

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 173
[Docket No. 99F-2907]
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 acidified sodium chlorite solutions as an antimicrobial agent on red meat parts and organs. This action is in response to a petition filed by Alcide Corp.

DATES: This rule is effective January 12, 2000; written objections and requests for a hearing by February 11, 2000.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, 202-418-3074.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of August 30, 1999 (64 FR 47193), FDA announced that a food additive petition (FAP 9A4692) had been filed by Alcide Corp., 8561 154th Ave. NE., Redmond, WA 98052. The petition proposed to amend the food additive regulation in 21 CFR 173.325 (§ 173.325) to provide for the safe use of acidified sodium chlorite solutions as an antimicrobial agent on red meat parts and organs.

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, that the additive will achieve its intended technical effect, and therefore, that the regulation in § 173.325 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.

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 Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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.

Any person who will be adversely affected by this regulation may at any time on or before February 11, 2000, 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 are to be submitted and are to 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.

List of Subjects in 21 CFR Part 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under

authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 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 173.325 is amended by revising paragraph (c) to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

* * * * *

(c) The additive is used as an antimicrobial agent in accordance with current industry practice in the processing of red meat, red meat parts, and organs as a component of a spray or in the processing of red meat parts and organs as a component of a dip. Applied as a dip or spray, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 ppm in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.5 to 2.9.

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Dated: December 30, 1999.

Janice F. Oliver,

Deputy Director for Operations, Center for Food Safety and Applied Nutrition.

[FR Doc. 00-691 Filed 1-11-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 314
[Docket No. 94N-0449]
RIN 0910-AA78
New Drug Applications; Drug Master Files
AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising its regulation governing drug master files (DMF's). FDA is removing the provision for submitting Type I DMF's and will no longer permit information submitted in a Type I DMF to be incorporated by reference in investigational new drug applications (IND's), new drug applications (NDA's), abbreviated new drug applications (ANDA's), or amendments or supplements to any of