Point of Origin and the 315° bearing, 30 NM position from the Point of Origin, thence west along that line until the point of beginning.

Area H. That airspace extending upward from 6,000 feet MSL to and including 11,000 feet MSL beginning at the 293° bearing, 30 NM position from the Point of Origin, thence southeast on the 293° bearing from the Point of Origin until the 26–NM arc from the Point of Origin, extending counterclockwise on the 26–NM arc from the Point of Origin until SH–377, thence southwest on SH–377 until the 30–NM arc from the Point of Origin, and extending clockwise on the 30–NM arc from the Point of Origin until the point of beginning.

* * * * *

Issued in Washington, DC, on August 7, 1997.

John S. Walker,

Program Director for Air Traffic, Airspace Management.

[FR Doc. 97–21410 Filed 8–11–97; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101 and 730

[Docket No. 96N–0174]

RIN 0910–AA69

Food and Cosmetic Labeling; Revocation of Certain Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking certain regulations that are obsolete. These regulations have been identified for revocation as the result of a page-by-page review of the agency's regulations. This review is in response to the Administration's ''Reinventing Government'' initiative which seeks to streamline Government to ease the burden on regulated industry and consumers.

DATES: This final rule will become effective September 11, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Felicia B. Satchell, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION:

I. Background

On March 4, 1995, President Clinton announced plans for the reform of the Federal regulatory system as part of the Administration's ''Reinventing Government'' initiative. In his March 4 directive, the President ordered all Federal agencies to conduct a page-by-page review of all of their regulations to ''eliminate or revise those that are outdated or otherwise in need of reform.''

In response to this directive, FDA has revoked a number of regulations through notice and comment rulemaking (e.g., 61 FR 58991, November 20, 1996; 61 FR 27771, June 3, 1996) and issued proposals to revoke additional regulations (e.g., 60 FR 53480, October 13, 1995; 60 FR 56513 and 56541, November 9, 1995; and 61 FR 29708, June 12, 1996). FDA has also issued two advance notices of proposed rulemaking to review standards of identity and other existing regulations to determine whether these regulations should also be considered for revocation or revision (e.g., 60 FR 67492, December 29, 1995; and 61 FR 29701, June 12, 1996). This document responds to comments submitted to its proposal entitled ''Food and Cosmetic Labeling; Revocation of Certain Regulations; Opportunity for Public Comment,'' which published in the **Federal Register** of June 12, 1996 (61 FR 29708) (hereinafter referred to as the June 12 revocation proposal).

FDA received 11 letters in response to the June 12 revocation proposal. Each letter contained one or more comments. The letters were from industry trade associations, academia, and consumer organizations. Some comments supported various provisions of the proposal. Other comments objected to the revocation of certain regulations. A summary of the comments and the agency's responses to the comments follow.

II. Food Labeling Regulations

A. Information Panel of Package Form Food (§ 101.2)

This regulation, in paragraph (a), defines the term ''information panel'' as it applies to packaged food, and in paragraph (b) provides that all information required to appear on the label of any package of food under certain referenced regulations shall appear either on the principal display panel or on the information panel, unless otherwise specified in the regulations. The referenced regulations are in part 101 (21 CFR part 101) and part 105 (21 CFR part 105) and are as follows: § 101.4 *Food; designation of ingredients*, § 101.5 *Food; name and place of business of manufacturer, packer, or distributor*, § 101.8 *Labeling of food with number of servings*, § 101.9 *Nutrition labeling of food*, § 101.12 *Reference amounts customarily consumed per eating occasion*, § 101.13 *Nutrient content claims general principles*, § 101.17 *Food labeling warning and notice statements*, subpart D of part 101, Specific Requirements for Nutrient Content Claims, and Part 105—Foods for Special Dietary Use. Section 101.2(c) requires that information required by the referenced regulations be in letters or numbers of at least one-sixteenth inch in height, unless otherwise exempted by regulation. However, § 101.2(c) also contains exemptions to this type-size requirement. FDA tentatively concluded in the June 12 revocation proposal that several of the exemptions are now obsolete and should be revoked.

1. Exemptions for Small Packages

Specifically, FDA proposed to revoke § 101.2(c)(1), (c)(2), and (c)(3). The exemptions set out in these paragraphs are for small packages (defined according to the surface area available to bear labeling) and were established before the enactment of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101–535). As fully discussed in the June 12 revocation proposal, these exemptions were designed to encourage firms to voluntarily provide nutrition information in accordance with § 101.9 and a full list of ingredients in accordance with the regulations in part 101, which was voluntary on some standardized foods before the enactment of the 1990 amendments. However, as a result of the 1990 amendments, nutrition labeling and full ingredient labeling is now required on most foods, and the agency has made specific provision for flexibility in the presentation of this information where space is limited.

For these reasons, the agency tentatively concluded in the June 12 revocation proposal that the exemptions in § 101.2(c)(1), (c)(2), and (c)(3) were now obsolete and should be revoked. Also in that document, FDA solicited comments on the need to retain any of these exemptions and stated that comments supporting retention of any of these exemptions should include information on specific products for which other type size exemptions are inadequate.

1. Two comments addressed the proposed revocation of § 101.2(c)(1), (c)(2), and (c)(3). One of these comments supported revocation of the exemptions.

The other comment opposed revocation of the exemptions and disagreed with the rationale the agency presented in the proposal for revoking them. The comment contended that nutrition labeling has been mandatory for many food products since the early 1970's, often because of the addition of a nutrient or use of a nutrition claim. Further, the comment argued that the impact of making the disclosure of ingredients in standardized food mandatory rather than voluntary has been exceedingly small. The comment also pointed out that the type size exemptions issued under the 1990 amendments apply only to nutrition labeling and not to the other mandatory label information, such as ingredient labeling. Consequently, the comment argued, unless the exemptions in § 101.2(c)(1), (c)(2), and (c)(3) are retained, mandatory information other than nutrition labeling will be required to appear in one-sixteenth inch type, even where this cannot realistically be accomplished. The comment urged the agency to retain the type-size exemptions in § 101.2(c)(1), (c)(2), and (c)(3).

The agency has not been persuaded by the latter comment that the exemptions in § 101.2(c)(1), (c)(2), and (c)(3) should be retained. The comment did not provide any information, as requested in the June 12 revocation proposal, on specific products for which the other type size exemptions provided in FDA's regulations (e.g., § 101.2(c)(5)) are inadequate. Nor did the comment point to any specific products that could not realistically bear the mandatory information in one-sixteenth inch type. Furthermore, the agency has not been presented with information suggesting that revocation of these exemptions would cause an economic burden on the industry because of the need to redesign packaging or print new labels. In the absence of such information, and for the reasons cited in the proposal, the agency concludes that the exemptions are now obsolete. Accordingly, FDA is revoking § 101.2(c)(1), (c)(2), and (c)(3), as proposed.

2. Nonretail Individual Serving Size Packages

Section 101.2(c)(5) provides that individual serving size packages of food served with meals in restaurants, institutions, and on board passenger carriers, and not intended for sale at retail, are exempt from the type-size requirements of § 101.2(c) under certain described conditions. Because declaration of all ingredients in standardized foods is now required, reference to § 101.6 is no longer appropriate. Consequently, FDA proposed to revise § 101.2 by revoking paragraph (c)(5)(iii).

2. The comments addressing this issue supported revocation of § 101.2(c)(5)(iii). Accordingly, FDA is revoking § 101.2(c)(5)(iii) and redesignating paragraph (c)(5)(iv) as paragraph (c)(5)(iii). The agency points out that revocation of existing § 101.2(c)(5)(iii) would not eliminate any ingredient listing requirements for nonretail individual serving size packages because this proposal does not pertain to any provisions of § 101.4.

B. Labeling of Foods With Number of Servings (§ 101.8)

The regulation in § 101.8(a) requires, among other things, that any package of a food that bears a representation as to the number of servings contained in the package bear in immediate conjunction with such statement, and in the same size type as is used for such statement, a statement of the net quantity (in terms of weight, measure, or numerical count) of each such serving. However, the latter statement may be expressed in terms that differ from the terms used in the required statement of net quantity of contents (for example, cups, tablespoons) when such differing term is common to cookery and describes a constant quantity.

FDA tentatively concluded in the June 12 revocation proposal that this regulation was obsolete in light of the mandatory nutrition labeling provisions in § 101.9. As discussed in the June 12 revocation proposal, § 101.9 defines a ''serving'' or ''serving size'' for the purpose of nutrition labeling as the amount of food, expressed in a common household measure that is appropriate for the food, customarily consumed per eating occasion by persons 4 years of age and older. Section 101.9 also gives guidance for determining serving size when the food is specially formulated or processed for use by infants or by toddlers. Thus, FDA proposed to revoke § 101.8.

3. All of the comments responding to this issue agreed that FDA's regulations governing mandatory nutrition labeling of foods which, in § 101.12, establish serving sizes for foods based on the reference amounts customarily consumed per eating occasion, render the provisions in § 101.8 obsolete. Accordingly, as proposed, FDA is revoking § 101.8. FDA advises, however, that manufacturers are expected to continue to adhere to its guidance that statements concerning the number of servings in a package that are presented in locations other than as part of the nutrition information be in the same terms as those that are used to express the serving size as part of the nutrition information. To do otherwise may render the labeling information misleading to consumers.

To conform its regulations to the revocation of § 101.8, FDA is removing the reference to § 101.8 in § 101.2(b) and (f).

C. Labeling of Kosher and Kosher-Style Foods (§ 101.29)

Section 101.29 of FDA's regulations is a statement of informal agency policy regarding the use of the terms ''kosher'' and ''kosher-style'' in the labeling of food products. Because this section only provides guidance and was not established through rulemaking, it does not have the force and effect of law. Furthermore, because the use of the terms ''kosher'' and ''kosher-style'' is, in fact, governed under the general misbranding provisions of the act, FDA proposed in the June 12 revocation proposal to remove this section. In addition, the agency solicited comments on whether it should prepare a Compliance Policy Guide (CPG) (an FDA informal guidance document used for efficient enforcement of the act) that reflects the policy that has been codified in § 101.29.

4. Six comments addressed the proposed revocation of § 101.29. Two of these comments supported the removal of § 101.29. Both comments noted that FDA has not traditionally sought to regulate kosher food labeling. These comments opined that religious authorities are well-equipped to police the use of ''kosher'' and other religious terminology in food labeling. Furthermore, these two comments questioned the constitutionality of any FDA action in this area. Finally, the comments urged that the agency not republish § 101.29 or any other policy regarding kosher labeling as a CPG.

Several other comments supported maintaining a written policy on the use of these terms. These comments contended that it is appropriate for the agency to concern itself with the proper use of the terms ''kosher'' and ''kosher-style'' on food labels because without such guidance, the potential for misuse of these terms would undoubtedly increase, resulting in significant consumer deception. Two of these comments supported retaining this policy in the form of a CPG. Further, one comment suggested that even as a CPG, § 101.29 did not go far enough in providing guidance to the industry or in providing adequate information to the consumer. Accordingly, the comment requested that as a part of a CPG, FDA create and maintain a certificate for

domestic and imported products that contains information regarding the manufacturer, certifying Rabbi and organization, effective dates of the certificate, and symbols used in product labeling. The comment opined that such a certificate, publicly available upon request, could greatly assist consumers in deciding whether the food in question meets their personal needs, because they would have access to information identifying not only the manufacturer but also the certifying organization. The comment further suggested that having a certificate on file could reduce difficulties currently experienced by persons wishing to import kosher products into the United States.

Another comment argued that the proper course for FDA is not to remove from the Code of Federal Regulations (CFR) its only pronouncement on kosher labeling but to assume a higher profile and initiate rulemaking that explicitly states its enforcement authority with regard to use of the terms ''kosher'' and ''kosher-style,'' thereby providing the kosher food consumer with effective and meaningful protection. The comment contended that such action was needed because misbranding of kosher foods is not uncommon. The comment further argued that such a regulation should prohibit the use of ''kosher-style'' on all food items, whether or not they conform to religious dietary standards. The comment stated, however, that if FDA would not prohibit the use of the term ''kosher-style,'' then FDA should establish a regulation consistent with the U.S. Department of Agriculture's (USDA's) policy and allow use of the term ''kosher-style'' only when the product is produced under ''rabbinical supervision.'' A second alternative suggested by the comment to prohibiting the term is to permit the term but require that the product label also bear a disclaimer if the product does not conform to religious dietary standards. The comment argued that such a regulation is necessary to adequately protect the kosher consumer and to reduce the potential for misbranding, fraud, error, and confusion as the kosher food industry grows.

FDA has evaluated the comments and finds that, while there is support for maintaining specific guidance on use of the terms ''kosher'' and ''kosher-style,'' FDA is not persuaded by the comments that such guidance should be retained in the CFR. The comments presented no compelling reason why this statement of policy should not be converted to a CPG, the form in which most agency policy statements are maintained. The goal of the President's Initiative is to develop a more efficient regulatory regime, and that goal is advanced by minimizing the number of policy statements in the CFR.

Nor have the comments persuaded the agency that a rulemaking on the use of the terms ''kosher'' and ''kosher-style'' is warranted. The use of the terms ''kosher,'' ''kosher-style,'' and any other term suggesting that a food has been prepared in accordance with certain religious practices is subject to the general misbranding provisions of section 403(a) of the act (21 U.S.C. 343(a)). Aside from providing this basic level of protection, FDA has no role in determining what food is kosher.

In light of the issues raised in the comments, however, the agency is concerned that if it did not maintain some statement on kosher labeling, there would be confusion and misinformation in the kosher food industry, which could result in a proliferation of misbranded products, and thus consumers could be adversely affected. Therefore, FDA will maintain a statement of its policy on labeling foods that conform to religious dietary laws but do so through the use of a CPG.

Accordingly, FDA is revoking § 101.29 as proposed. It intends to prepare a CPG in accordance with the Good Guidance Principles published in the **Federal Register** of February 27, 1997 (62 FR 8961). In developing the CPG, the agency will fully consider the alternatives suggested in the comments and will provide an opportunity for comment. The agency believes that this approach will provide the kosher food industry with the guidance needed to minimize false or misleading labels.

III. Cosmetic Regulations

Parts 710 and 720 (21 CFR parts 710 and 720) of FDA's regulations provide for the Voluntary Cosmetic Reporting Program (VCRP) under which cosmetic firms voluntarily register cosmetic product establishments (part 710) and cosmetic product ingredient and raw material composition statements (part 720). Part 730 (21 CFR part 730) provides for the voluntary filing of cosmetic product experience reports (VCPE) by the cosmetics industry.

During the 23 years the VCPE has been in place, companies have submitted information about adverse reactions that consumers have reported to them. FDA has performed a statistical assessment of the data to calculate the ''baseline'' adverse reactions (expected number of reactions per million units distributed) that occur for the different cosmetic product categories identified in the program.

While the VCPE has provided useful information regarding relative adverse reaction baseline rates, it has suffered from some serious limitations. As fully discussed in the June 12 revocation proposal, this program no longer provides any new information about cosmetic adverse reactions, and it no longer serves the important purpose of helping to find harmful cosmetics and to remove them from the marketplace. Thus, FDA proposed to revoke part 730. However, the agency solicited comments on whether this section should be eliminated in its entirety, reduced in scope, or some other alternative.

5. Three comments addressed the proposed revocation of part 730. Two comments supported the proposal to revoke this part in its entirety. One comment suggested, however, that FDA replace the voluntary program by: (1) Enhancing its MEDWATCH program to include cosmetic adverse reactions; (2) referring consumers with adverse reactions directly to the cosmetic company; and (3) maintaining a process for voluntary industry analysis of product experience and reporting of any serious reactions to FDA.

The third comment asserted that, although the VCPE program had failed, part 730 should not be revoked but completely revised to require cosmetic companies to file with FDA all consumer adverse reaction reports. The comment suggested that a mandatory reporting system would provide data that would be useful in increasing the safety of cosmetics and protecting the public health. Further, the comment recommended that FDA mandate the registration of cosmetic manufacturing establishments and product formulations, continue with the establishment of a toll-free telephone hotline for consumers to report adverse reactions, and enhance its MEDWATCH program to include cosmetic products.

The agency rejects the assertion in the latter comment that the VCPE has failed. During the years that this program has been in effect, it has provided FDA with useful information and data. Using these data, FDA has been able to establish baseline adverse reaction rates. Thus, the function for which the program was intended has been achieved, and from the point of view of establishing a baseline level, any further data would be of little value. The comment has not persuaded the agency to change this view. Accordingly, FDA is revoking part 730 in its entirety.

However, the agency recognizes that there may be some merit to the other arguments made in this and another comment. As suggested by one

comment, the agency will consider enhancing its MEDWATCH program to include cosmetic products and will maintain the availability of adverse reaction reporting forms, which may be submitted to the agency. Further, FDA intends to perform a thorough evaluation of the cosmetic adverse reaction information that it has received over the years and to prepare an indepth report that will be useful to both the cosmetic industry and the public in understanding adverse reaction trends for different product categories and the baseline rates of adverse reactions. However, the comment did not provide a factual basis for making an adverse reaction reporting system or a registration system mandatory for cosmetics.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) and (a)(8), respectively, that the actions to revoke or revise several food labeling regulations in part 101 and to eliminate or modify part 730 of the cosmetic regulations are of a type that do not individually or cumulatively have a significant effect on the environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Benefit-Cost Analysis

FDA has examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million; adversely affecting some sector of the economy in a material way; adversely affecting jobs or competition; or raising novel legal or policy issues.

In the proposal, FDA based the economic impact analysis on the effects of revoking the following: Certain type-size exemptions, labeling with number of servings other than as specified in the 1990 amendments, the statement of informal agency policy regarding the terms ''kosher'' and ''kosher-style,'' and the Voluntary Cosmetic Experience Program. None of the comments on the proposal directly addressed the economic impact analysis. The one comment that opposed revocation of the current minimum type-size exemptions did not mention costs directly, but implied (''can not realistically be accomplished'') that the revocation could impose additional labeling costs for some products. The net effect of revoking the type-size and serving-size exemptions will be to reduce compliance costs for businesses. In the absence of evidence that the revocation would impose significant labeling costs, the agency has not altered its conclusion that the net economic benefits of this final rule are positive.

FDA finds that this final rule does not constitute a significant rule as defined by Executive Order 12866. Furthermore, it has been determined that this final rule is not a major rule for purposes of Congressional Review (Pub. L. 104–121).

VI. Small Business Analysis

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities.

No comments dealt with the proposal's statement that the rule would not have a significant impact on a substantial number of small businesses. One comment that came from an organization representing entrepreneurial cosmetic firms supported terminating the Voluntary Cosmetic Experience Program. The comment agreed with the agency's conclusion that the program's benefits had already been realized. Terminating the program will impose no costs on participating small firms.

Although it is possible that revoking the type-size exemptions could impose costs on some small entities, the reduced costs of interpreting labeling regulations and determining how they apply to individual products will more likely, if anything, reduce the costs of labeling for small entities. The removal of the kosher and kosher-style labeling guidance, because it is a guidance, will impose no additional costs on small entities.

FDA finds that under the Regulatory Flexibility Act, this final rule will not have a significant economic impact on a substantial number of small entities. Accordingly, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commissioner of Food and Drugs certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

VII. The Paperwork Reduction Act of 1995

In the June 12 revocation proposal, FDA solicited comment on whether the proposed rule to revoke certain regulations that the agency believes are obsolete imposes any paperwork burden. FDA did not receive any comments on this issue. Thus, FDA concludes that this final rule contains no reporting, recordkeeping, labeling, or other third party disclosure requirements. Thus there is no ''information collection'' necessitating clearance by the Office of Management and Budget.

List of Subjects

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 730

Cosmetics, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 101 and 730 are amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

§ 101.2 [Amended]

2. Section 101.2 *Information panel of package form food* is amended in paragraphs (b) and (f) by removing the reference to § 101.8; by removing paragraphs (c)(1) through (c)(3) and paragraph (c)(5)(iii); by redesignating paragraph (c)(5)(iv) as paragraph (c)(5)(iii); and by redesignating paragraphs (c)(4) and (c)(5) as paragraphs (c)(1) and (c)(2), respectively.

§ 101.8 [Removed]

3. Section 101.8 *Labeling of food with number of servings* is removed.

§ 101.29 [Removed]

4. Section 101.29 *Labeling of kosher and kosher-style foods* is removed.

PART 730—VOLUNTARY FILING OF COSMETIC PRODUCT EXPERIENCES

PART 730—[REMOVED]

5. Part 730 is removed.

Dated: July 10, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–21156 Filed 8-11-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 92F–0261]

Indirect Food Additives: Adhesives and Components of Coatings

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 3-pentadecenyl phenol mixture (obtained from cashew nutshell liquid) reacted with formaldehyde and ethylenediamine in a ratio of 1:2:2 as an epoxy curing agent in resins and coatings intended for contact with food. This action is in response to a petition filed by Cardolite Corp.

DATES: The regulation is effective August 12, 1997. Submit written objections and requests for a hearing by september 11, 1997.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3089.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 21, 1992 (57 FR 32226), FDA announced that a food additive petition (FAP 2B4326) had been filed by Cardolite Corp., c/o 1414 Fenwick Lane, Silver Spring, MD 20910 (now c/o Regulatory Assistance Corp., 17 Clearview Circle, Hopewell Junction, NJ 12533). The petition proposed to amend the food additive regulations in § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) to provide for the safe use of 3-pentadecenyl phenol mixture (obtained from cashew nutshell liquid) reacted with formaldehyde and ethylenediamine in a ratio of 1:2:2 (CAS Reg. No. 68413–28–5) as an epoxy curing agent in resins and coatings intended for contact with food.

FDA's review of the subject petition indicates that the additive may contain trace amounts of formaldehyde and ethylenediamine as impurities. The potential carcinogenicity of formaldehyde and ethylenediamine was reviewed by the Cancer Assessment Committee (the Committee) of FDA's Center for Food Safety and Applied Nutrition.

The Committee noted that for many years formaldehyde has been known to be a carcinogen by the inhalation route, but it concluded that these inhalation studies are not appropriate for assessing the potential carcinogenicity of formaldehyde in food. The Committee's conclusion was based on the fact that the route of administration (inhalation) is not relevant to the safety of formaldehyde residues in food and the fact that tumors were observed only locally at the portal of entry (nasal turbinates). In addition, the agency has received literature reports of two drinking water studies on formaldehyde: (1) A preliminary report of a carcinogenicity study purported to be positive by Soffritti et al. (1989), conducted in Bologna, Italy (Ref. 1) and (2) a negative study by Til, et al. (1989), conducted in The Netherlands (Ref. 2). The Committee reviewed both studies and concluded, concerning the Soffritti study, '' * * * that the data reported were unreliable and could not be used in the assessment of the oral carcinogenicity of formaldehyde'' (Ref. 3). This conclusion is based on a lack of critical details in the study, questionable histopathologic conclusions, and the use of unusual nomenclature to describe the tumors. Based on the Committee's evaluation, the agency has determined that there is no basis to conclude that formaldehyde is a carcinogen when ingested.

The Committee also evaluated the results of a 2-year study submitted by the petitioner on ethylenediamine dihydrochloride (EDA•2HCl) in Fisher 344 rats (Ref. 4). The committee concluded that data from this study do not demonstrate carcinogenic potential for (EDA•2HCl) in Fisher 344 rats (Ref. 5). Based on the Committee's evaluation, the agency has determined that based upon the available data and information, there is no basis to conclude that ethylenediamine is a carcinogen.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive is safe, that the additive will have its intended technical effect, and therefore, that the regulations in § 175.300 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before September 11, 1997, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons