



Agency Response Letter GRAS Notice No. GRN 000245

CFSAN/Office of Food Additive Safety

June 19, 2008

Robert S. McQuate, Ph.D.

GRAS Associates, LLC

20482 Jacklight Lane

Bend, OR 97702-3074

Re: GRAS Notice No. GRN 000245

Dear Dr. McQuate:

The Food and Drug Administration (FDA) is responding to the notice, dated March 24, 2008, that you submitted on behalf of NattoPharma ASA in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received the notice on April 01, 2008, filed it on April 02, 2008, and designated it as GRAS Notice No. GRN 000245.

The subject of the notice is Menaquinone-7. The notice informs FDA of the view of NattoPharma ASA that Menaquinone-7 is GRAS, through scientific procedures, for use as a source of vitamin K2 in specific foods constituting the dairy products category and butter and margarine substitutes.

In a letter dated June 2, 2008, you withdrew your notice. Given your request, we ceased to evaluate the GRAS notice, effective June 2, 2008, the date that we received your letter.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter responding to GRN 000245, as well as a copy of the information in this notice that conforms to the information in the proposed GRAS exemption claim (21 CFR 170.36(c)(1)), is available for public review and copying on the homepage of the Office of Food Additive Safety (on the Internet at <http://www.cfsan.fda.gov/~lrd/foodadd.html>).

Sincerely,

Antonia Mattia, Ph.D.

Director

Division of Biotechnology and GRAS Notice Review

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition