



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD

JUN 06 2012

FCE No: 20909 SID No: 2012-01-25/001-015

The enclosed low-acid canned food process filing form(s) submitted by your firm is being returned because the information provided appears to indicate the product(s) may not currently be covered by our regulations.

- The product(s) appears to be an acid food(s), 21 CFR 114.3(a), having a natural raw pH value of 4.6 or below.
- The product(s) appears to be an acid food containing small amounts of low-acid food(s) that do not significantly alter the pH, 21 CFR 114.3(a), (b).
- The product(s) appears to be fermented to a pH value of 4.6 or below.
- The product(s) has a maximum water activity at less than or equal to 0.85, 21 CFR 114.3(b), (d).
- The food(s) is not a thermally processed Low-acid food(s), 21 CFR 113.3(e).
- The food(s) is normally stored and distributed under refrigerated conditions, 21 CFR 113.3(e).
- The food contains more than 3% raw meat (red meat) and/or raw poultry, or contains 2% or more cooked meat (red meat) and/or cooked poultry in the formulation. This product is under the jurisdiction of the U.S. Department of Agriculture, Food Safety and Inspection Service.

If the critical factors of your product(s) fall within the specifications described above, your firm does not need to file a scheduled process for this product.

Sincerely yours,

Emily R. Mallory

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