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.

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

[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)).

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

notice also contains a correction of a citation in the interim rule.

EFFECTIVE DATE: July 6, 1998.

FOR FURTHER INFORMATION CONTACT: H. Edward Odom, Chief, Legislation and Regulations Division, Visa Services, Department of State, Washington, DC 20520–0106, (202) 663–1204.

SUPPLEMENTARY INFORMATION: An interim rule implementing the new subsection 222(g) of the Immigration and Nationality Act (INA), and requesting comments, was published on January 7, 1998 [63 FR 669]. The period for comments has expired; no comments have been received. The rule will thus stand as originally published, with a correction of the reference to INA 214(k) in 22 CFR 41.101(c)(1) which should read 214(l). As there are now two 214(l)'s in the INA, this reference is to the first one, i.e., the subsection relating to a waiver of the 2-year foreign residence requirement.

As the final regulation is identical to the interim regulation other than for the correction of a citation, it is not being reprinted in full herein.

List of Subjects in 22 CFR Part 41

Aliens, Nonimmigrants, Passports, Visas.

In view of the foregoing, the interim rule amending 22 CFR parts 40 and 41 which was published at 63 FR 669 on January 7, 1998, is adopted as a final rule with the following change:

PART 41—[CORRECTED]

1. The authority citation for part 41 continues to read:

Authority: 8 U.S.C. 1104.

§ 41.101 [Corrected]

2. In § 41.101(c)(1), correct the reference to ''INA 214(k)'' to read ''INA 214(l)''.

Dated: May 20, 1998.

Donna J. Hamilton,

Acting Assistant Secretary for Consular Affairs.

[FR Doc. 98–17735 Filed 7–2–98; 8:45 am]

BILLING CODE 4710–06–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300666; FRL–5794–6]

RIN 2070–AB78

Pyriproxyfen (2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of pyriproxfen in or on cotton seed and cotton gin byproducts. Valent U.S.A. Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170).

DATES: This regulation is effective July 6, 1998. Objections and requests for hearings must be received by EPA on or before September 4, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300666], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300666], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300666]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Joseph Tavano, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-6411, e-mail: tavano.joseph@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 6, 1998 (63 FR 11240) (FRL–5777–5), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP 6F4737) for tolerance by Valent U.S.A. Corporation, 1333 N. California Blvd., Walnut Creek, CA 94596. This notice included a summary of the petition prepared by Valent U.S.A. Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.534 be amended by establishing tolerances for combined residues of the insecticide, pyriproxfen, in or on cotton seed and cotton gin byproducts at 0.05 and 2.0 parts per million (ppm) respectively.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''