DFI, OPMAS, OFCSDSI, HFP, FDA, February 3, 2026.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

§ 73.530 [Amended]

■ 2. Section 73.530 is amended by revising paragraphs (b) and (c) to read as follows:

§ 73.530 Spirulina extract.

* * * * *

(b) *Specifications.* Spirulina extract must conform to the following specifications and must be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Lead, not more than 0.2 milligrams per kilogram (mg/kg) (0.2 parts per million (ppm));

(2) Arsenic, not more than 0.3 mg/kg (0.3 ppm);

(3) Mercury, not more than 0.1 mg/kg (0.1 ppm);

(4) Cadmium, not more than 0.3 mg/kg (0.3 ppm); and

(5) Negative for microcystin toxin.

(c) *Uses and restrictions.* Spirulina extract may be safely used for coloring human foods generally at levels consistent with good manufacturing practice, except that it may not be used to color products that are subject to regulation by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*); infant formula; or foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of the added color is authorized by such standards.

* * * * *

Lowel M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–02314 Filed 2–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2024–C–1085]

Listing of Color Additives Exempt From Certification; Beetroot Red

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; order.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the safe use of beetroot red for the coloring of human foods generally, at levels consistent with current good manufacturing practice, except in products under the jurisdiction of the United States Department of Agriculture (USDA), infant formula, or foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), unless the use of the added color is authorized by such standards. We are taking this action in response to a color additive petition (CAP) submitted by Phytolon, Ltd. (Phytolon or petitioner).

DATES: This order is effective March 23, 2026. See section XI for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the order by March 9, 2026.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 9, 2026. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. 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–2024–C–1085 for ''Listing of Color Additives Exempt From Certification; Beetroot Red.'' 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 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.'' We will review this copy, including the claimed confidential information, in its consideration of comments. 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 comments 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 comments 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: Christopher Kampmeyer, Office of Pre-Market Additive Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1255; or Meadow Platt, Office of Policy and International Engagement, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of March 12, 2024 (89 FR 17789), we announced that we filed a color additive petition (CAP 4C0326) submitted by Phytolon, Ltd., Ha-Tsmikha St, Yokne'am Illit, Israel. The petition proposed to amend the color additive regulations in part 73 (21 CFR part 73), ''Listing of Color Additives Exempt From Certification,'' to provide for the safe use of beetroot red for the coloring of foods generally, in amounts consistent with current good manufacturing practice, except in products under the jurisdiction of the USDA, in infant formula, and foods for which standards of identity have been promulgated under section 401 of the FD&C Act unless added color is authorized by such standards.

II. Background

Beetroot red is a reddish-purple liquid or powder produced by fermentation using a modified strain of the yeast, *Saccharomyces cerevisiae* (*S. cerevisiae*), expressing the genes for betanin biosynthesis from red beets (*Beta vulgaris* L. var. rubra). The principal coloring component in beetroot red is betanin (CAS Reg. No. 7659–95–2). Betanin is a type of betacyanin, which in turn is a type of betalain. Betalains are a class of water-soluble pigments present primarily in red beets and in plants belonging to the order, Caryophyllales (*e.g.,* quinoa, spinach, amaranths, and others). Betalains are divided into two subclasses: betacyanins (reddish to violet, including betanin) and betaxanthins (yellow to orange). Beetroot red contains a similar betacyanin pigment composition to dehydrated beets (21 CFR 73.40).

The color additive is manufactured by the following steps: (1) construction of the *S. cerevisiae* production strain that is genetically engineered to express the genes involved in the biosynthesis of betanin; (2) expression of betanin product via controlled fermentation by the *S. cerevisiae* production strain; (3) removal of the production organism from the fermentation broth; and (4) water evaporation to produce the liquid form of the product and optional drying to produce a powder form of the product.

The petitioner proposed the following specifications for beetroot red: total betacyanin, not less than 0.6 percent by weight; betanin purity, not less than 75 percent of the total betacyanin; total betacyanin other than betanin, not more than 20 percent; lead, not more than 0.15 milligram per kilogram (mg/kg); arsenic, not more than 0.05 mg/kg; mercury, not more than 0.01 mg/kg; cadmium, not more than 0.05 mg/kg. FDA concluded that the petitioner's proposed specifications for total betacyanin, betanin purity, and total betacyanin other than betanin are not needed in the codified regulation (Ref. 1).

III. Safety Evaluation

Under section 721(b)(4) of the FD&C Act (21 U.S.C. 379e(b)(4)), a color additive may not be listed for a particular use unless the data and other information available to FDA establish that the color additive is safe for that use. Our color additive regulations at 21 CFR 70.3(i) define ''safe'' to mean that there is convincing evidence establishing with reasonable certainty that no harm will result from the intended use of the color additive.

As part of our safety evaluation to establish with reasonable certainty that a color additive is not harmful under its intended conditions of use, we consider the additive's manufacturing and stability, the projected dietary exposure to the additive and any impurities resulting from the petitioned use of the additive, the additive's toxicological data, and other relevant information (such as published literature) available to us.

IV. Safety of the Petitioned Use of the Color Additive

A. Dietary Exposure Estimate

The petitioner requested that beetroot red be permitted at levels consistent with current good manufacturing practice and provided the representative maximum use levels for the proposed uses of the color additive. The petitioner used food consumption data from the 2017–2018 National Health and Nutrition Examination Survey (NHANES) to estimate the dietary exposure to betanin from the proposed use of beetroot red. The petitioner stated that the use of the color additive would be substitutional for current food uses of beetroot powder (21 CFR 73.40), and therefore, the proposed use of the color additive will not increase the current dietary exposure to betanin in the diet.

The petitioner estimated the eaters-only (that is, only those individuals in the population who consume the foods of interest) dietary exposure to betanin, the principal coloring component, from the intended uses of beetroot red (Ref. 2). However, FDA noted that the petitioner did not provide an estimate of dietary exposure to the powder or liquid forms of beetroot red. Therefore, we conducted our own estimate of dietary exposure to betanin and beetroot red. In addition, the petitioner included food codes for meat and poultry in the dietary exposure estimate and indicated that removal of these food codes would not impact the dietary exposure estimate because beetroot red is proposed for uses in plant-based meat analog products, and due to the limited availability of plant-based meat codes, the petitioner used the comminuted meat and poultry product food codes as surrogates. We noted that NHANES contains food codes for meat substitutes and, therefore, including the surrogate food codes is not necessary.

We estimated the dietary exposure to betanin from the use of beetroot red using 2-day food consumption data from the 2015–2020 NHANES for food and dietary supplements to be 27 mg/person/day (mg/p/d) at the mean and 53 mg/p/d at the 90th percentile for the U.S. population aged 2 years and older and 19 mg/p/d at the mean and 37 mg/p/d at the 90th percentile for children aged 2 to 5 years. Additionally, using the average total betacyanin and percent betanin from betacyanins, we estimated the dietary exposure to beetroot red powder and liquid forms to be 1.8 gram (g)/p/d and 4.4 g/p/d at the mean, respectively and 3.7 g/p/d and 8.9 g/p/d at the 90th percentile, respectively, for the U.S. population aged 2 years and older and 1.3 g/p/d and 3.2 g/p/d at the

mean, respectively and 2.5 g/p/d and 6.1 g/p/d at the 90th percentile, respectively, for children aged 2–5 years (Ref. 2).

B. Toxicological Considerations

To establish that beetroot red is safe for use as a color additive, the petitioner used a weight-of-evidence approach based on the following: (1) the history of widespread and safe consumption of betalains, including the betacyanin, betanin; (2) the results of safety studies conducted with beetroot red as the test article; and (3) an allergenicity assessment of protein sequences introduced into the production strain.

Betanin, as part of beetroot red, is a natural dietary constituent, and FDA acknowledges the long history of safe consumption of betanin from existing dietary sources, including red beetroot and purple dragon fruit (Ref. 3). In 1967, FDA published a regulation authorizing the use of dehydrated beets (beet powder) (21 CFR 73.40), which contains betanin, but we did not specify a maximum daily intake because no significant safety concerns existed. Furthermore, FDA acknowledges that *S. cerevisiae* has a prior history of safe use in a variety of food applications, and we conclude the *S. cerevisiae* strain developed by the petitioner for the production of beetroot red is non-toxicogenic and non-pathogenic (Ref. 3).

We reviewed the mutagenicity and genotoxicity studies (a bacterial reverse mutation assay, an *in vitro* mammalian chromosome aberration assay, an *in vitro* mammalian cell micronucleus assay, an *in vivo* mammalian erythrocyte Pig-a gene mutation assay, and an *in vivo* mutagenicity assessment using duplex sequencing in liver, stomach, and intestine tissues collected from a Pig-a gene mutation assay) using beetroot red as a test article (id.). We agree with the petitioner that beetroot red is not mutagenic or genotoxic under the experimental procedures and conditions applied.

We reviewed the subchronic (90-day) toxicity study in rats using beetroot red as a test article (id.). The no-observed-adverse-effect-levels (NOAELs) established in this study are 3,581 mg beetroot red/kg body weight (bw)/d in male rats and 4,055 mg beetroot red/kg bw/d in female rats, the highest dose tested (id.).

We consider the subchronic toxicity study on betanin-enriched beetroot red in rats to provide an important new set of data that corroborates the existing safety information for beetroot red (see id.). The petitioner states that the beetroot color test article used in the subchronic toxicity study was specifically manufactured to include pigment at the highest concentration possible (approximately 4.5% of betanin) to maximize the margin of exposure for the safety assessment (see id.).

In its assessment of the allergenicity of beetroot red, the petitioner examined the incidence of beetroot allergy in consumers and conducted bioinformatic analyses to determine if protein sequences introduced into the production strain share significant identity with the protein sequences of known allergens (see id.). The petitioner identified several reports of allergic reactions associated with consumption of beetroot but concluded there is no evidence that betalains are associated with these cases of allergic reactions (see id.). The petitioner did not identify known allergens sharing significant sequence identity with the introduced protein sequences, and we independently verified the results of the allergenicity assessment (see id.). We agree with the petitioner that there is no evidence of allergenic potential of the introduced protein sequences.

Based on the weight of evidence, such as the long history of consumption of beetroot and its color components, including betanin, the safety of orally administered betanin-enriched beetroot red in the subchronic rat study, and the lack of evidence of allergenic potential of introduced protein sequences, we conclude that beetroot red is safe for the petitioned uses (id.).

V. Comments

We received one comment in response to FDA's filing of the beetroot red color additive petition. The commenter requested that we decline to name the color additive ''beetroot red'' or any similar name using the term ''beetroot'' because the color additive is not derived from beetroot. The commenter further requested that the color additive be named ''betanin.'' After consideration of the comment, we are listing this color additive as ''beetroot red'' because (1) the color additive is expressed by genes from red beets (*Beta vulgaris* L. var. rubra), and we consider the phrase ''beetroot red'' appropriately descriptive of the identity of the color additive; and (2) while the color additive contains betanin as its principal coloring component, the color additive is composed of other pigments and non-pigment constituents (as discussed previously in II. Background), and therefore the color additive would not accurately be identified solely as ''betanin.''

VI. Conclusion

Based on the data and information in the petition and other available relevant information, we conclude that the petitioned use of beetroot red is safe for use as a color additive in foods generally and at levels consistent with current good manufacturing practices, except that it may not be used to color products under the jurisdiction of the USDA, infant formula, and foods for which standards of identity have been promulgated under section 401 of the FD&C Act unless added color is authorized by such standards.

We further conclude that this color additive will achieve its intended technical effect and is suitable for the petitioned use. Therefore, we are amending the color additive regulations in part 73 to provide for the safe use of beetroot red as set forth in this document. In addition, based on the factors in 21 CFR 71.20(b), we conclude that batch certification of beetroot red is not necessary to protect the public health.

VII. Public Disclosure

In accordance with § 71.15(a) (21 CFR 71.15(a)), the petition and the documents that 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 § 71.15(b), we will delete from the documents any materials that are not available for public disclosure.

VIII. Analysis of Environmental Impact

As stated in the March 12, 2024, **Federal Register** notification of petition for CAP 4C0326, the petitioner claimed that this action is categorically excluded under 21 CFR 25.32(r) because it applies to an action for substances which occur naturally in the environment, and for which the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment. We stated that, if FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. We did not receive any new information or comments regarding this claim of categorical exclusion. We considered the petitioner's claim of categorical exclusion and determined that this action is categorically excluded under 21 CFR 25.32(r) (Ref. 4). Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This order contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Section 301(ll) of the FD&C Act

Our review of this petition was limited to section 721 of the FD&C Act. This order is not a statement regarding compliance with other sections of the FD&C Act. For example, section 301(ll) of the FD&C Act (21 U.S.C. 331(ll)) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1) to (4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food containing this color additive. Accordingly, this order should not be construed to be a statement that a food containing this color additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all color additive orders that pertain to food and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

XI. Objections

This order is effective as shown in the **DATES** section, except as to any provisions that may be stayed by the filing of proper objections. If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.* We will publish notice of the objections that we have received or lack thereof in the **Federal Register**.

XII. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://regulations.gov.*

1. Memorandum from B. Petigara, Division of Color Certification and Technology, Color Technology Branch, Office of Cosmetics and Colors, Office of the Chief Scientist, FDA to C. Kampmeyer, Division of Food Ingredients (DFI), Office of Pre-Market Additive Safety (OPMAS), Office of Food Chemical Safety, Dietary Supplements, and Innovation (OFCSDSI), Human Foods Program (HFP), FDA, February 2, 2026.
2. Memorandum from T. Todorov, Chemistry Evaluation Branch, DFI, OPMAS, OFCSDSI, HFP, FDA to C. Kampmeyer, DFI, OPMAS, OFCSDSI, HFP, FDA, February 2, 2026.
3. Memorandum from A. Khan, Toxicology Evaluation Branch, DFI, OPMAS, OFCSDSI, HFP, FDA to C. Kampmeyer, DFI, OPMAS, OFCSDSI, HFP, FDA, February 2, 2026.
4. Memorandum from D. Wafula, Environmental Review Team, OPMAS, HFP, FDA to C. Kampmeyer, DFI, OMPAS, OFCSDSI, HFP, FDA, February 2, 2026.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 2. Add § 73.39 to subpart A to read as follows:

§ 73.39 Beetroot red.

(a) *Identity.* (1) The color additive beetroot red is a powder or liquid prepared from controlled fermentation of a non-pathogenic and non-toxicogenic strain of the yeast, *Saccharomyces cerevisiae,* genetically engineered to express genes from *Caryophyllales* sp. (*e.g., Beta vulgaris* L. var. rubra) involved in the synthesis of betanin. The product is further processed by filtration. Betanin is the principal coloring component of the color additive and imparts a reddish-purple color.

(2) Color additive mixtures made with beetroot red may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Beetroot red must conform to the following specifications and must be free from impurities, other than those named, to the extent that such impurities may be avoided by good manufacturing practice:

(1) Lead, not more than 0.15 milligrams per kilogram (mg/kg) (0.15 part per million (ppm));

(2) Arsenic, not more than 0.05 mg/kg (0.05 ppm);

(3) Mercury, not more than 0.01 mg/kg (0.01 ppm); and

(4) Cadmium, not more than 0.05 mg/kg (0.05 ppm).

(c) *Uses and restrictions.* Beetroot red may be safely used for coloring human foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color products that are subject to regulation by the United States Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*); infant formula, or foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of the added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes must conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches of the color additive are exempt from the certification requirements of section

721(c) of the Federal Food, Drug, and Cosmetic Act.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–02313 Filed 2–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 516, 520, 522, 529, 556, and 558

[Docket No. FDA–2025–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Application; Change of Sponsor; Change of Sponsor Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), and conditionally approved new animal drug applications (CNADAs) during July, August, and September 2025. The animal drug regulations are also being amended to improve their accuracy and readability.

DATES: This rule is effective February 6, 2026.

FOR FURTHER INFORMATION CONTACT: Cathie Marshall, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, *cathie.marshall@fda.hhs.gov,* 240–402–5693.

SUPPLEMENTARY INFORMATION:

I. Approval of Applications

FDA is amending the animal drug regulations to reflect approval actions for NADAs, ANADAs, and CNADAs during July, August, and September 2025, as listed in table 1. Documentation of environmental review required under the National Environmental Policy Act, summaries of the basis of approval under the Freedom of Information Act (FOIA summaries), and marketing exclusivity and patent information are available at Animal Drugs @FDA: *https://animaldrugsatfda.fda.gov/adafda/views/#/search.*

TABLE 1—ORIGINAL, CONDITIONAL, AND SUPPLEMENTAL APPLICATIONS APPROVED DURING JULY, AUGUST, AND SEPTEMBER 2025

Date of approval	Application No.	Sponsor (drug labeler code [1])	Product name	Effect of the action	21 CFR sections
July 8, 2025	200–807	Huvepharma EOOD (016592)	MGA (melengestrol acetate Type A medicated article) and EXPERIOR (lubabegron Type A medicated article) and MONOVET (monensin Type A medicated article).	Original approval as a generic copy of NADA 141–590.	558.330
July 8, 2025	200–808	Huvepharma EOOD (016592)	MGA (melengestrol acetate Type A medicated article) and EXPERIOR (lubabegron Type A medicated article) and MONOVET (monensin Type A medicated article) and TYLOVET (tylosin phosphate Type A medicated article).	Original approval as a generic copy of NADA 141–591.	558.625
July 8, 2025	200–815	Felix Pharmaceuticals Pvt. Ltd. (086101).	Cefpodoxime Proxetil Tablets (cefpodoxime proxetil tablets).	Original approval as a generic copy of NADA 141–232.	520.370
July 10, 2025	141–599	Intervet, Inc. (000061)	BRAVECTO QUANTUM (fluralaner for extended-release injectable suspension).	Original approval	522.998
July 11, 2025	200–816	Cronus Pharma Specialities India Private Ltd. (069043).	Meloxisol (meloxicam oral suspension 1.5 mg/mL).	Original approval as a generic copy of NADA 141–213.	520.1367
July 17, 2025	141–607	Intervet, Inc. (000061)	EXZOLT (fluralaner oral solution)	Original approval	520.999 556.290
July 18, 2025	200–759	ZyVet Animal Health, Inc. (086117).	Furosemide Tablets (furosemide tablets)	Original approval as a generic copy of NADA 034–621.	520.1010
July 21, 2025	200–817	Felix Pharmaceuticals Pvt. Ltd. (086101).	Meloxicam Oral Suspension (meloxicam oral suspension 1.5mg/mL).	Original approval as a generic copy of NADA 141–213.	520.1367
August 5, 2025	200–818	Bimeda Animal Health Ltd. (061133).	MOXICLOPRID for dogs (imidacloprid and moxidectin).	Original approval as a generic copy of NADA (141–251).	524–1146
August 14, 2025	200–794	Cronus Pharma Specialities India Private Ltd. (069043).	MELOXISOL (meloxicam oral suspension 0.5mg/mL).	Original approval as a generic copy of NADA 141–213.	520.1367
August 28, 2025	200–821	Parnell Technologies Pty. Ltd. (068504).	Isoflurane (isoflurane liquid)	Original approval as a generic copy of NADA 135–773.	529.1186
August 28, 2025	200–819	Bimeda Animal Health Ltd. (061133).	GAMROZYNE (gamithromycin)	Original approval as a generic copy of NADA 141–328.	522.1014
September 19, 2025	200–824	Felix Pharmaceuticals Pvt. Ltd. (086101).	Dexmedetomidine (dexmedetomidine hydrochloride sterile injectable solution).	Original approval as a generic copy of NADA 141–267.	522.558
September 30, 2025	141–616	Zoetis Inc., (054771)	DECTOMAX–CA1 (doramectin injectable solution).	Conditional approval	516.570

[1] See 21 CFR 510.600(c) for sponsor addresses.

II. Withdrawal of Approval of Applications

Elanco US Inc., 450 Elanco Circle, Indianapolis, IN 46211 (drug labeler code 058198) requested that FDA withdraw approval of the NADA listed in table 2 because the product information has been combined with NADA 010–918. No change to the regulatory text is required.