 209,000 pounds of material under the category "wax, shellac," and in 1975, 9 companies reported the use of 'wax, shellac" to be 227,000 pounds. The Select Committee on GRAS Substances (the Select Committee) noted in its report, however, that some evidence indcated that these poundage data reflect use of both shellac and shellac wax.

Other use data (Refs. 2 and 7) indicate that the amount of shellac wax used annually as a food ingredient is about 2,000 or 3,000 pounds, and that nearly all of the shellac wax is used as a polishing agency for chewing gum. Based on these data, the Select Committee estimated the per capita daily consumption of shellac wax to be 0.075 milligram (mg) (Ref. 2).

A representative of the shellac industry reported to the Select Committee that the approximate annual poundage of shellac used in the food industry is on the order of 200,000 pounds. About 80 percent of this quantity is used for coating citrus fruit and avocados and would not be ingested, leaving about 20 percent or about 40,000 pounds for use as a direct food ingredient, primarily in confections. From this report and the survey data, the Select Committee estimated the per capita daily intake of shellac to be 0.25 mg (Ref. 2).

The agency has estimated the average per capita daily disappearance of shellac based on updated poundage information from a shellac trade assocation (Ref. 8). The association advised FDA that between November 1, 1983, and October 31, 1984, 397,823 pounds of shellac were used directly in food. Based on this figure, the agency estimated the per capital daily disappearance for shellac to be 2.1 mg. The agency's estimate of the per capita disappearance (2.1 mg) of shellac is significantly higher than the combined per capita estimate for shellac and shellac wax that was reported in the Select Committee's report (0.32 mg).

The agency also estimated consumer exposure based on dietary survey and usage information (Refs. 5, 6, 7, and 13). On this basis, its exposure estimate for an average consumer of shellac-coated candies, cakes, fresh fruits, fresh vegetables, cones, and fruit cakes is 28 mg per person per day (mg/person/day) and for a 90th percentile consumer, 55 mg/person/day. However, the agency recognizes that the latter intake estimates are very conservative given the Select Committee's finding that 80 percent of the shellac used to coat fruits and vegetables is not ingested. If a correction is made for what is discarded on the peels of fruits and vegetables, then the estimated daily intake (EDI) of shellac from its current uses drops to about 10 mg/person/day. The agency has used this intake estimate, as well as the per capita disappearance estimate of shellac, in its evaluation of the safety of shellac and shellac wax as food ingredients.

IV. Opinion of the Select Committee on Shellac and Shellac Wax

Shellac and shellac wax were the subjects of a search of the scientific literature from 1920 to the present. The criteria used in the search were chosen to discover any articles that considered (1) chemical toxicity, (2) occupational hazards, (3) metabolism, (4) reaction products, (5) degradation products, (6) carcinogenicity, teratogenicity, or mutagenicity, (7) dose-response, (8) reproducitive effects, (9) histology, (10) embryology, (11) behavioral effects, (12) detection, and (13) processing. A total of 47 abstracts on shellac and shellac wax were reviewed, and 21 particularly pertinent reports from the literature survey were summarized in a scientific literature review.

Information from the scientific literature review and other available studies has been summarized in a report to FDA by the Select Committee, which is composed of qualified scientists chosen by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology (FASEB). The Select Committee issued its final report on shellac and shellac wax in 1981. In the Select Committee's opinion:

Shellac is a polyester resin of animal origin. Shellac wax is a refined, bleached by-product of the processing of regular shellac. Shellac is currently used as a coating for certain fruits and vegetables and as a furface-finishing agent in a manner which might contribute to a per capita daily intake of about 0.25 mg. Shellac wax utilized as a polishing agent for chewing gum and as a stabilizer-thickening agent in cakes might provide a per capita daily intake of 75 μg.

The Select Committee acknowledges the long history of use of shellac in food coatings as well as the absence of reports attributing any adverse effects to such food applications. Nevertheless, there are few biological data regarding the effects of shellac and shellac wax on animal or man following oral ingestion. One preliminary report of a 90-day rat feeding study, while presenting no cause for concern, was technically incomplete and could not be judged as evidence of safety. Food-grade standards should be developed for shellac wax (Ref. 2, p. 10).

The Select Committee therefore concluded that:

> In view of the deficiency of relevant biological studies, the Select Committee has insufficient data upon which to base an evaluation of shellac and shellac wax when they are used as food ingredients.

Before the issuance of the Select Committee's final report, the agency published a notice in the **Federal Register** of April 25,1980 (45 FR 27992), announcing the Select Committee's tentative finding of insufficient data upon which to evaluate the safety of shellac and shellac wax and provided an opportunity for a public hearing. A public hearing was held but produced no new information. Accordingly, the Select Committee's final report affirmed its tentative conclusion.

V. FDA's Evaluation

FDA completed its review of all available information on shellac and shellac wax and agreed with the conclusion of the Select Committee. As a result of this conclusion, FDA toxicologists considered what additional information would be needed to assist the agency in determining the GRAS status of shellac and shellac wax, given the long history of use of shellac and shellac wax on food. FDA advised a representative of the American Bleached Shellac Manufacturers Association, Inc. (ABSMA), who had participated in the public hearing on the safety of shellac and shellac wax, on the minimum toxicology studies that would be needed to affirm the GRAS status of the use of these ingredients. Specifically, the agency advised that a 90-day feeding study of shellac in rats with in utero exposure and a mutagenicity test of shellac was in *Salmonella typhimurium* were needed to assure that shellac use in foods is safe. Subsequently, FDA dropped its request for a mutagenicity test because a new test using more sensitive organisms was submitted by ABSMA, and this test demonstrated that shellac was not mutagenic.

ABSMA submitted to FDA an unpublished report of the 90-day feeding study in rats (Ref. 9). In this study doses of 1,000, 3,000, and 10,000 parts per million (ppm) of shellac were administrated in the diets of Sprague-Dawley rats. The study showed an increase in some pancreatic leasions, described as mild, in male rats fed the high dose of 10,000 ppm shellac. The agency has determined that the no-effect level for shellac including the was is 3,000 ppm in the dies or 9 mg/person/day (Ref. 10).

As noted above, the Select Committee acknowledged tha. shellac and shellac

wax have a history of use in food before 1958 with no reports of adverse effects and are of natural biological origin. The agency searched the Adverse Reaction Monitoring System (ARMS) described in Ref. 16 to determine if it had received any reports of adverse effects from the Use of shellac and shellac wax. There were no such reports. The agency also conducted a computer search of the scientific literature from 1981 through 1989 for any adverse reaction reports. There were no reports of adverse reactions in the literature on shellac and shellac was (Ref. 17).

Consequently, shellac and shellac wax have had a long history of common use in food for certain technical effects without any apparent associated safety problems. Under 21 CFR 170.30(b), this history of use provides an appropriate basis for a determination that there is general recognition among qualified experts that shellac and shellac wax are safe for their current uses. Section 170.30(b) also provides that this determination can be made without the quantity or quality of scientific data required for approval of a food additive regulation.

Nonetheless, FDA has looked to the 90-day rat study for corroborative evidence of the safety of shellac and shellac wax. Based on this study, the agency has estimated that the acceptable daily intake (ADI) for shellac and shellac wax is 9 mg/person/day, which is comparable to the EDI (10 mg/person/day). Because the EDI for shellac and shellac wax does not significantly exceed the ADI, agency scientists are satisfied that current food uses of these substances are safe.

As provided for under 21 CFR 170.30(b), FDA has tentatively determined that the rat study, coupled with the history of safe use of these ingredients since before 1958, provides an adequate basis upon which to affirm these ingredients as GRAS under their current conditions of use. FDA is therefore proposing to affirm shellac and shellac wax as GRAS with specific limitations to current conditions of use. The limitations will ensure that the ADI and EDI will remain in balance. Any significant new uses of shellac and shellac wax will require that additional studies be performed to establish the safety of those uses (Ref. 12).

VI. The Listing Regulation

A. Nomenclature

ABSMA informed FDA that the term "shellac" is used by the industry to refer to bleached shellac, bleached shellac (wax-free), orange shellac, or orange shellac (wax-free), and that shellac wax is a separate item of commerce (Refs. 2 and 11). Based on this information, and on the fact that the Select Committee did not differentiate between the forms of shellac, either on the basis of their food uses or their safety, FDA has tentatively decided to cite the generic term "shellac" in the proposed regulation to include bleached shellac, bleached shellac (wax-free), orange shellac, and orange shellac (wax-free). The agency is proposing to include shellac wax under a separate regulation.

B. Food Uses

The agency identified the uses of shellac and shellac wax that are listed in the proposed regulations based on information from the NAS/NRC surveys (Refs. 5, 6, and 7), information from the shellac industry, opinion letters issued by the agency (Ref. 13), and information contained in the Select Committee's report on shellac and shellac wax (Ref. 2).

The agency notes that shellac was reported in the 1975 NAS/NRC survey for use on shelled nut products. However, it was not reported for that use in the subsequent survey or in the Select Committee's report (SCOGS 19–II). Because there were no subsequent reports of this use in the updated surveys, the agency has not included the use of shellac on nut products in this proposal. Persons interested in the use of shellac on nut products may have that use considered by submitting to the Dockets Management Branch (address above), as a comment on this proposal, appropriate published or unpublished safety data and use and exposure information.

In addition, the agency received a request for an advisory opinion on the use of shellac as a component of an ink for marking shell eggs. The agency has estimated the increase in exposure that would result from this use and has concluded that the exposure would be too small to constitute a significant toxicological concern (Ref. 15). (Shellac, as noted above, is currently approved for use in inks for marking food supplements in tablet form, gum, and confectionery in 21 CFR 73.1(b)(1)(i).)

The uses of shellac provided for in the proposed regulation 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 regulation are as a surface finishing agent in chewing gum and as a stabilizer or thickener in cakes.

The proposed regulation sets forth the conditions of use (technical effects and food categories) for shellac and shellac wax that FDA evaluated and found to be safe. In addition, the indirect uses of shellac and shellac wax are authorized by § 184.1(a). FDA is not proposing to include limitations on the levels of use of shellac and shellac wax in the listed foods or food categories. The agency has tentatively concluded that the use of shellac and shellac wax in the listed foods or food categories is self-limiting because at higher levels, these ingredients no longer perform their intended technical effects, and that these self-limiting levels of use of shellac and shellac wax in the types of food in, and under the conditions for, which they are currently used will not significantly increase the total consumption of shellac and shellac wax.

C. Specifications

The Select Committee noted that the "Food Chemicals Codex" lists food-grade specifications for "shellac, bleached" and "shellac, bleached, wax-free" but not for shellac wax. It recommended the development of food-grade specifications for shellax wax. The agency also notes that there is a need to develop specifications for orange shellac and orange shellac (wax-free).

Therefore, the agency will work with the Committee on Food Chemicals Codex to develop appropriate specifications for orange shellac, orange shellac (wax-free), and shellac wax. When acceptable specifications are developed, the agency will incorporate them into the regulations. Until specifications are developed, FDA has determined that the public health will be adequately protected so long as orange shellac, orange shellac (wax-free), and shellac wax comply with the description in the proposed regulations and are of appropriate food-grade purity in accordance with 21 CFR 184.1(b) and 170.30(h)(1).

In the case of indirect uses of shellac and shellac wax, FDA believes that the general requirements of 21 CFR 186.1(a) that indirect GRAS ingredients be of a purity suitable for their intended use in accordance with § 170.30(h)(1) and used in accordance with current good manufacturing practice, are sufficient to ensure the safe use of these ingredients.

D. Conclusion

Based upon the Select Committee's evaluation of shellac and FDA's subsequent evaluation of all available

data, the agency tentatively concludes that:

1. The current uses of shellac and shellac wax are safe based upon the history of use of these substances of natural biological origin in food since before 1958 without any evidence of adverse effects from consumption of these ingredients and the 90-day study that was conducted after the Select Committee's final report.

2. The safety information is sufficient to support the limited use provided for in the regulation.

3. Shellac and shellac wax should be listed separately in the regulations because they are separate items of commerce.

4. The agency is working with Food Chemicals Codex to develop appropriate specifications for shellac.

Copies of the scientific literature review of shellac and shellac wax and the report of the Select Committee are available for review at the Dockets Management Branch (address above) and may be purchased from the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161, as follows:

Title	Order number	Price code	Price*
Shellac (scientific literature review)	PB-287-165/AS	A02	$6.00
Shellac wax (mutagenic evaluation)	PB-245-484/AS	A03	$7.50
Shellac and shellac wax (Select Committee Report)	PB-82-160383	A01	$6.00

* Price subject to change.

This proposed action does not affect the current use of shellac and shellac wax in pet food or animal feed.

VII. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be reviewed by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Monograph on "Shellac, Bleached and Shellac, Bleached, Wax-Free," Committee on Codex Specifications, *Food Chemicals Codex*, 3d Ed., National Academy Press, Washington, DC, pp. 270–271, 1981.

2. "Evaluation of the Health Aspects of Shellac and Shellac Wax as Food Ingredients," Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, Bethesda, MD, 1981.

3. Monograph on "Shellac," Informatics, Inc., Rockville, MD, 1978.

4. Monographs on "Pharmaceutical Glaze and Shellac," *United States Pharmacopeia XX/The National Formulary XV:* supp. 2, 1981, Mack Publishing Co., pp. 210, 219, The United States Pharmacopeial Convention, Inc., Easton, PA.

5. Subcommittee on Review of the GRAS List—Phase II, 1972, "A Comprehensive Survey of Industry on the Use of Food Chemicals Generally Recognized as Safe (GRAS)," prepared under DHEW Contract No. FDA 70–22 with the Committee on Food Protection, Division of Biology and Agriculture, National Research Council, National Academy of Sciences, Washington, DC.

6. Memorandum of telephone conversation dated February 12, 1987, between R. Rehwoldt, National Academy of Sciences and J. W. Gordon, FDA.

7. Committee on GRAS List Survey—Phase III, 1979, "The 1977 Survey of Industry on the Use of Food Additives," prepared under DHEW Contract No. FDA 223–77–2025 with the Food and Nutrition Board, Division of Biological Sciences, National Research Council, National Academy of Sciences, Washington, DC.

8. Letter dated January 11, 1985, from P. R. Donovan, American Bleached Shellac Manufacturers Assocation, Inc., to J. W. Gordon, FDA.

9. "90-Day (in utero) Dietary Toxicity Study of Regular Bleached Shellac in Sprague-Dawley Rats, Final Report," Food and Drug Research Laboratories Inc., 1984, American Bleached Shellac Manufacturers Association.

10. Memorandum dated May 31, 1985, from M. J. Wade, FDA to J. W. Gordon, FDA.

11. Memoranda of telephone conversations dated December 2, 1986, August 24, 1987, and October 20, 1987, between P. R. Donovan, American Bleached Shellac Manufacturers Association and J. W. Gordon, FDA.

12. Memorandum dated June 17, 1988, from C. B. Johnson, FDA to J. W. Gordon, FDA.

13. Letter dated September 21, 1959, from Arthur A. Checchi, FDA to P. H. Groggins, Food Machinery and Chemical Corp.

14. Letter dated August 3, 1939, from W. G. Campbell to Wm. Howlett Gardner, Shellac Research Bureau, Polytechnic Institute of Brooklyn.

15. Memorandum dated June 22, 1988, from C. B. Johnson, FDA to C. J. Bailey, FDA.

16. Tollefson, L., "Monitoring Adverse Reactions to Food Additives in the U.S. Food and Drug Administration," *Regulatory Toxicology and Pharmacology*, 8:438–446, 1988.

17. Computer printout of the search of the scientific literature reports of adverse reports.

VIII. Economic and Environmental Assessment

The agency has determined under 21 CFR 25.24(b)(7) that this action 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.

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this proposal would have on small entities including small businesses and has determined that the effect of this proposal is to maintain current known uses of the substances covered by this proposal by both large and small businesses. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Executive order 12291, FDA has carefully analyzed the economic effects of this proposal and has determined that the final rule, if promulgated, will not be a major rule as defined by the Order.

The agency's findings of no economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

IX. Prior Sanctions

The agency is unaware of any prior sanction for the use of these ingredients in foods under conditions different from those identified in this document. Any

person who intends to assert or rely on such a sanction shall submit proof of its existence in response to this proposal. The action proposed above will constitute a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act (21 U.S.C. 342), and the failure of any person to come forward with proof of such an applicable prior sanction in response to this proposal constitutes a waiver of their right to assert or rely on it later. Should any person submit proof of the existence of a prior sanction, the agency hereby proposes to recognize such use by issuing an appropriate final rule under Part 181 (21 CFR Part 181) or affirming it as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

Interested persons may, on or before September 25, 1989, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. to 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 184

Food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, it is proposed that Part 184 be amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR Part 184 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046–1047 as amended, 1055–1056 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10, 5.61.

2. New §§ 184.1705 and 184.1706 are added to Subpart B to read as follows:

§ 184.1705 Shellac.

(a) Shellac (CAS Reg. No. 9000–59–3) is a resinous material derived from the hardened secretion of the lac insect, species *Lucifer* (Tachardia) *lacca Kerr* (family *Coccidae*), also known as *Kerria lacca* (Kerr). The extent of refining of the crude lac secretion defines the food-grade product as bleached shellac; bleached shellac, wax-free; orange shellac; or orange shellac, wax-free.

(b) The ingredient meets the specifications for shellac, bleached, or shellac, bleached, wax-free of the "Food Chemicals Codex", 3d Ed. (1981), pp. 270–271, which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC. For orange shellac and orange shellac, wax-free, the Food and Drug Administration is developing food-grade specifications in cooperation with the National Academy of Sciences. In the interim, orange shellac and orange shellac, wax-free must be of a purity suitable for their intended use.

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following limitations;

Category of food	Functional use
Cakes, cones, and fruitcakes.	Surface-finishing agent, § 170.3(o)(30) of this chapter.
Chewing gum, § 170.3(n)(6) of this chapter.	Do.
Confections and frosting, § 170.3(n)(9) of this chapter.	Do.
Shell eggs, § 170.3(n)(14) of this chapter.	Color and coloring adjunct, § 170.3(o)(4) of this chapter.
Fresh fruits, § 170.3(n)(16) of this chapter.	Surface-finishing agent, § 170.3(o)(30) of this chapter.
Fresh vegetables, § 170.3(n)(19) of this chapter.	Do.
Soft candy, § 170.3(n)(38) of this chapter.	Do.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 184.1706 Shellac wax.

(a) Shellac wax (CAS Reg. No. 97766–50–2) is obtained as the refined, bleached byproduct of the primary processing of shellac (§ 184.1705).

(b) The Food and Drug Administration is developing food-grade specifications for shellac wax in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following limitations:

Category of food	Functional use
Cakes	Stabilizer, thickener, § 170.3(o)(28) of this chapter.
Chewing gum, § 170.3(n)(6) of this chapter.	Surface-finishing agent, § 170.3(o)(30) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Dated: July 18, 1989.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89–17390 Filed 7–25–89; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 110

[CGD11–89–14]

Anchorage Ground; Long Beach Harbor, CA

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is considering a proposal to redefine Commercial Anchorage D in Long Beach Harbor. In 1988, the Port of Long Beach began construction on the Pier J Expansion Project which will ultimately lead to the creation of 147 acres of new landfill. This new land will be situated in the present northwest end of Commercial Anchorage D. This proposed regulation will redefine Commercial Anchorage D to reflect the changes imposed by the Pier J Expansion Project.

DATES: Comments must be received on or before September 11, 1989.

ADDRESSES: Comments should be mailed to Commander (oan), Eleventh Coast Guard District, 400 Oceangate, Suite 702, Long Beach, CA 90822–5399. The comments and other materials referenced in this notice will be available for inspection and copying at the above address. Normal office hours are between 7:00 a.m. and 3:30 p.m., Monday through Friday, except holidays. Comments may also be hand delivered to this address.

FOR FURTHER INFORMATION CONTACT: LTJG Mike Lodge, telephone (213) 499–5419.

SUPPLEMENTARY INFORMATION: Interested persons are invited to