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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 92F-0397]

Great Lakes Chemical Corp.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 2B4343) proposing that the food additive regulations be amended to provide for the safe use of an aqueous solution of 1-bromo-3-chloro-5,5-dimethylhydantoin as a sanitizing solution to be used on food processing equipment and utensils and on food-contact surfaces in public eating places.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In a notice published in the FEDERAL REGISTER of December 7, 1992 (57 FR 57838), FDA announced that a food additive petition (FAP 2B4343) had been filed by Great Lakes Chemical Corp., P.O. Box 2200, West Lafayette, IN 47906. The petition proposed to amend the food additive regulations in § 178.1010 Sanitizing solutions (21 CFR 178.1010) to provide for

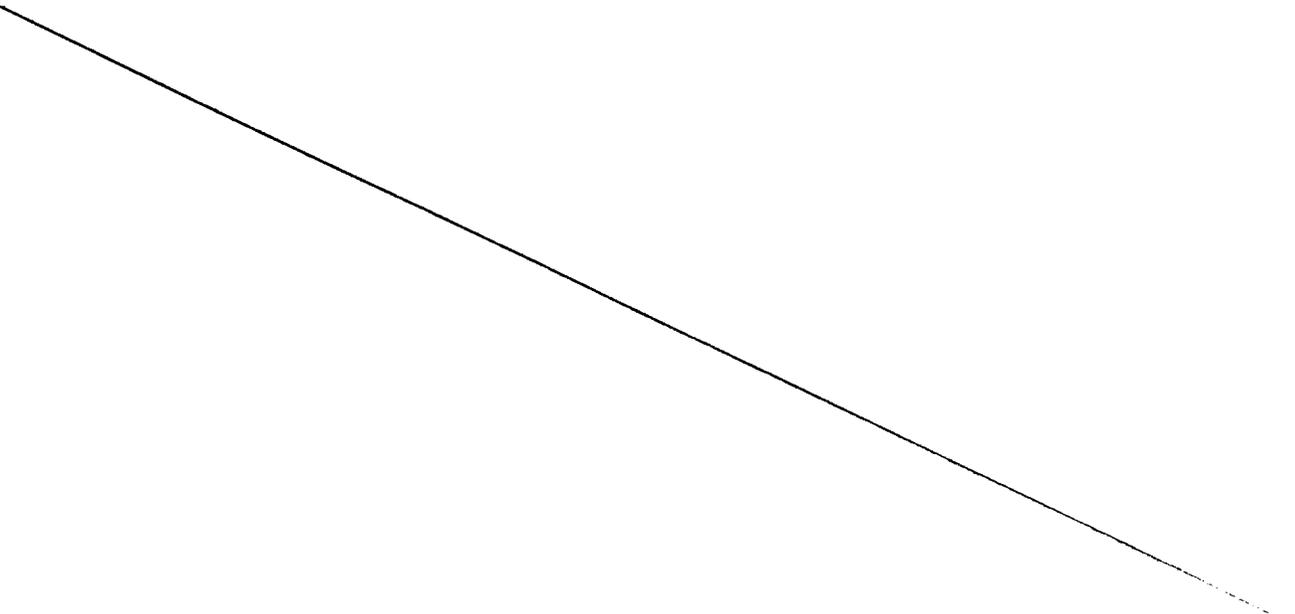
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the safe use of an aqueous solution of 1-bromo-3-chloro-5,5-dimethylhydantoin as a sanitizing solution to be used on food processing equipment and utensils and on food-contact surfaces in public eating places.

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170), which was enacted on August 3, 1996, amended the Federal Food, Drug, and Cosmetic Act (the act) and provided the Environmental Protection Agency (EPA) with the regulatory authority over the petitioned use of this substance. Under FQPA, the petitioned use of this substance is regulated as a pesticide chemical under section 408 of the act (21 U.S.C. 346a). Thus, post-FQPA, the petitioned use of this substance is no longer subject to FDA's regulatory authority as a food additive under section 409 of the act (21 U.S.C. 348).

In response to a request by the petitioner, which was prompted by the change in regulatory authority over the antimicrobial substance that is the subject of this petition, FDA transferred the records for FAP 2B4343,



including all of FDA's reviews of information in the petition,
to EPA. Great Lakes Chemical Corp. has now withdrawn the
petition without prejudice to a future filing (21 CFR 171.7).

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Dated: July 15, 1998
July 15, 1998

George H. Pauli

George H. Pauli
Acting Director
Office of Premarket Approval
Center for Food Safety and Applied
Nutrition

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