

factors: (1) The multi-step purification process used in the manufacture of ACK and (2) the volatility of methylene chloride (Ref. 1).

IV. Conclusion

FDA has reviewed the information available in its files on ACK and its hydrolysis products, as well as the current petition, and concludes that there is a reasonable certainty that no harm will result from the use of ACK as a general-purpose sweetener and flavor enhancer in foods. However, in accordance with a memorandum of understanding between the Food Safety and Inspection Service (FSIS), United States Department of Agriculture, and FDA (65 FR 51758, August 25, 2000), a restriction from use "in meat and poultry" is included in the ACK regulation. This restriction is applied when the petitioner does not specify that the food additive is intended for such use. At this time, FSIS has not evaluated data on the suitability of use of ACK in meat or poultry. Therefore, FDA concludes that the food additive regulations should be amended as set forth in this document.

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. As provided in § 171.1(h), FDA will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

V. Environmental Effects

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

VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Objections

Any person who will be adversely affected by this regulation may at any

time file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections on or before January 30, 2004. 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 Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

VIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from D. Robie, Division of Petition Review, Chemistry Review Group, to B. Anderson, Division of Petition Review, Regulatory Group II, October 7, 2002, and addendum memorandum from S. E. Carberry, Division of Petition Review, Chemistry Review Group, to B. Anderson, Division of Petition Review, Regulatory Group I, August 28, 2003.

2. Memorandum from D. Robie, Division of Petition Review, Chemistry Review Group to B. Anderson, Division of Petition Review, Regulatory Group II, March 19, 2003, and addendum memorandum from S. E. Carberry, Division of Petition Review, Chemistry Review Group, to B. Anderson, Division of Petition Review, Regulatory Group I, August 28, 2003.

3. Memorandum to the file, July 7, 2003.

4. Memorandum from M. Bleiberg, Division of Petition Review, Toxicology Review Group I, to B. Anderson, Division of Petition Review, Regulatory Group I, December 18, 2002.

5. Memorandum from M. Bleiberg, Division of Petition Review, Toxicology Review Group I, to B. Anderson, Division of Petition Review, Regulatory Group II, April 2, 2003.

List of Subjects in 21 CFR Part 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 revising the introductory paragraph and paragraph (c), and by removing paragraphs (d) and (e) to read as follows:

§ 172.800 Acesulfame potassium.

Acesulfame potassium (CAS Reg. No. 55589-62-3), also known as acesulfame K, may be safely used as a general-purpose sweetener and flavor enhancer in foods generally, except in meat and poultry, in accordance with current good manufacturing practice and in an amount not to exceed that reasonably required to accomplish the intended technical effect in foods for which standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use, under the following conditions:

(a) * * *

(b) * * *

(c) If the food containing the additive is represented to be for special dietary uses, it shall be labeled in compliance with part 105 of this chapter.

Dated: December 17, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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