



December 21, 2021

GRAS Notice No. AGRN 47

Ms. Riette van Laack
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, DC 20005

Dear Ms. van Laack:

The Food and Drug Administration's (FDA, we) Center for Veterinary Medicine (CVM) is granting your request, on behalf of IRP Health Pty Ltd., dated September 14, 2021, to cease our evaluation of the generally recognized as safe (GRAS) notice No. (AGRN) 47, filed on April 16, 2021.

The notice informs FDA of IRP Health Pty Ltd.'s view that the intended use of berberine, is generally recognized as safe (GRAS), through scientific procedures, for use as a preservative in broiler chicken feed at a maximum concentration of 0.03g/kg. In a teleconference on September 2, 2021, CVM discussed the issues identified during our evaluation of the notice. Specifically, CVM has questions on the chemistry, manufacturing, and controls, the functionality of the intended use of the notified substance, the target animal safety, and the microbiologic safety as GRAS. CVM also discussed the opportunity for IRP Health Pty Ltd. to request CVM to cease our evaluation of AGRN 47 and to re-submit a new GRAS Notice in the future.

In accordance with 21 CFR 570.275(b)(2), the text of this letter responding to AGRN 47 is accessible to the public on our website for the Current Animal Food GRAS Notices Inventory at <https://www.fda.gov/animal-veterinary/generally-recognized-safe-gras-notification-program/current-animal-food-gras-notices-inventory>.

Sincerely,

/s/

David Edwards, Ph. D.
Director, Division of Animal Feeds
Office of Surveillance and Compliance
Center for Veterinary Medicine

U.S. Food and Drug Administration
Center for Veterinary Medicine
Division of Animal Feeds, HFV-220
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