consumers can trust ''Made in the USA'' claims.[11] My colleagues believe the Commission's 80 year MUSA enforcement program was a failure and only a rule and the imposition of penalties will deter false MUSA claims. I believe administrative consents, which were an integral part of this program, can be an appropriate remedy to address deceptive MUSA claims, consistent with the views of bipartisan Commissions during the last 25 years. I support seeking monetary relief where appropriate but cannot support acting outside the constraints of our legislative authority.[12]

I fear as well this Commission's desire to promulgate or utilize our regulatory authority in ways that exceed the boundaries of underlying statutes and corresponding Congressional intent will continue. The Supreme Court's recent decision in *AMG*[13] has eliminated the FTC's ability to seek equitable monetary relief under Section 13(b) of the FTC Act to compensate consumers. Thus, the temptation to test the limits of our remaining sources of authority is strong. I urge my colleagues to pause. Previous FTC forays into areas outside its jurisdictional authority have resulted in swift condemnation from the courts and Congress.[14] Expansive interpretations of our rulemaking authority will not engender confidence among members of Congress who have in the past expressed qualms about the FTC's history of frolics and detours.[15]

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[11] The FTC has issued over 150 closing letters to companies making misleading U.S.-origin claims. Made in USA Workshop Report at 3 (June 2020). Companies only receive closing letters if they demonstrate to staff they will come into compliance with the FTC's Enforcement Policy Statement on ''Made in the USA.'' The staff's workshop report explains ''companies often produce substantiation for updated claims to the FTC staff, and then present a plan that includes training staff, updating online marketing materials (*e.g.,* company websites and social media platforms), updating hardcopy marketing materials (*e.g.,* product packaging, advertisements, tradeshow materials), and working with dealers, distributors, and third-party retailers to ensure downstream claims are in compliance.'' *Id.* at 3 n.7. The FTC has also settled over 25 enforcement actions, charging that companies refused to come into compliance or engaged in outright fraud. *Id.*

[12] I would note as well that seeking civil penalties for deceptive MUSA claims, as defined under the Commission's Rule, could have adverse market effects. Excessive penalties, divorced from harm, can result in over-deterrence. Importantly, the costs associated with over-deterrence are likely to increase with the expansiveness of the definition of labelling.

[13] *AMG* v. *FTC*, slip op No. 19–508 (Apr. 22, 2021), *https://www.supremecourt.gov/opinions/20pdf/19-508_l6gn.pdf.*

[14] *See* Federal Trade Commission Improvements Act of 1980, Public Law 96–252, 94 Stat. 374 (1980) (reforming the ability of the FTC to promulgate rules by requiring a multi-step process with public comment and subject to Congressional review). This Act also authorized $255 million in funding for the Commission and was the first time since 1977 the agency was funded through the traditional funding process after the backlash from Congress over its rulemaking activities. *See* Kintner, Earl, *et al.,* ''The Effect of the Federal Trade Commission Improvements Act of 1980 on the FTC's Rulemaking and Enforcement Authority,'' 58 Wash. U. Law Rev. 847 (1980); *see also* J. Howard Beagles III and Timothy J. Muris, FTC Consumer Protection at 100: 1970s Redux or Protecting Markets to Protect Consumers?, 83 Geo. Wash. L. Rev. 2157 (2015) (describing the ''disastrous failures'' of the FTC in the 1970s and the 1980s from enforcement and regulatory overreach and quoting Jean Carper, The Backlash at the FTC, Wash. Post, C1 (Feb. 6, 1977) (describing the backlash from Congress at the FTC, after a period of intense rulemaking activity culminating in the agency's being dubbed the ''National Nanny'')); *see also* Alex Propes, Privacy and FTC Rulemaking: A Historical Context, IAB (Nov. 6, 2018) (discussing how the FTC's rulemaking history could be influencing Congressional comfort with vesting the FTC with additional privacy authority), *https://www.iab.com/news/privacy-ftc-rulemaking-authority-a-historical-context/.*

[15] *See* Transcript: Oversight of the Federal Trade Commission: Strengthening Protections for Americans' Privacy and Data Security (May 8, 2019), *available at: https://docs.house.gov/meetings/IF/IF17/20190508/109415/HHRG-116-IF17-Transcript-20190508.pdf.* At this Hearing, Rep. McMorris Rogers stated: ''In various proposals, some groups have called for the FTC to have additional resources and authorities. I remain skeptical of Congress delegating broad authority to the FTC or any agency. However, we must be mindful of the complexities of this issue as well as the lessons learned from previous grants of rulemaking authority to the Commission.'' Transcript at 8–9. Rep. Walden similarly stated: ''it has been a few decades, but there was a time when the FTC, as we heard, was given broad rulemaking authority but stepped past the bounds of what Congress and the public supported. This required further congressional action and new restrictions on the Commission.'' Transcript at 62.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2020–F–1289]

Food Additives Permitted in Feed and Drinking Water of Animals; Selenomethionine Hydroxy Analogue

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of selenomethionine hydroxy analogue as a source of selenium in feed for beef and dairy cattle. This action is in response to a food additive petition filed by Adisseo France S.A.S.

DATES: This rule is effective July 14, 2021. See section V of this document for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by August 13, 2021.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before August 13, 2021. The *https://www.regulations.gov* electronic filing system will accept objections until 11:59 p.m. Eastern Time at the end of August 13, 2021. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting objections. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–F–1289 for ''Food Additives Permitted in Feed and Drinking Water

of Animals; Selenomethionine Hydroxy Analogue.'' Received objections, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies in total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of objections. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your objections and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper objections received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Chelsea Cerrito, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV–221), Rockville, MD 20855, 240–402–6729, *chelsea.cerrito@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the **Federal Register** of May 11, 2020 (85 FR 27692), FDA announced that we had filed a food additive petition (animal use) (FAP 2312) submitted by Adisseo France S.A.S.; Immeuble Antony Parc II, 10 Place du Général de Gaulle, 92160 Antony, France. The petition proposed that the regulations for food additives permitted in feed and drinking water of animals be amended to provide for the safe use of selenomethionine hydroxy analogue as a source of selenium in feed for beef and dairy cattle.

II. Conclusion

FDA concludes that the data establish the safety and utility of selenomethionine hydroxy analogue as a source of selenium in feed for beef and dairy cattle and that the food additive regulations should be amended as set forth in this document.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and documents we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 571.1(h), we will delete from the documents any materials that are not available for public disclosure.

IV. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

■ 1. The authority citation for part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 2. In § 573.920, revise paragraphs (a)(6), (h)(2) and (3) introductory text to read as follows:

§ 573.920 Selenium.

(a) * * *

(6) Paragraphs (b) through (h) of this section provide the currently acceptable levels of selenium supplementation.

* * * * *

(h) * * *

(2) Selenium, as selenomethionine hydroxy analogue, is added to feed as follows:

(i) In complete feed for chickens, turkeys, swine, beef cattle, and dairy cattle at a level not to exceed 0.3 ppm.

(ii) In feed supplements for limit feeding for beef cattle at a level not to exceed an intake of 3 milligrams per head per day.

(iii) In salt-mineral mixtures for free-choice feeding for beef cattle up to 120 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of 3 milligrams per head per day.

(3) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling of selenomethionine hydroxy analogue in its packaged form shall contain:

* * * * *

Dated: July 7, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

Dated: July 12, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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