



November 9, 2021

GRAS Notice No. AGRN 46

Mr. Helmut Grabherr  
CEO  
Agromed Austria GmbH  
Bad Haller Straße 23  
A-4550 Kremsmünster  
Austria

Dear Mr. Grabherr:

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM, we) is granting your request, dated September 17, 2021, to cease our evaluation of generally recognized as safe (GRAS) notice No. AGRN 46, filed on April 9, 2021.

The notice informs FDA of Agromed Austria GmbH's view that the intended use of wood-based lignocellulose is GRAS, through scientific procedures, as a source of dietary fiber for swine and poultry at a use rate up to 2% for pigs, piglets, broilers, laying hens, and turkeys and 4% for sows. In a teleconference on September 8, 2021, CVM discussed the issues identified during our evaluation of the notice. Specifically, chemistry, manufacturing, and controls concerns on origin of the contents of undesirable constituents and validated methods to quantify these undesirable constituents were identified. These questions will also impact the evaluation of the target animal safety section of the Notice. In addition, the utility section raised questions about the application of the provided literature to some of the intended species. Also, CVM discussed the opportunity for Agromed Austria GmbH to request we cease our evaluation of AGRN 46 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 46 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**  
**12225 Wilkins Avenue**  
**Rockville, MD 20852**  
[www.fda.gov](http://www.fda.gov)