OFFICE OF SURVEILLANCE AND COMPLIANCE

ANIMAL FOOD GENERALLY RECOGNIZED AS SAFE (GRAS) NOTICE EVALUATION TIMELINE

I. Purpose 1
II. Policy 1
III. Procedures 1
IV. Responsibilities 2
V. References 2
VI. Version History 2
Appendix 1. Animal Food GRAS Notification Evaluation Timeline Post-Filing Expected Milestones 3

I. PURPOSE

This document describes the evaluation timeline for Generally Recognized as Safe (GRAS) notice submissions, including amendments, from receipt to issuing and posting the Food and Drug Administration's (FDA or the Agency) response. With the exception of the total review time of up to 270 days identified in Title 21, Code of Federal Regulations 570.265(b) (21 CFR 570.265(b)), the dates specified in this document represent internal process goals rather than mandated regulatory deadlines. While the FDA Center for Veterinary Medicine (CVM) will make every effort to meet these target dates, target dates may be adjusted based on emergency situations, resource constraints, federal holidays, and other operational factors.

II. POLICY

On August 17, 2016, the Agency finalized the GRAS Notification Program regulations located in 21 CFR part 170 (human food) and part 570 (animal food). Part 570, subpart E, describes the GRAS Notification Program procedure under which a person may notify the CVM of a conclusion that a substance is GRAS under the conditions of its intended use in animal food based on scientific procedures or common use prior to 1958. CVM's Division of Animal Food Ingredients (DAFI) is responsible for the processing and evaluation of notices in accordance with the regulations in 21 CFR part 570.

III. PROCEDURES

GRAS notice submissions are received and logged into CVM's Submission Tracking and Reporting System (STARS) by DAFI within the Office of Surveillance and Compliance. A pre-file evaluation is conducted by an administrative reviewer (AR)[1] within 30 days of submission receipt.[2]

If the submission is deemed suitable for filing, a letter is prepared by the AR and issued to the notifier under the signature of the Director of DAFI. The date of the suitable for

[1] Administrative reviewers are responsible for maintaining the administrative record of each submission, performing the cursory pre-filing evaluation, corresponding with the notifier, and preparing the Agency's final response. All correspondence should be directed to animalfood-premarket@fda.hhs.gov.

[2] For the purposes of this document, all references to days indicate calendar days.

filing letter is the GRAS notice filing date. The filing date is day 1 of the 180-day evaluation timeframe, which may be extended by 90 days (21 CFR 570.265(b)). A GRAS submission is referred to as a GRAS notice only after it has been filed.

On day 1, DAFI assigns the appropriate scientific reviewers (SR).[3] Separately, the AR also sends the filed GRAS notice, in its entirety, to the FDA Freedom of Information Act (FOIA) staff for disclosure review in accordance with 21 CFR part 20. Once the entire notice is reviewed for disclosure purposes and redacted as necessary, the Agency is required to make the document compliant with section 508 of the Rehabilitation Act of 1973 (508 compliant).[4] Notices are posted as soon as they are reviewed for disclosure purposes and 508 compliant, which may occur after the 270-day maximum evaluation timeframe.

IV. RESPONSIBILITIES

DAFI is responsible for evaluating submissions, maintaining records in the CVM electronic archiving system (Corporate Document Management System), issuing letters to the notifier, and posting the 508 compliant notices and response letters to the public.[5]

The FDA FOIA staff is responsible for reviewing GRAS notices in accordance with 21 CFR part 20 before they are posted to the public.

The Agency is responsible for making the notices 508 compliant before they are posted to the public.

V. REFERENCES

GRAS Final Rule (August 17, 2016)

Substances Generally Recognized as Safe, 81 FR 54960[6]

VI. VERSION HISTORY

September 22,2026 – Original version.

[3] SRs are responsible for evaluating technical sections of GRAS notices based on their specific scientific knowledge.

[4] https://www.fda.gov/about-fda/about-website/accessibility-fda

[5] https://www.fda.gov/animal-veterinary/generally-recognized-safe-gras-notification-program/current-animal-food-gras-notices-inventory

[6] https://www.govinfo.gov/content/pkg/FR-2016-08-17/pdf/2016-19164.pdf

APPENDIX 1. ANIMAL FOOD GRAS NOTICE EVALUATION TIMELINE POST-FILING TARGET MILESTONES

Day 1: GRAS Notice filed (Note: If DAFI finds the GRAS submission acceptable, the date of the suitable filing letter issued by DAFI is considered the filing date (Day 1) for the GRAS notice.)

Day 75: Internal reviewer meeting

Day 85: First round of questions due to an AR from the SR(s)

Day 90: AR sends first round of questions to the firm via email

Day 104: Target for first amendment by firm (optional 1 week extension granted on occasion)

Day 127: Second round of questions due from SR(s) to AR (if needed)

Day 134: Second round of questions sent to the firm (if needed)

Day 148: Target for second amendment by firm (no extensions will be granted)

Day 180: 90-day extension letter issued to the firm

Day 185: Internal scientific consulting reviews completed (if no second amendment)

Day 215: Response letter issued to firm (if no second amendment)

Day 225: Internal scientific consulting reviews completed (if second amendment was submitted)

Day 270: Response letter issued to firm (if second amendment was submitted)