Airplane Flight Manual (AFM) Revision

(f) Within 72 hours after the effective date of the AD: Revise the Limitations Section of the EMBRAER ERJ 170 AFM by inserting a copy of EMBRAER Operational Bulletin 170–011/04, Revision 1, dated December 23, 2004, into the AFM.

Network Interface Card (NIC) Test

(g) Within 30 days after the effective date of this AD, or before or concurrently with doing the software installation required by paragraph (h) of this AD, whichever occurs first: Do a test to determine proper operation of the NIC communications in accordance with the Accomplishment Instructions of EMBRAER Service Bulletin 170–31–0003, dated December 23, 2004. If any failure is detected, before further flight, repair the airplane in accordance with a method approved by either the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate; or the Departmento de Aviacao Civil (DAC) (or its delegated agent).

Software Installation

(h) Within 40 days or 300 flight hours after the effective date of this AD, whichever occurs first: Install the software version of the PRIMUS EPIC system identified as ''load 15.3'' or higher, in accordance with the Accomplishment Instructions of EMBRAER Service Bulletin 170–31–0002, dated December 23, 2004. After installation of this software, remove the AFM revision required by paragraph (f) of this AD.

Submission of Test Results Not Required

(i) Although EMBRAER Service Bulletin 170–31–0003 specifies to submit certain information to the airplane manufacturer, this AD does not include that requirement.

Alternative Methods of Compliance (AMOCs)

(j) The Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Related Information

(k) Brazilian emergency airworthiness directive 2004–12–04, effective December 27, 2004, also addresses the subject of this AD.

Material Incorporated by Reference

(l) You must use the service information that is specified in Table 1 of this AD to perform the actions that are required by this AD, unless the AD specifies otherwise. (Only the first pages of EMBRAER Service Bulletins 170–31–0002 and Service Bulletin 170–31–0003 contain the issue date of those documents; no other page of those documents is dated.) The Director of the Federal Register approves the incorporation by reference of those documents in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. For copies of the service information, contact Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil. You can review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW, room PL–401, Nassif Building, Washington, DC; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

TABLE 1.—MATERIAL INCORPORATED BY REFERENCE

EMBRAER Service Document	Revision level	Date
Operational Bulletin 170–011/04	1	December 23, 2004.
Service Bulletin 170–31–0002	Original	December 23, 2004.
Service Bulletin 170–31–0003	Original	December 23, 2004.

Issued in Renton, Washington, on December 23, 2004.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–28707 Filed 12–29–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 2003F–0128]

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 finfish and crustaceans. This action is in response to a petition filed by Alcide Corp.

DATES: The regulation is effective December 30, 2004. Submit written or electronic objections and requests for a hearing by January 31, 2005. See section VI of this document for information on the filing of objections.

ADDRESSES: You may submit written objections and requests for a hearing identified by Docket No. 2003F–0128, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2003F–0128 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mical E. Honigfort, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1278.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of April 10, 2003 (68 FR 17656), FDA announced that a food additive petition (FAP 3A4743) had been filed by Alcide Corp., 8561 154th Ave. NE., Redmond, WA 98052–3557. The petition proposed to amend the food additive regulations in § 173.325

Acidified sodium chlorite solutions (21 CFR 173.325) to expand the permitted use concentration and to expand the pH range for acidified sodium chlorite solutions as an antimicrobial agent in water and ice intended for use on seafood (fresh or saltwater).

Under the Antimicrobial Regulation Technical Corrections Act of 1998 (ARTCA) (Public Law 105–324), the use of acidified sodium chlorite solutions as an antimicrobial agent on seafood is subject to regulation by FDA as a food additive. Such solutions are to be used on food in the preparing, packing, or holding of the food for commercial purposes, and therefore, such use is exempt from the definition of the term ''pesticide chemical'' (21 U.S.C. 321(q)(1)(B)(i)). Moreover, in the ''Legal and Policy Interpretation of the Jurisdiction Under the Federal Food, Drug, and Cosmetic Act of the Food and Drug Administration and the Environmental Protection Agency Over the Use of Certain Antimicrobial Substances'' (63 FR 54532 at 54541, October 9, 1998), FDA discussed, in the context of its jurisdiction over antimicrobial substances, what constitutes ''processing'' of seafood; this interpretation is unchanged by ARTCA. FDA stated that fish that is harvested is ''processed.'' Consequently, activities done postharvest to seafood, such as handling, storing, preparing, heading, eviscerating, shucking, or holding, would be activities done to ''processed food,'' not raw agricultural commodities. Therefore, under ARTCA, fish processing operations and commercial fishing vessels would not be considered a ''field'' or a ''treatment facility where raw agricultural commodities are the only food treated'' (21 U.S.C. 321(q)(1)(B)(i)), and thus, an antimicrobial applied to seafood at such locations would not be subject to regulation as a ''pesticide chemical,'' but instead would be subject to regulation as a ''food additive'' under the Federal Food, Drug, and Cosmetic Act (the act).

Although the use of acidified sodium chlorite solutions as an antimicrobial agent on seafood is regulated under section 409 of the act (21 U.S.C. 348) as a food additive, this intended use may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Therefore, manufacturers intending to market acidified sodium chlorite solutions for such use should contact the Environmental Protection Agency to determine whether this use requires a pesticide registration under FIFRA.

II. Conclusion

In consultation with the agency, the petitioner agreed to limit the proposed use of the additive to a concentration of 1,200 parts per million (ppm) and pH ranging from 2.3 to 2.9 as an antimicrobial agent to reduce pathogenic bacteria on finfish and crustaceans. 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. Therefore, 21 CFR part 173 is amended as set forth in this document.

The agency is including as a condition of use that seafood treated with acidified sodium chlorite solutions at a concentration of 1,200 ppm must be cooked prior to consumption to ensure that there are no detectable residues on the treated products (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. 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 file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VII. Reference

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 Review Group II, ''Acidified solutions of sodium chlorite in processing waters intended for use on seafood or freshwater fish,'' June 21, 2004.

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 redesignating paragraph (d) as paragraph

(d)(1) and by adding new paragraph (d)(2) to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

* * * * *

(d)(1) * * *

(2) The additive is used as a single application in processing facilities as an antimicrobial agent to reduce pathogenic bacteria due to cross-contamination during the harvesting, handling, heading, evisceration, butchering, storing, holding, packing, or packaging of finfish and crustaceans; or following the filleting of finfish; in accordance with current industry standards of good manufacturing practice. Applied as a dip or spray, the additive is used at levels that result in a sodium chlorite concentration of 1,200 ppm, in combination with any GRAS acid at levels sufficient to achieve a pH of 2.3 to 2.9. Treated seafood shall be cooked prior to consumption.

* * * * *

Dated: December 21, 2004.

Leslye M. Fraser,

Director, Office of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 04–28577 Filed 12–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Chlortetracycline

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to add the approved withdrawal time to the limitations to conditions of use for chlortetracycline Type C medicated feeds for chickens when fed at the 500 gram per ton level. This change is being made to improve the accuracy of the regulations.

DATES: This rule is effective December 30, 2004.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV– 6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4567, e-mail: *george.haibel@fda.gov.*

SUPPLEMENTARY INFORMATION: FDA has found that the April 1, 2004, edition of Title 21, Parts 500 to 599 of the Code of Federal Regulations (CFR) does not reflect the approved withdrawal time for chlortetracycline in Type C medicated feeds for chickens when fed at the 500 gram per ton level. The approved 24-hour withdrawal time at this dose level was inadvertently removed for all sponsors at the time of a supplemental approval of a zero-day withdrawal time for AUREOMYCIN Type C medicated chicken feeds under NADA 48–761 (63 FR 57245 at 57247, October 27, 1998). At this time, FDA is amending the regulations to correct this error in 21 CFR 558.128. This action is being taken to improve the accuracy of the regulations.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 2. Section 558.128 is amended by revising paragraph (e)(1)(iv) to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(1) * * *

Chlortetracycline amount	Indications for use	Limitations	Sponsor
*	*	*	*
(iv) 500 g/ton	Chickens: For the reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.	1. Feed for 5 d; 0-day withdrawal time when formulated from AUREOMYCIN Type A medicated articles or Type B medicated feeds under NADA 48–761. 2. Feed for 5 d; withdraw 24 h prior to slaughter; do not feed to chickens producing eggs for human consumption.	046573 017519, 046573, 048164, 066104
*	*	*	*