DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 2002F–0181]

Secondary Direct Food Additives Permitted in Food for Human Consumption

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 cetylpyridinium chloride as an antimicrobial agent in poultry processing. This action is in response to a petition filed by Safe Foods Corp.

DATES: This rule is effective April 2, 2004. Submit written or electronic objections and requests for a hearing by May 3, 2004. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 173.375 as of April 2, 2004.

ADDRESSES: Submit written objections and requests for hearing to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic objections to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3071.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of May 7, 2002 (67 FR 30716), FDA announced that a food additive petition (FAP 2A4736) had been filed by Safe Foods Corp., c/o Keller and Heckman LLP, 1001 G St. NW., Washington, DC 20001. The petition proposed to amend the food additive regulations in part 173 (21 CFR part 173) to provide for the safe use of cetylpyridinium chloride as an antimicrobial agent in poultry processing.

II. Conclusion

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe and the additive will achieve its intended technical effect as an antimicrobial agent in poultry processing. Therefore, part 173 is amended as set forth in this document.

The agency is including as a condition of use in this regulation the requirement that cetylpyridinium chloride be captured and recycled during poultry processing. Because byproducts resulting from poultry processing are typically recycled back into animal feed, the additive could also become a component of animal feed unless controls to prevent such a situation are established. In situations where human food additives become components of animal feed, possibly in substantially higher amounts than in human food, FDA estimates the amount of additive likely to be consumed by the animals and assesses the safety of such additives for the animals themselves and of the human food that may be produced by such animals. To mitigate any potential concerns associated with the possibility of the additive becoming a component of animal feed, the petitioner proposed a system which ensures capture and recycling of the additive and disposal of residual cetylpyridinium chloride in an appropriate manner. The agency agrees with this approach. Therefore, as stated in paragraph (c) in the codified section of this document, the agency is requiring use of a capture and recycle technology to limit the potential for bioaccumulation of cetylpyridinium chloride in animal feed and thus to avoid the possibility of additional exposure to humans who consume poultry.

The petitioner proposes to apply cetylpyridinium chloride as an aqueous solution at a level not to exceed 0.3 gram of cetylpyridinium chloride per pound of poultry. As a further condition of use, the regulation provides that the applied solution contain propylene glycol at a level 1.5 times that of cetylpyridinium chloride. The propylene glycol is included as part of the applied solution in order to: (1) Maintain the solubility and stability of the cetylpyridinium chloride solution, and (2) reduce the absorption of cetylridinium chloride on the treated poultry (Ref. 1).

III. Public Disclosure

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 contact person listed in this document (see **FOR FURTHER INFORMATION CONTACT**). 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.

IV. Environmental Impact

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

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 Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

V. 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.

VI. Objections and Hearing Requests

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 (see **DATES**). Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which the objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested must state that a hearing is requested. Failure to request a hearing for any particular objection will constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested must 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 must be submitted and must be identified with the docket number found in the brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following reference has 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 the Chemistry Review Group to the Regulatory Group II, ''Cetylpyridinium Chloride (CPC) For Use as an Antimicrobial Treatment for Use on Poultry,'' dated November 19, 2002.

List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 2. Section 173.375 is added to read as follows:

§ 173.375 Cetylpyridinium chloride.

Cetylpyridinium chloride (CAS Reg. No. 123–03–5) may be safely used in food in accordance with the following prescribed conditions:

(a) The additive meets the specifications of the United States Pharmacopeia (USP)/National Formulary (NF) methods described in USP 24/NF 19, p. 370, January 2000, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(b) The additive is used in food as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter to treat the surface of raw poultry carcasses. The additive is applied as a fine mist spray of an ambient temperature aqueous solution to raw poultry carcasses prior to immersion in a chiller, at a level not to exceed 0.3 gram cetylpyridinium chloride per pound of raw poultry carcass. The aqueous solution shall also contain propylene glycol (CAS Reg. No. 57–55–6) complying with § 184.1666 of this chapter, at a concentration of 1.5 times that of the cetylpyridinium chloride.

(c) The additive shall be used in systems that collect and recycle solution that is not carried out of the system with the treated poultry carcasses.

Dated: March 26, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–7399 Filed 4–1–04; 8:45 am]

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DEPARTMENT OF THE TREASURY

31 CFR Part 1

Treasury Inspector General for Tax Administration; Privacy Act of 1974; Implementation

AGENCY: Departmental Offices, Treasury.

ACTION: Final rule.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, the Department of the Treasury exempts the following six systems of records from provisions of the Privacy Act: DO .303–TIGTA General Correspondence; DO.306–TIGTA Recruiting and Placement; DO .307–TIGTA Employee Relations Matters, Appeals, Grievances, and Complaint Files; DO .308–TIGTA Data Extracts; DO .309–TIGTA Chief Counsel Case Files; and, DO .310–TIGTA Chief Counsel Disclosure Section Records.

EFFECTIVE DATE: April 2, 2004.

FOR FURTHER INFORMATION CONTACT: Lori Creswell, Assistant Chief Counsel, Treasury Inspector General for Tax Administration, 1125 15th Street, Room 700A, Washington, DC 20005, 202–622–4068.

SUPPLEMENTARY INFORMATION: The Department of Treasury published a notice of a proposed rule on September 22, 2003, at 68 FR 55016–55020 exempting six systems of records from certain provisions of the Privacy Act of 1974, as amended. The Department of Treasury published the systems notices in their entirety at 68 FR 55086–55098 (September 22, 2003).

Under 5 U.S.C. 552a(j)(2), the head of an agency may promulgate rules to exempt any system of records within the agency from certain provisions of the Privacy Act of 1974, as amended, if the system contains investigatory material and is maintained by an agency which performs as its principal function activities pertaining to the enforcement of criminal laws. The following systems contain investigatory material compiled by TIGTA, an agency that performs activities pertaining to the enforcement of criminal laws:

DO .303–TIGTA General Correspondence;
DO .307–TIGTA Employee Relations Matters, Appeals, Grievances, and Complaint Files;
DO .308–TIGTA Data Extracts;
DO .309–TIGTA Chief Counsel Case Files; and,
DO .310–TIGTA Chief Counsel Disclosure Section Records.

The provisions of the Privacy Act from which these systems of records are exempt pursuant to 5 U.S.C. 552a(j)(2) are as follows: 5 U.S.C. 552a(c)(3), (c)(4), (d), (d)(4), (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(4)(I), (e)(5), (e)(8), (f), and (g).

Under 5 U.S.C. 552a(k)(2), the head of an agency may promulgate rules to exempt any system of records within the agency from certain provisions of the Privacy Act of 1974, as amended, if the system is investigatory material compiled for law enforcement purposes. The following systems contain investigatory material compiled for law enforcement purposes:

DO .303–TIGTA General Correspondence;
DO .307–TIGTA Employee Relations Matters, Appeals, Grievances, and Complaint Files;
DO .308–TIGTA Data Extracts;
DO .309–TIGTA Chief Counsel Case Files; and,
DO .310–TIGTA Chief Counsel Disclosure Section Records.

The provisions of the Privacy Act from which these systems of records are exempt pursuant to 5 U.S.C. 552a(k)(2) are as follows: 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H) and (e)(4)(I), and (f).

Under 5 U.S.C. 552a(k)(5), the head of an agency may promulgate rules to exempt any system of records within the agency from certain provisions of the Privacy Act of 1974, as amended, if the system is investigatory material compiled for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, Federal contracts, or access to classified information. DO. 306 TIGTA–Recruiting and Placement Records contains investigatory material compiled for use in determining suitability, eligibility or qualifications for Federal employment, Federal contracts, or access to classified information. The provisions of the Privacy Act from which this system of records is exempt pursuant to 5 U.S.C. 552a(k)(5) are as follows: 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I), and (f).