4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0434]

# Acidified Foods; Draft Guidance for Industry; Withdrawal of Draft Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the withdrawal of a draft guidance for industry, entitled "Draft Guidance for Industry: Acidified Foods." The draft guidance was intended to complement our regulations regarding acidified foods (including regulations for specific current good manufacturing practice, establishment registration, and process filing) by helping commercial food processors determine whether their food products are subject to these regulations by providing for voluntary submission of process filings by processors of non-acidified foods (e.g., some acid foods or fermented foods), and by helping processors of acidified foods in ensuring safe manufacturing, processing, and packing processes and in employing appropriate quality control procedures. We are withdrawing the draft guidance, in part, because many of the topics addressed in the draft guidance are now being addressed in other documents.

DATES: The withdrawal is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Michael Mignogna, Center for Food Safety and Applied Nutrition (HFS-302), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1565.

SUPPLEMENTARY INFORMATION:

In a notice published in the Federal Register of September 27, 2010 (75 FR 59268), we announced the availability of a draft guidance entitled "Draft Guidance for Industry: Acidified Foods" and gave interested parties an opportunity to submit comments by December 27, 2010, for us to consider before beginning work on the final version of the guidance. The draft guidance was intended to complement our regulations regarding acidified foods (including regulations for specific current good manufacturing practice (21 CFR part 114), establishment registration (21 CFR 108.25(c)(1)), and process filing (21 CFR 108.25(c)(2)) by helping commercial food processors in determining whether their food products are subject to these regulations and by providing for voluntary submission of process filings by processors who conclude that their products are non-acidified foods (e.g., acid foods or fermented foods). The draft guidance also was intended to help processors of acidified foods in ensuring safe manufacturing, processing, and packing processes and in employing appropriate quality control procedures.

We are withdrawing the draft guidance, in part, because the procedures for voluntary submission of process filings by processors of non-acidified foods are addressed by our recently issued guidance entitled "Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format" (80 FR 60909, October 8, 2015). We also are withdrawing the draft guidance, in part, because we recently issued a final rule entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" (80 FR 55908, September 17, 2015), and that rule, along with guidance documents we are developing as a companion to that rule, should help processors in ensuring

safe manufacturing, processing, and packing processes and in employing appropriate quality control procedures.

Dated: December 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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