



MAR 24 2014

Joseph Corby
Executive Director
Association of Food and Drug Officials
2550 Kingston Road, Suite 311
York, Pennsylvania 17402

Dear Mr. Corby:

I am sending this letter as an update on Food and Drug Administration (FDA) activities on areca (betel) nut, which was the subject of Association of Food and Drug Officials (AFDO) Resolution Number 2 adopted at your 116th Annual Education Conference held on June 8-12, 2013, in Louisville, Kentucky. AFDO Resolution Number 2 seeks clarification of FDA's position on areca (betel) nut as an adulterated food, what enforcement actions would be appropriate, and whether labeling could be used to support a religious exemption.

There is no FDA regulation providing for the safe use of areca (betel) nut in conventional foods, and FDA is not aware of any basis for concluding that areca (betel) nut is generally recognized as safe for use in conventional food.

FDA is currently developing an Import Alert for refusal of admission of areca (betel) nuts and food containing areca (betel) nuts offered for import into the United States, based on the World Health Organization's International Agency for Research on Cancer (IARC) classification of areca (betel) nut as a human carcinogen (IARC, 2004, 2012). When finalized, the Import Alert will provide guidance to FDA field personnel on refusing admission of finished products and dietary supplements, as well as bulk ingredients, containing areca (betel) nuts, under section 801(a) (3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) on the grounds that such food appears to be adulterated under the FD&C Act.

Based on the 2004 and 2012 IARC findings, FDA has tentatively concluded that a food (other than a dietary supplement) containing areca (betel) nut appears to contain a poisonous or deleterious substance which may render it injurious to health under section 402(a) (1) of the FD&C Act. In addition, FDA has tentatively concluded that a dietary supplement that contains areca (betel) nut appears to present a significant or unreasonable risk of illness or injury under the conditions of use set out in the labeling or, if none are set out in the labeling, under customary conditions of use under section 402(f) (1) (A) of the FD&C Act.

The Import Alert would not cover shipments consisting only of betel leaves, which are from a different plant (*Piper betle* L.) than areca (betel) nuts. The IARC concluded that betel leaves lack evidence suggesting carcinogenicity in animal studies.

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Issues surrounding possible religious exemptions are complex and are currently under discussion within the Agency. FDA is considering whether and how to address these issues in the Import Alert described above.

FDA appreciates AFDO's engagement in this area and we look forward to continued collaboration in addressing this and other public health matters.

Sincerely,

A handwritten signature in cursive script that reads "Roberta F. Wagner".

Roberta F. Wagner
Deputy Director for Regulatory Affairs
Center for Food Safety
and Applied Nutrition