4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1119]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA or we) is correcting a notice that appeared in the Federal Register of August 14, 2014. The notice announced that a proposed collection of information had been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. In this document, we correct some errors that appeared in the notice.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In FR Doc. 2014-19241, appearing on page 47642 in the Federal Register of August 14, 2014 (79 FR 47642), we make the following corrections:

1. On page 47643, in the second column, in the Response to Comment 3, delete the sentence starting with “The scope of the voluntary submission…and the product label.”

2. On page 47643, in the second column, in the Response to Comment 3, in the sentence starting with “Consequently, we have proposed...,” delete “institute the voluntary

consultation process discussed in this document" and replace it with "provide for the voluntary registration and Form FDA 2541e submission process".

3. On page 47643, in the second and third columns, in the Response to Comment 3, delete the sentences starting with "The ability to submit a voluntary submission…of part 114" and the remaining sentences in the response and replace them with "FDA has authority to implement the voluntary submission process under sections 402 and 404 of the FD&C Act."

4. On page 47643, in the third column, in the Response to Comment 4, replace the response with the following: "A voluntary process filing submission will not result in part 114 applying to products that are not acidified foods as defined in 21 CFR 114.3(b). Further, the voluntary process filing submission process will not result in any changes to part 114."

5. On pages 47643 to 47644, in the third column on page 47643 and in the first column on page 47644, in the Response to Comment 5, replace the response with the following: "Our inspectors will not expect all manufacturers to submit voluntary submissions."

6. On page 47644, in the first column, in the Response to Comment 7, replace the response with the following: "As discussed in the response to Comment 4, if a product is not an acidified food, the product is not subject to the good manufacturing practice requirements in part 114 and will not become subject to those regulations as a result of a voluntary submission."

7. On page 47644, in the first and second columns, in the Response to Comment 8, replace the response with the following: "The draft guidance did address the issue of what constitutes a fermented food. We expect that the acidified foods guidance, when finalized, will provide guidance on what constitutes a fermented food."

8. On page 47644, in the second column, in the Response to Comment 9, replace the response with the following: "Manufacturers are free to decide whether to make a voluntary

submission, and we believe that some manufacturers may choose to do so. For FDA, the voluntary submission results in increased efficiency."

9. On page 47644, in the second and third columns, in the Response to Comment 10, delete the first paragraph of the response and delete the second sentence in the second paragraph of the response.

10. On page 47645, in the first column, in the Response to Comment 13, in the second sentence in the second paragraph of the response, delete "to prevent the detention of product".

11. On page 47645, in the third column, in the Response to Comment 20, in the first sentence of the response, replace "and provides" with "and, when finalized, will provide".

12. On page 47646, in the first column, in the Response to Comment 21, in the first sentence of the response, delete "from the coverage of part 114" and, at the end of the first sentence of the response, insert "or that do not otherwise meet the definitions of acidified food."

13. On page 47646, in the first column, in the Response to Comment 22, replace the response with the following: "FDA does not agree that the 'Food Product Group' categories in any way indicates FDA's thinking as to whether all fruit and vegetable juices are acidified foods and are therefore subject to the acidified foods regulations in parts 108 and 114. Rather, the 'Food Product Group' categories are designed to help FDA understand the nature of products. For more information on what constitutes an acidified food, we recommend manufacturers consult the definition of acidified foods in § 114.3(b)."

14. On page 47646, in the second column, in the Response to Comment 24, replace the second paragraph of the response with the following: "When optional information about the

'Food Product Group' category is provided, we will use it to help us understand the nature of the products and to help us prioritize which facilities to inspect."

Dated: October 30, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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