



Laura Boivin
Fumoir Grizzly Inc.
159 Rue d'Amsterdam
Saint-Augustin-de-Desmaures
Quebec, G3A 2V5
CANADA

Re: GRAS Notice No. GRN 000762

Dear Ms. Boivin:

The Food and Drug Administration (FDA, we) is granting your request to cease our evaluation of GRN 000762, which we filed on March 23, 2018. We received your request on July 18, 2018.

The subject of the notice is *Carnobacterium divergens* M35 preparation. The notice informs FDA of Fumoir Grizzly, Inc.'s (Fumoir Grizzly) view that *Carnobacterium divergens* M35 preparation is GRAS, through scientific procedures, for use as an antimicrobial to inhibit growth of *Listeria monocytogenes* in smoked Coho, sockeye, and Atlantic salmon, and smoked rainbow trout, applied by spraying to obtain a final concentration of 10⁶ CFU per g of smoked product.

In an email dated June 28, 2018, we informed you of significant deficiencies in the notice including the need for a more thorough safety discussion for the microorganism that is the subject of the notice. We also asked for additional information about the manufacturing process, specifications, and intended use of the substance. Given the scope of the information required, we recommended that Fumoir Grizzly request that we cease our evaluation of the notice. In an email dated July 18, 2018, Fumoir Grizzly requested that we cease our evaluation of GRN 000762 to give the company the opportunity to revise and resubmit their notice.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000762 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

Digitally signed by Susan J. Carlson -S
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ou=HHS, ou=FDA, ou=People,
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15, cn=Susan J. Carlson -S
Date: 2018.08.14 14:59:57 -0400'

Susan Carlson, Ph.D.
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