Marc C. Sanchez, Esq.
Contract In-house Counsel
Fresh Hemp Foods, Ltd.
1717 Pennsylvania Ave #1025
Washington, DC 20006

Re: GRAS Notices Nos. GRN 000765, GRN 000771, and GRN 000778

Dear Mr. Sanchez:

The Food and Drug Administration (FDA, we) completed our evaluation of the supplement that you submitted on behalf of Fresh Hemp Foods Ltd. to GRN 000765, GRN 000771, and GRN 000778. We received the supplement on November 5, 2019. The supplement states that the specification for aflatoxin of <0.5 ppb in the original GRAS notices was incorrect; the correct specification is <5 ppb.[1]

We previously responded to GRN 000765, GRN 000771, and GRN 000778 on December 20, 2018. We stated that we had no questions at that time regarding Fresh Hemp Foods' conclusion that dehulled hemp seed, hemp seed protein powder, and hemp seed oil are GRAS for the intended uses described in the respective GRAS notices.

The correction to the specification for aflatoxin does not change Fresh Hemp Foods' conclusion that the intended uses of dehulled hemp seed, hemp seed protein powder, and hemp seed oil are GRAS.[2]

Conclusions

Based on the information that Fresh Hemp Foods provided, as well as other information available to FDA, we have no questions at this time regarding Fresh Hemp Foods' conclusion that dehulled hemp seed, hemp seed protein powder, and hemp seed oil are GRAS under their intended conditions of use. This letter is not an affirmation that dehulled hemp seed, hemp seed protein powder, and hemp seed oil are GRAS under 21 CFR 170.35. Unless noted above, our review did not address other provisions of the Federal Food, Drug, and Cosmetic Act. Food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.

[1] Fresh Hemp Foods states that the analytical method it uses to measure aflatoxin has a limit of quantification of 5 ppb.
[2] FDA's action level for aflatoxin in foods is 20 ppb (µg/kg), which represents the limit at or above which FDA will take legal action to remove products from the market.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to the supplement to GRN 000765, GRN 000771, and GRN 000778 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2020.02.10 16:36:18 -05'00'

Susan Carlson, Ph.D.
Director
Division of Food Ingredients
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