2300 East Devon Avenue, Des Plaines, Illinois.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth W. Payauys, Airframe Branch, ACE-120C; telephone (312) 694-7426. Mailing address: FAA, Chicago Aircraft Certification Office, 2300 East Devon Avenue, Des Plaines, Illinois 60018.

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments specified above will be considered by the Administrator before taking action on the proposed rule. The proposals contained in this Notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA/public contact, concerned with the substance of this proposal, will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this Notice must submit a self-addressed, stamped post card on which the following statement is made: "Comments to Docket Number 89-NM-111-AD." The post card will be date/time stamped and returned to the commenter.

Discussion

Following an accident involving a CASA Model C-212 airplane, the National Transportation Safety Board (NTSB) noted following their investigation that the passenger steps on the airplane, installed under STC SA906GL, could obstruct the visibility of and access to the interior door latch for the passenger entry door. This condition, if not corrected, could result in the impairment of passenger egress during an emergency evacuation.

This airplane model is manufactured in Spain and Indonesia and type certificated in the United States under the provisions of § 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement.

Since this condition is likely to exist or develop on other airplanes of the same type design registered in the United States, an AD is proposed which would require removal of the step, handrails, door latch modifications, and associated hardware installed under STC SA906GL, and restore the door handle to the original CASA configuration.

It is estimated that 6 airplanes of U.S. registry would be affected by this AD, that it would take approximately 8 manhours per airplane to accomplish the required actions, and that the average labor cost would be $40 per manhour. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be less than $1,920.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft evaluation prepared for this action is contained in the regulatory docket. A copy of it may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend Part 39 of the Federal Aviation Regulations as follows:

PART 39—[AMENDED]

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Casa: Applies to Model C-212 series airplanes equipped with a passenger entry step installed under Supplemental Type Certificate (STC) SA906GL, certificated in any category. Compliance is required within 60 days after the effective date of this AD, unless previously accomplished.

To prevent delay in opening the passenger door in the event of an emergency evacuation, accomplish the following:

A. Remove the step, handrails, door latch modifications, and associated hardware installed in accordance with Fischer Brothers Aviation, Inc., Installation Instructions for FBD-206, Revision F, dated June 5, 1985.

B. Restore the door handle to the original CASA configuration.

C. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Chicago Aircraft Certification Office, ACE-115C, FAA, Central Region.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who will either concur or comment and then send it to the Manager, Chicago Aircraft Certification Office, ACE-115C.

D. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

The applicable service information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or the Chicago Aircraft Certification Office, 2300 East Devon Avenue, Des Plaines, Illinois.

Issued in Seattle, Washington, on July 14, 1989.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 89-17473 Filed 7-25-89; 8:45 am]

BILLING CODE 4910-13-M

Office of the Secretary

14 CFR Parts 380 and 399

[OST Docket No. 46410; Notice No. 89-6]

RIN 2105-AB50

Price Advertising

AGENCY: Office of the Secretary, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department is proposing to amend its rule and policy statement with respect to air transportation price advertising under 14 CFR Parts 380 and 399 to comport with its current enforcement policy. The proposal would allow advertisers to list government-imposed and government-approved charges that are levied on a per

passenger basis separately in price advertisements. It also would codify current practice allowing the advertisement of one-way fares that are available only on a round-trip basis, provided the ads are clear with regard to the round-trip conditions.

DATES: Comments are due on or before August 25, 1989.

ADDRESSES: Comments must be filed in Room 4107, Docket 46410, U.S. Department of Transportation, 400 7th St., SW., Washington, DC 20590. Late-filed comments will be considered to the extent possible.

FOR FURTHER INFORMATION CONTACT: Samuel E. Whitehorn, Office of the General Counsel, C–50, (202) 366–9307, Department of Transportation, 400 Seventh Street, SW., Washington, DC, 20590.

SUPPLEMENTARY INFORMATION: The Department of Transportation's (DOT or Department) policy on advertising of air transportation, 14 CFR 399.84, states that all price advertisements of flights, tours, or components of tours must state the entire price of the advertised flight, tour, or tour component or the ads will be considered to be unfair and deceptive and thus in violation of Section 411 of the Federal Aviation Act of 1958 (49 U.S.C 1381) ("Act"). Similarly, our public charter rules, 14 CFR 380.30(e), require that any price listed in charter solicitation materials from direct or indirect air carriers or their agents state the entire price of the charter, tour, or any tour component. The policy and the rule are directed at preventing consumer harm that could result from unfair or deceptive trade practices.

On December 24, 1985 (Order 85–12–68), the Department issued an exemption from the price advertising rule and policy statement to permit direct and indirect air carriers for scheduled and charter service and tour operators to state the United States international departure tax separately from other charges in advertisements and promotional materials, provided that the ads clearly state both the amount of the tax and that it must be paid by the passenger. In two other orders, Orders 88–3–25 and 88–8–2, the Department sought to expand the 1985 exemption to cover similar charges, i.e., immigration fees and security surcharges. These two orders were recently struck down by the U.S. Court of Appeals on procedural grounds. *Alaska* v. *Skinner* (868 F. 2d 441 (D.C. Cir. (1989)))

Proposed Change to Rule: Parts 380 and 399

The Department proposes to amend both the charter and scheduled-service price advertising provisions. Consistent with the Department's current enforcement policy, the proposal would permit a separate listing of government-imposed or -approved charges where the charges are levied on individual passengers and, in the case of government-imposed charges, the advertiser collects them to be remitted to the levying government. For the reasons stated in the orders cited above [1] the Department does not consider such ads to be unfair or deceptive provided they are clear and the total amount to be paid by the consumer can be calculated easily by adding the separately-stated fixed amounts. An ordinary person reading such ads would be aware of the total amount to be paid for the transportation and, in addition, would be provided with valuable information on associated government-imposed or -approved surcharges. The Department's experience indicates that these kinds of ads do not cause passenger harm.

The change to the codified provisions would not cover all taxes, charges, fees, and surcharges levied by Federal, state, local or foreign governments, but only those levied on a per passenger basis. Separate listings of passenger surcharges that are not government approved but are set by a carrier in response to a governmental charge that was not levied on a per passenger basis would be considered deceptive. For example, if a local government imposed a per-gallon tax on aviation fuel purchased at its airport, a carrier would be free to increase ticket prices for flights departing from or arriving at that airport. However, such additional fees must be included in the total advertised air fare—not listed separately. If listed separately on a per passenger basis, such surcharge would likely provide inaccurate information on the per passenger cost to the airline of the government fee.

The proposal would continue to allow the separate listing of the $3 U.S. international departure tax. (See Order 85–12–68). Under the proposal, and consistent with existing practice which the Department has not found to have caused any confusion in the past, advertisers also would be able to continue to advertise one-way fares that require round-trip purchases, provided that the advertisement indicates clearly that these fares are available only in conjunction with a round-trip purchase.

Advertisers, under the new rule, would continue to be able to list components of a tour package separately, as long as all of the costs are stated clearly, and also list separately any government-approved or -imposed charges levied on a per passenger basis. The proposed change would not effect the current Internal Revenue Code requirements regarding the eight percent federal tax on all tickets for domestic transportation (see 26 U.S.C 7275). It should also be noted that the Anti-Head tax provision of the Act (49 U.S.C. 1513) precludes certain state and local fees to be imposed on a per-passenger basis.

Under section 411, the Department is responsible for protecting aviation consumers from unfair and deceptive trade practices. These changes are intended to implement that authority fully and clearly and without placing any restrictions on the industry that are not necessary and that would tend to limit airline price competition. The specific charges that would be permitted to be listed separately either are limited, or apply only in certain markets or for certain flights, thus making if difficult or impossible to publich advertisements with one way and round-trip fares to multiple destinations and include the charges in single advertised rates. Commenters should address what effects the proposed changes will have upon consumers and upon advertisers. Would the changes be sufficiently clear so that advertisers will be able to comply? Is the proposed language sifficiently broad so that consumers will be able to discern what is being offered in a given ad and at what price?

On April 21, during the drafting of this document, the Air Transport Association of America (ATA) filed a petition asking the Department to initiate rulemaking. This NPRM is consistent with that request, and thus the request is granted.

Federalism

Under Executive Order 12612, the Department in promulgating regulations is required to review the implications of its actions on the states. In this case, the responsibility for regulating and setting advertising standards for the aviation industry has long been a function and responsibility of the Federal government, as provided by the Federal Aviation Act. Thus, Federalism ramifications will be minimal, if any. In addition, this rulemaking will codify longstanding Federal practices, recently overturned by a court on purely procedural grounds.

In particular areas the states' ability to enforce advertising rules and policies has been preempted by the DOT rules. For example, states would be preempted from regulating airline advertising of

[1] The order were not published in the **Federal Register**.

fares and schedules since DOT has specific rules covering deceptive practices in these areas. To allow the 50 states to regulate price advertising and institute related enforcement proceedings would subject the carriers to inconsistent standards and thus seriously interfere with interstate commerce. The Airline Deregulation Act of 1978 enabled carriers to offer their services on a competitive basis, in terms of services and prices. Prosecutorial action and court decisions in different jurisdictions could affect a carrier's ability to compete. For example, if a state attorney general in state A forced an air carrier to include all taxes in its quoted fare (as opposed to the proposal which would allow the carrier to separate the per capita taxes), the carrier could be placed at an unfair competitive position vis-a-vis other carriers not before the state enforcement authority or one who advertised in an out-of-state publication, or vis-a-vis a foreign carrier. In addition, section 105 of the Federal Aviation Act specifically prohibits state regulation related to airline rates, routes and services and state regulation of advertising that can significantly affect airline rates, routes and services could clearly violate that provision. Thus, the Federal aviation Act and the commerce clause dictate that there be one industry-wide price advertisement standard.

In reviewing whether it would be feasible for each of the states to regulate price advertising as they saw fit, there are a number of possible considerations. For example, the states could help to curb advertising abuses. On the other hand, without a uniform policy, carriers would find it virtually impossible to put together nation-wide advertising programs that accurately portray the price of their services. Price competition would suffer, thus depriving consumers of lower fares. Comments are requested on what, if any, are the Federalism implications of this rulemaking.

Paperwork

The Paperwork Reduction Act (Pub. L. No. 96–511) establishes policies and procedures for controlling paperwork burdens imposed by Federal agencies on the public. If a rule does in fact impose such a burden, approval from the Office of Management and Budget is necessary before the burden can be imposed.

This proposal does not impose any paperwork burdens on advertisers. This rule merely codifies existing practices and enforcement policies. In addition, even if the NPRM were not merely codifying existing practices and policies, there would be no burdens imposed on the industry since the rule would not require that an advertiser state surcharges separately; it merely permits that form of advertisement.

Regulatory Impact Analysis and Review

Executive Order 12291 on "Federal Regulation" and the DOT Policies and Procedures require the preparation of a regulatory impact analysis for every "major" rule. A major rule is defined as a regulation that is likely to result in: An annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individuals, industries, Federal, State or local governments, or geographic regions; or a significant adverse effect on competition, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises. Under the above criteria, this rule is not considered "major". However, due to public interest, it is considered to be "significant" under the DOT Policies and Procedures. The economic impact of this rulemaking will be so minimal that an economic evaluation is not warranted. Those subject to the rule and policy will be able to continue to advertise their services, consistent with past industry practices, so there should be no additional costs to consumers or advertisers. Moreover, uniform rules could make advertising more efficient.

Regulatory Flexibility Act

The Regulatory Flexibility Act, Pub. L. No. 96–354, is designed to ensure that agencies consider flexible approaches to the regulation of small businesses and other small entities. It requires regulatory flexibility analyses for rules that will have a significant economic impact on a substantial number of small entities.

While this proposal may affect a substantial number of small entities, the proposed changes will not have a significant impact on them. Therefore, I certify that this rulemaking will not have a significant impact on a substantial number of small businesses or entities.

List of Subjects

14 CFR Part 380

Public charters, Surety bonds, Advertising, Antitrust, Charter flights, Consumer protection, Education study program, Travel agents, Tour operators.

14 CFR Part 399

Administrative practice and procedures, Advertising, Air carriers, Antitrust, Agreements, Archives and records, Consumer protection, Foreign air carriers, Reporting and recordkeeping requirements, Travel agents.

In consideration of the foregoing, Parts 380 and 399 of Title 14, Code of Federal Regulations, are amended to read as follows:

PART 380—[AMENDED]

1. The authority citation for 14 CFR Part 380 is revised to read as follows:

Authority: Secs. 101(3), 102, 204, 401, 402, 403, 404, 407, 411, 416, and 1102 of the Federal Aviation Act of 1958, as amended; 49 U.S.C. 1301, 1302, 1324, 1371, 1372, 1373, 1374, 1377, 1381, 1386, and 1502).

2. Section 380.30 is amended by revising paragraph (e) as follows:

§ 380.30 Solicitation materials.

* * * * *

(e) In any solicitation material from a direct air carrier, indirect air carrier, or an agent of either, for a charter, charter tour (i.e., a combination of air transportation and ground accommodations), or a charter tour component (e.g., a hotel stay), any price stated for such charter, tour, or component shall be the entire price to be paid by the participants to the air carrier, or agent, for such charter, tour, or component, except:

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

(2) 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 (e) (4) of this section.

(3) 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 (e) (4) of this section.

(4) All advertisements and promotional materials in which the charges described in paragraphs (e)(2) and (e) (3) 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.

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]

BILLING CODE 4160–01–M

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