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.

## IX. References

The following sources are referred to in this document. References marked with an asterisk (*) have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. References without an asterisk are not on display; they are available as published articles, books, and reports.

*1. Memorandum, from M. DiNovi, Chemistry Review Branch, to P. Hansen, Biotechnology Policy Branch, dated April 28, 1994.

*2. Memorandum to the file FAP 0A4212, from M. DiNovi, K. Ekelman, and P. Hansen, dated June 3, 1998.

*3. Memorandum, from M. DiNovi, Chemistry Review Branch, to P. Hansen, Biotechnology Policy Branch, dated November 9, 1994.

*4. Memorandum, from K. Ekelman, Division of Health Effects Evaluation, to P. Hansen, Regulatory Policy Branch, dated June 2, 1998.

5. Green, W. L., ''Mechanisms of Action of Antithyroid Compounds,'' pp. 77–87 in: *The Thyroid*, edited by S. C. Werner and S. H. Ingbar, Harper & Row, New York, 1978.

6. Hill, R. N. et al., ''Thyroid Follicular Cell Carcinogenesis,'' *Fundamental and Applied Toxicology*, 12:629–697, 1989.

*7. Report, Borzelleca, J. F., C. C. Capen, M. S. Christian, and B. N. LaDu, ''Summary and Consensus of the Acesulfame K Scientific Expert Panel on the Safety of Acetoacetamide-N-Sulfonic Acid and Acetoacetamide,'' dated October 13, 1992.

*8. Letter, from C.C. Capen, Ohio State University, to J. Simplicio, Hoechst-Celanese Corp., dated December 6, 1991.

9. Gaylor, D. W., and R. L. Kodell, ''Linear Interpolation Algorithm for Low Dose Assessment of Toxic Substances,'' *Journal of Environmental Pathology and Toxicology*, 4:305–315, 1980.

10. National Academy of Sciences/National Research Council, ''Risk Assessment in the Federal Government: Managing the Process,'' Washington, DC, 1983.

11. Lorentzen, R. J., ''FDA Procedures for Carcinogenic Risk Assessment,'' *Food Technology*, pp. 108–111, 1984.

12. Gold, L.S. et al., ''Target Organs in Chronic Bioassays of 533 Chemical Carcinogens,'' *Environmental Health Perspectives*, 93:233–246, 1991.

13. McConnell, E. E., ''Thyroid Follicular Cell Carcinogenesis: Results from 343 2–Year Carcinogenicity Studies Conducted by the NCI/NTP,'' *Regulatory Toxicology and Pharmacology*, 16:177–188, 1992.

14. IRIS (1995), Cincinnati: Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, EPA.

15. Curran, P. G., and L. J. DeGroot, ''The Effect of Hepatic Enzyme-Inducing Drugs on Thyroid Hormones and the Thyroid Gland,'' *Endocrine Reviews*, 12(2):135–150, 1991.

16. Donaich, I., ''Aetiological Considerations of Thyroid Carcinoma,'' vol. 6, pp. 55–72, in: *Tumors of the Thyroid Gland*, edited by D. Smithers, E & S Livingstone, Edinburgh, 1970.

17. Capen, C. C. and S. L. Martin, ''Mechanisms that Lead to Disease in the Endocrine System in Animals,'' *Toxicologic Pathology*, 17:234–249, 1989.

18. *Handbook of Carcinogenic Potency and Genotoxicity Databases*, edited by L. S. Gold and E. Zeiger, CRC Press, Boca Raton, FL, 1997.

19. Goddard, M. J., D. J. Murdoch, and D. Krewski, ''Temporal Aspects of Risk Characterization,'' *Inhalation Toxicology*, 7:1005–1018, 1995.

20. Kodell, R. L., D. W. Gaylor, and J. J. Chen, ''Using Average Lifetime Dose Rate for Intermittent Exposures to Carcinogens,'' *Risk Analysis*, 7:339–345, 1987.

*21. Memorandum, from F. Hines, Diagnostic Pathology Branch, to L. Taylor, Additives Evaluation Branch, dated June 6, 1986.

22. ''Health Effects Test Guidelines,'' U.S. EPA, June, 1996.

*23. Memorandum, from L. Taylor, Additives Evaluation Branch, to P. McLaughlin, Petitions Control Branch, dated November 17, 1982.

*24. Memorandum, Cancer Assessment Committee (CAC) (covers conferences of November 21, 1983, February 21, 1985, December 12, 1985, and June 17, 1986, and information in Ref. 25 of this document).

*25. Memorandum, from L. Taylor, Additives Evaluation Branch, to Cancer Assessment Committee, dated June 19, 1986.

## List of Subjects in 21 CFR 172

Food additives, 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 part 172 is amended as follows:

## PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

**Authority:** 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Section 172.800 is amended by adding paragraph (c)(13) to read as follows:

**§ 172.800 Acesulfame potassium.**

* * * * *

(c) * * *

(13) Nonalcoholic beverages, including beverage bases.

* * * * *

Dated: June 29, 1998.

**Michael A. Friedman,**

*Acting Commissioner of Food and Drugs.*

[FR Doc. 98–17700 Filed 6–30–98; 10:34 am]

BILLING CODE 4160–01–F

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 172

**[Docket No. 93F–0286]**

## Food Additives Permitted for Direct Addition to Foods for Human Consumption; Acesulfame Potassium

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; response to objection, confirmation of effective date.

**SUMMARY:** The Food and Drug Administration (FDA) is overruling the objection that it has received on the final rule that amended the food additive regulations to provide for the safe use of acesulfame potassium (ACK) as a nonnutritive sweetener in alcoholic beverages. After reviewing the objection to the final rule, the agency has concluded that the objection does not provide a basis for revoking the amendment to the regulation. Therefore, FDA is confirming the effective date for the final rule. The final rule was issued in response to a food additive petition filed by Hoechst Celanese Corp.

**DATES:** The effective date of the final rule published at 60 FR 21700 is confirmed as May 3, 1995.

**FOR FURTHER INFORMATION CONTACT:** Patricia A. Hansen, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3093.

**SUPPLEMENTARY INFORMATION:**

## I. Introduction

In the **Federal Register** of May 3, 1995 (60 FR 21700), FDA issued a final rule amending its regulations to permit the use of acesulfame potassium (ACK) as a nonnutritive sweetener in alcoholic beverages (the ''alcoholic beverages final rule''). This amendment of the regulation, codified at 21 CFR 172.800(c)(12), was issued in response to a food additive petition (FAP No. 3A4391) filed by Hoechst Celanese Corp. FDA based its decision to permit the use of ACK in alcoholic beverages on the data in this petition and other relevant information in its files, including data and information from

previous petitions for various uses of ACK.[1]

## II. Summary of Objection

Following the publication of the alcoholic beverages final rule, the Center for Science in the Public Interest (CSPI) filed a timely submission objecting to the approval of ACK for use in alcoholic beverages. CSPI's submission consisted of a letter, dated June 1, 1995, and a copy of CSPI's objections to FDA's original approval decision on ACK (the ''dry uses final rule'') (July 28, 1988, 53 FR 28379).[2] CSPI specifically requests that FDA ''withdraw this approval, and, instead, require that acesulfame potassium (including its breakdown products) be evaluated for carcinogenicity in properly conducted long-term animal feeding tests.'' CSPI also requests that FDA reconsider and act favorably on its previous objections to the dry uses final rule, alleging that FDA has not addressed these previous objections in a substantive manner. CSPI does not request a hearing on its objection to the alcoholic beverages final rule, nor does it request a stay of the rule.[3]

## III. Provisions for Objections and Hearing Requests

The agency's regulations regarding food additive petitions (21 CFR 171.110) provide that objections and hearings relating to food additive regulations are to be governed by part 12 (21 CFR part 12). Under § 12.24(a), the Commissioner of Food and Drugs is to review all objections and hearing requests and make three determinations: (1) Whether the regulation at issue should be modified or revoked, (2) whether a hearing has been justified, and (3) whether an alternative form of hearing (e.g., before a Public Board of Inquiry under 21 CFR part 13), if requested, has been justified. As provided for in § 12.30(a), a person may submit objections and waive the right to a hearing; such waiver may be express or may result from the failure to request a hearing (see § 12.22(a)). Even when no hearing has been requested, the Commissioner has the discretion to order a hearing under § 12.30(b) and should exercise such discretion when it is in the public interest to do so. Because issuance of a final rule constitutes a finding that such action is in the public interest, a substantial showing is required to justify the Commissioner's exercise of his discretion to order a hearing to reconsider a final rule.

The objector to the alcoholic beverages final rule for ACK, CSPI, has waived its right to a hearing by failing to request a hearing (see § 12.22(a)(4)). Thus, the only remaining question under § 12.24(a) is whether CSPI's objection, and the information submitted in support of the objection, establish that the food additive regulation for ACK should be revoked or modified. If revocation or modification has not been justified, FDA must then evaluate the record to determine whether there is a reason for the Commissioner to exercise his discretion to order a hearing.

As discussed in detail in section IV of this document, FDA has concluded that CSPI has not established a basis for revocation or modification of the food additive regulation for ACK. Thus, the agency is overruling CSPI's objection. Likewise, because CSPI has not identified new relevant information or articulated an interpretation of existing information not previously addressed by FDA, there is no factual dispute to be resolved. Further, there has been no showing that such a hearing would otherwise be in the public interest. Accordingly, there is no reason for the Commissioner to exercise his discretion and order a hearing.

## IV. Analysis of the Objection

In order to justify a revocation or modification of the food additive regulation authorizing the use of ACK in alcoholic beverages, CSPI must establish that FDA failed to conduct a fair evaluation of the evidence in the record and thus erroneously concluded that there is a reasonable certainty of no harm from the use of ACK in alcoholic beverages. As shown in section IV of this document, CSPI's objections cite no new data or information and simply reiterate issues that FDA has previously considered and resolved. Thus, FDA has concluded that there is no basis to modify or revoke the food additive regulation for ACK.

### *A. FDA's Determination of Safety*

In its June 1, 1995 letter, objecting to the alcoholic beverages final rule, CSPI quotes from an FDA memorandum[4] ''* * * The use of acesulfame potassium in alcoholic beverages contributes only a very small percentage of acesulfame potassium intake to the total because of the limited number of users of these products and their low intakes.'' CSPI indicates its agreement with FDA's assessment of the dietary intake of ACK, but also goes on to state: ''* * * we expect minimal public exposure to acesulfame potassium in the alcoholic beverages covered in the approval. However, *de minimis* exposure of the public does not solve the safety problems associated with acesulfame potassium * * *.''

Although CSPI implies that FDA's decision on the safe use of ACK in alcoholic beverages was based on intake data alone, this is not the case. In concluding that the use of ACK in alcoholic beverages was safe, FDA reviewed data and information in the petition as well as other relevant information from its files, including data and information contained in previous petitions for various uses of ACK. As discussed in the alcoholic beverages final rule (60 FR 21700 at 21701), FDA made its determination based on an analysis of the safety data and a consideration of conditions relevant to the proposed use in alcoholic beverages, including the estimated low increase in dietary exposure to ACK from its use in alcoholic beverages.[5]

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[1] Acesulfame potassium, the potassium salt of 6-methyl-1,2,3-oxathiazine-4(3*H*)-one-2,2-dioxide, was first approved for a variety of uses as a nonnutritive sweetener on July 28, 1988 (53 FR 28379). Subsequent to its initial approval decision on the use of ACK, FDA approved the following additional uses for ACK in response to petitions in: Baked goods and baking mixes, including frostings, icings, and fillings for baked goods; yogurt and yogurt-type products; frozen and refrigerated desserts; sweet sauces, toppings, and syrups; and alcoholic beverages on December 1, 1994 (59 FR 61538, 61540, 61543) and on May 3, 1995 (60 FR 21700).

[2] In its 1988 objections to the dry uses final rule, CSPI objected to the agency conclusions drawn from each of the three long-term safety studies of ACK conducted in rodents and sought revocation of the rule. CSPI asked FDA to consider four separate objections to the rule and to hold a public evidentiary hearing on the issues raised in each of its objections. FDA considered the issues raised by CSPI and responded to them, in detail, in the **Federal Register** of February 27, 1992 (57 FR 6667, ''1992 response to objections''). The agency concluded, after reviewing the objections, that no genuine issues of material fact had been raised that would justify a hearing and, accordingly, denied CSPI's requests for a hearing.

[3] In its 1988 objections to the dry uses final rule, CSPI requested a stay of the rule until the hearing it had also requested could be held. FDA denied both the requests for a hearing and a stay.

[4] Memorandum from M. DiNovi, Chemistry Review Branch, CFSAN, FDA to P. Hansen, Biotechnology Policy Branch, CFSAN, FDA, April 28, 1994 (Ref. 1 in the alcoholic beverages final rule).

[5] Specifically, in its original review of the safety of ACK, FDA concluded that a review of animal feeding studies showed that there is no association between neoplastic disease (cancer) and consumption of this additive (53 FR 28379 at 28380 and 28381, July 28, 1988). FDA also established an acceptable daily intake (ADI) for ACK, based on the information from the animal feeding studies. Based on all of the information before it, FDA concluded that ACK was safe for the uses proposed in the original petition.

In its evaluation of the safety of ACK for use in alcoholic beverages, FDA considered, among other things, various conditions relevant to the proposed use. One consideration was whether an individual's estimated daily intake (EDI) of ACK would be less

Continued

CSPI's objection to the alcoholic beverages final rule does not provide any new evidence or identify any evidence that FDA overlooked in previous evaluations that would call into question FDA's determination of safety. Moreover, CSPI has not provided a basis for concluding that the information FDA has evaluated is inadequate to support a finding that the use of ACK in alcoholic beverages is safe. Thus, with respect to this issue, CSPI has not provided any basis for FDA to revoke the alcoholic beverages final rule.

*B. Long-Term Testing; Breakdown Products of ACK*

As previously noted, in CSPI's objection to the alcoholic beverages final rule, the organization requests that FDA require long-term animal testing of the breakdown products of ACK.[6] CSPI's submission does not, however, provide any information to support its view that such testing is necessary to establish the safety of ACK for use in alcoholic beverages. Because CSPI's submission provides no information to support its request, it provides no basis for FDA to reconsider its decision to issue the alcoholic beverages final rule. Thus, the agency is overruling this aspect of CSPI's objection and is denying the request that FDA require additional testing of the breakdown products of ACK.

*C. Long-Term Testing; ACK*

In its objection to the alcoholic beverages final rule, CSPI also asks that FDA require additional long-term testing of ACK.[7] CSPI alleges that ''* * * technical flaws render several key safety studies inadequate, and * * * available evidence suggests that acesulfame potassium may pose a cancer risk'' and mentions four specific issues with respect to the existing long-term animal testing of ACK, quoting directly from its objections to the dry uses final rule. In support of this aspect of its objection to the alcoholic beverages final rule, CSPI submitted a copy of its objections to the dry uses final rule. CSPI asked FDA to ''* * * reconsider and act favorably on our 1988 objections.''

One of the issues raised by CSPI in its June 1, 1995, letter concerns the adequacy of one of the long-term studies of ACK that was conducted in rats: ''* * * the doses of acesulfame potassium given in the petitioner's second long-term rat study were too low to make that study adequate to show that the chemical does not cause cancer in rats * * *.'' CSPI raised exactly the same issue in its objections to the dry uses final rule, and FDA responded, in detail, to this issue in the agency's 1992 response to objections.[8] In its objection to the alcoholic beverages final rule, CSPI provides no additional evidence or analysis to support its assertion regarding dosing. Thus, the agency incorporates its 1992 discussion of the dosing in the second rat study, in full, into the present response. Specifically, FDA reaffirms its earlier determination that the dosing levels in this study were appropriate to evaluate the safe use of ACK, and that this study demonstrated the safety of ACK (57 FR 6667 at 6669, see also 53 FR 28379, 28380).

Once an issue has been considered in a prior proceeding, a party is estopped from raising that same issue in a subsequent proceeding in the absence of new evidence.[9] Because CSPI's objection to the alcoholic beverages final rule neither identifies nor contains any new evidence or new analysis to support its assertion that the dosing in the second rat study was inadequate, it provides no basis for reconsideration of this issue by FDA. Moreover, CSPI's objection does not provide any information that links this issue to FDA's determination that the use of ACK in alcoholic beverages is safe and, thus, provides no basis for FDA to revoke the alcoholic beverages final rule.

Another issue raised by CSPI in its June 1, 1995, letter concerns the adequacy of the long-term study of ACK that was conducted in mice: ''* * * the petitioner's long-term mouse study fell short of FDA guidelines and standards because: (1) A subchronic study needed to set the proper high dose was not done, and the high dose used was too low, and (2) the chronic study lasted only 80 weeks, not the minimum 104 weeks * * *.'' CSPI made precisely the same claims in its objections to the dry uses final rule, and FDA responded, in detail, to this issue in the agency's 1992 response to objections.[10] In its objection to the alcoholic beverages final rule, CSPI provides no additional evidence or analysis to support its assertions regarding dosing and study length. Thus, the agency incorporates its 1992 discussion of the mouse study, in full, into the present response. Specifically, FDA reaffirms its earlier determination that both the length of, and the dosing in, the mouse study were adequate for an assessment of ACK's carcinogenic potential and that the mouse study demonstrated the safety of ACK (57 FR 6667 at 6669, see also 53 FR 28379, 28380).

As noted, once an issue has been considered in a prior proceeding, a party is estopped from raising that same issue in a subsequent proceeding in the absence of new evidence. Because CSPI's objection to the alcoholic beverages final rule neither identifies nor contains any new evidence or new analysis to support its assertion that the mouse study was inadequate, it provides no basis for reconsideration of

than the ADI that had been previously established from toxicological information. The agency concluded that the EDI for ACK resulting from its use in alcoholic beverages, as well as all uses listed at that time and other uses in a pending petition, was well below the ADI. On the basis of all the information before it, FDA concluded that the proposed use in alcoholic beverages was safe.

[6] These products are acetoacetamide-N-sulfonic acid (AAS) and acetoacetamide (AAA).

[7] As discussed in detail in the dry uses final rule (53 FR 28379 at 28380), the safety data originally submitted by the petitioner included a feeding study performed in mice and a feeding study performed in rats. FDA concluded that the mouse study was adequate for the safety evaluation of ACK, but that the rat study (''the first rat study'') was inadequate for a safety evaluation of ACK. The petitioner then conducted a second feeding study in rats (''the second rat study''); the agency concluded that this second rat study was adequate to assess the safety of ACK. The agency also concluded that the results of the second rat study, together with the results of the mouse study, established that there was no association between neoplastic disease (cancer) and consumption of ACK.

[8] In the 1992 response to objections (57 FR 6667 at 6669) FDA denied CSPI's request for a hearing on this issue because the data and information identified by CSPI in support of this objection, even if established at a hearing, would not have been adequate to justify resolution, in CSPI's favor, of the factual questions about adequacy of dosing. Because the information cited was not sufficient to establish CSPI's factual assertion, a hearing was not granted on this issue (see § 12.24(b)(3)).

[9] Even if the objections raise material issues of fact, FDA need not grant a hearing if those same issues were adequately raised and considered in an earlier proceeding. Once an issue has been so raised and considered, a party is estopped from raising that same issue in a later proceeding without new evidence. The various judicial doctrines dealing with finality are validly applied to the administrative process. In explaining why these principles ''self-evidently'' ought to apply to an agency proceeding, the D.C. Circuit wrote: ''The underlying concept is as simple as this: Justice requires that a party have a fair chance to present his position. But overall interests of administration do not require or generally contemplate that he will be given more than a fair opportunity.'' (*Retail Clerks Union, Local 1401, R.C.I.A.* v. *National Labor Relations Board*, 463 F.2d 316, 322 (D.C. Cir. 1972). (See *Costle* v. *Pacific Legal Foundation*, 445 U.S. 198, 214–215 (1980), *reh. den.*, 445 U.S. 947 (1980). See also *Pacific Seafarers, Inc.* v. *Pacific Far East Line, Inc.*, 404 F.2d 804 (D.C. Cir. 1966))).

[10] In the 1992 response to objections (57 FR 6667 at 6669 through 6670) FDA denied CSPI's request for a hearing on this objection because the data and information identified by CSPI in support of this objection, even if established at a hearing, would not have been adequate to justify resolution, in CSPI's favor, of the factual questions about the duration of, and dosing used in, this study. Because the information cited was not sufficient to establish CSPI's factual assertion, a hearing was not granted on this issue (see § 12.24(b)(3)).

this issue by FDA. Moreover, CSPI's objection does not provide any information that would link this issue to FDA's determination that the use of ACK in alcoholic beverages is safe and, thus, provides no basis for FDA to revoke the alcoholic beverages final rule.

A third issue raised by CSPI in its June 1, 1995, letter concerns the results of the first rat study: ''* * * the petitioner's first long-term rat study shows that acesulfame potassium induced tumors in rats, even though design flaws biased this study against finding carcinogenicity* * *.'' CSPI has raised this particular issue twice before, once as a comment on the petition that supported the dry uses final rule and once as an objection to the dry uses final rule. FDA considered this issue and addressed it in the dry uses final rule; FDA also responded, in detail, to this issue in the agency's 1992 response to objections.[11] In its objection to the alcoholic beverages final rule, CSPI provides no additional evidence or analysis to support its claim that ACK induced tumors in the animals used in the first rat study. Thus, the agency incorporates both of its earlier discussions of this issue (from both the dry uses final rule and the agency's 1992 response to objections), in full, into the present response. Specifically, the agency reaffirms its earlier determination that the data and information from the first rat study do not establish a carcinogenic effect of ACK (57 FR 6667 at 6670).[12]

Again, because this particular issue has been considered in a prior proceeding, CSPI is estopped from raising that same issue subsequently in the absence of new evidence. Because CSPI's objection to the alcoholic beverages final rule neither identifies nor contains any new evidence or new analysis to support its assertion that the first rat study shows that ACK induces tumors in rats, it provides no basis for reconsideration of this issue by FDA. Moreover, CSPI's objection does not provide any information that would undermine FDA's determination that the use of ACK in alcoholic beverages is safe and, thus, provides no basis for FDA to revoke the alcoholic beverages final rule.

A fourth issue raised by CSPI in its June 1, 1995, letter concerns the results of the second rat study: ''* * * the second long-term rat study shows that acesulfame potassium induces tumors in rats * * *.'' CSPI raised precisely this same issue in its objections to the dry uses final rule, and FDA responded, in detail, to this issue in the agency's 1992 response to objections.[13] In its objection to the alcoholic beverages final rule, CSPI provides no additional evidence or analysis to support its assertion regarding the results of the second rat study. Thus, the agency incorporates its 1992 discussion of the results of the second rat study, in full, into the present response. Specifically, FDA reaffirms its earlier determination that the second rat study did not demonstrate an association between the occurrence of tumors and treatment with ACK (57 FR 6667 at 6674, see also 53 FR 28379 at 28380 and 28381).

Once an issue has been considered in a prior proceeding, a party is estopped from raising that same issue in a subsequent proceeding in the absence of new evidence. Because CSPI's objection to the alcoholic beverages final rule neither identifies nor contains any new evidence or new analysis to support its assertion that the second rat study shows that ACK induces tumors in rats, it provides no basis for reconsideration of this issue by FDA. Moreover, CSPI's objection provides no information that would call into question FDA's determination that the use of ACK in alcoholic beverages is safe and, thus, provides no basis for FDA to revoke the alcoholic beverages final rule.

[11] CSPI claimed that there were increased incidences in lymphoreticular tumors and several types of other tumors; CSPI also disputed FDA's reasons for concluding that this study was inadequate for a safety evaluation of ACK. FDA considered and addressed all of the points in this objection in the 1992 response to objections (57 FR 6667 at 6670 to 6677). FDA denied CSPI's request for a hearing on this objection on several different grounds, specifically, a threshold burden of identifying specific evidence was not met (see § 12.24(b)(2)), the data and information identified were insufficient to justify the factual determination in CSPI's favor (see § 12.24(b)(3)), and the factual issues identified were not determinative with respect to the action requested (see § 12.24(b)(4)).

[12] Because of deficiencies and confounding factors in the first rat study, FDA further concluded that this study is ''inadequate for assessing the carcinogenic potential of the test compound or for any other purposes of a safety evaluation'' (53 FR 28379 at 28381). As noted, the petitioner subsequently performed a second study in a different strain of rat.

[13] CSPI identified two issues in this objection: (1) The incidence of rare tumors and (2) the incidence of mammary gland tumors. CSPI also raised four separate points with regard to the occurrence of mammary tumors. FDA considered and addressed all of the points in this objection in the 1992 response to objections (57 FR 6667 at 6674 through 6675). FDA denied CSPI's request for a hearing on this objection on several different grounds: (1) A threshold burden of identifying specific evidence was not met (see § 12.24(b)(2)), (2) the data and information identified were insufficient to justify the factual determination in CSPI's favor (see § 12.24(b)(3)), and (3) the factual issues identified were not determinative with respect to the action requested (see § 12.24(b)(4)).

## V. Conclusions

The safety of ACK has been thoroughly tested and the data have been reviewed by the agency. As discussed previously, FDA concluded that the available data and information establish the safety of ACK as a nonnutritive sweetener in alcoholic beverages.

The petitioner has the burden to demonstrate safety before FDA can approve a particular use of a food additive. Nevertheless, once the agency makes a finding of safety in an approval document, the burden shifts to an objector, who must come forward with evidence that calls into question FDA's conclusion (*American Cyanamid Co.* v. *FDA*, 606 F2d. 1307, 1314–1315 (D.C. Cir. 1979)).

CSPI has not identified any information in the record to support its claim that the FDA incorrectly concluded that the use of ACK in alcoholic beverages is safe. Nor has CSPI established that the agency overlooked significant information in reaching its conclusion. Indeed, the objection has not presented any information or analysis that has not already been carefully reviewed and weighed by the agency. FDA has determined that the objection provides no basis for FDA to revoke the alcoholic beverages final rule or to require additional safety testing. Accordingly, FDA is overruling the objection.

FDA is confirming May 3, 1995, as the effective date of the amendment to the regulation.

Dated: June 29, 1998.

**Michael A. Friedman,**

*Acting Commissioner of Food and Drugs.*

[FR Doc. 98–17701 Filed 6-30-98; 10:34 am]

BILLING CODE 4160–01–F

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## DEPARTMENT OF STATE

### 22 CFR Parts 40 and 41

**[Public Notice 2800]**

### Documentation of Nonimmigrants Under the Immigration and Nationality Act, as Amended—Place of Application

**AGENCY:** Bureau of Consular Affairs, DOS.

**ACTION:** Final rule; correction.

**SUMMARY:** This document confirms as a final rule the interim rule published on January 7, 1998, that establishes the venue for a nonimmigrant visa application by an applicant whose previous nonimmigrant visa has been voided due to an overstay of an authorized period of admission. This