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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 984

[Doc. No. AMS–SC–24–0076]

Walnuts Grown in California; Changes to Administrative Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule implements a recommendation from the California Walnut Board (Board) to make changes to the administrative requirements prescribed under the Federal marketing order for walnuts grown in California (Order). This final rule provides a schedule for required handler assessment payments, establishes interest and late payment charges on overdue assessments owed, and modifies the existing reporting requirements for handler acquisitions of walnuts.

DATES: Effective September 16, 2026.

FOR FURTHER INFORMATION CONTACT: Jeffery Rymer, Marketing Specialist, or Abigail Maharaj, Chief, West Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA; telephone: (559) 487–5901; or email: *JefferyM.Rymer@usda.gov* or *Abigail.Maharaj@usda.gov.*

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This final rule is issued under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674) (the Act), amending Marketing Order No. 984, (7 CFR part 984, the Order), regulating the handling of walnuts grown in California. The Board locally administers the Order and is comprised of growers and handlers of California walnuts operating within the area of production, and a public member.

This action is exempt from the Office of Management and Budget (OMB) review process required by Executive Order 12866. This final rule amends existing Marketing Order No. 984, as amended (7 CFR part 984), Walnuts Grown in California, and is necessary for the continued operation of Marketing Order No. 984. Additionally, this action is exempt from the requirements of Executive Order 14192, ''Unleashing Prosperity Through Deregulation,'' pursuant to section 5(c).

This final rule has been reviewed under Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' which requires Federal agencies to consider whether their rulemaking actions would have Tribal implications. The Agricultural Marketing Service (AMS) has determined that this final rule is unlikely to have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

This final rule has been reviewed under Executive Order 12988, ''Civil Justice Reform.'' This final rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608(c)(15)(A) of the Act, any handler subject to an order may file with the U.S. Department of Agriculture (USDA) a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This final rule provides a defined payment schedule for required handler assessment payments. Additionally, the rule establishes interest and late payment charges on overdue handler assessments owed under the Order. Lastly, this action modifies the reporting requirements for walnut acquisitions. These changes were unanimously approved by the Board, in two separate votes, with eight in favor and none opposed, during Board meetings held on August 8, and November 6, 2024.

Section 984.69(a) of the Order provides that each handler shall pay the Board, on demand, his or her pro rata share of the Board's authorized expenses. Currently, each handler's assessment obligation is invoiced throughout the marketing year based upon the quantity of walnuts the handler has acquired and reported to the Board by January 15 of each year on the Order's CWB Form #1. However, the schedule of when assessments are invoiced, and payments are due, is not yet specified in the Order's regulations.

Further, § 984.69(c) of the Order provides the authority to establish late payment charges and interest charges on assessments that are not paid within the time period specified by the Board. While such late payment penalties are authorized under the Order, specific late payment charges and interest rate charges on past due assessments have not yet been established in the Order's regulations.

Additionally, § 984.73 of the Order provides the authority to require handlers to submit reports of their walnut receipts. Under that authority, § 984.473, ''Report of walnut receipts,'' was established to require handlers to report walnut acquisitions, on or before January 15 of each marketing year, on forms supplied by the Board. Currently, under that section of the Order, handlers are only required to submit one report each marketing year, with no provision providing instruction for reporting walnuts that may be acquired after January 15.

This final rule modifies the Order's current administrative requirements to enhance the efficient collection of assessments from handlers, strengthening the Board's oversight of the program operations and administration of the Order. The Board believes that these changes and additions will augment the Order's administrative requirements and incentivize compliance. AMS determined that these amendments would effectuate the declared policy of the Act by strengthening administrative requirements that support the effective operation of the Order.

Specifically, this final rule adds a new § 984.348, ''Payment of assessments,'' to the Order's requirements to establish the payment schedule for handler assessments. Each handler would pay assessments, based on the quantity of walnut receipts reported by the handler pursuant to § 984.473, in three equal installments invoiced by the Board, on January 31, April 30, and July 31 of each marketing year. This specific payment schedule is based on industry practice. Based on Board discussions, establishing this schedule in the Order itself will help stabilize and smooth revenue streams by distributing assessment collection evenly over staggered payments. Such stability will help the Board's operability by reducing uncertainty about when assessments are due and provide handlers with clear expectations and timeframe. This schedule is not clear in the Order or provided for in its administrative regulations.

In addition, through the authority provided by § 984.69(c) of the Order, this final rule also establishes late payment penalties and interest charges for handler assessment payments under a new § 984.349, ''Late payment and interest charges.'' This, in conjunction with the establishment of the payment schedule, will help the Board address issues of handler confusion with late payment submissions. A late payment charge of ten percent (10%) will be imposed on any assessment payment that has not been received within sixty (60) days of the invoice date on the handler's assessment statement. Further, assessment payments not received within sixty (60) days after the invoice date will also be subject to an ongoing one and one-half percent (1.5%) per month interest charge, accruing monthly until the total balance due, including any late payment charge, is paid. The inclusion of a late payment penalty and interest charges provision establishes a clear formula for the Board to apply to a handler's account when in arrears. This final rule also provides an incentive for handlers to comply with the payment installment schedule.

Finally, this action modifies the reporting requirements in § 984.473, ''Report of walnut receipts,'' which requires handlers to report walnut acquisitions on or before January 15 of each marketing year on forms supplied by the Board. This final rule adds provisions for reporting walnuts that are acquired after the January 15 reporting deadline. Although the occurrence of walnuts arriving to handlers after January 15 is not common, when it does occur, it creates confusion concerning how the reporting requirements and assessment collections are applied to those late arriving walnuts. As such, the Board's solution is: each handler acquiring walnuts from growers after submission of his or her initial report of walnut receipts will also be required to file a revised report of walnut receipts by the 15th of the month following such receipt. Handlers must pay assessments on such receipts upon demand, as requested by the Board, following receipt of the revised report.

These changes collectively aim to reinforce the integrity of the Order, promote compliance, and reduce reliance on legal remedies for collection. By requiring transparency, timely reporting, and punctual payments, these measures are expected to facilitate the orderly marketing of California walnuts and enhance the continued effectiveness of the program for the benefit of industry stakeholders.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this final rule on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act are unique regulations in that they are brought about through group action of typically small entities.

There are approximately 68 handlers subject to regulation under the Order and approximately 4,500 growers of California walnuts in the production area. At the time this analysis was prepared, the Small Business Administration (SBA) defined small agricultural service firms as those having annual receipts of less than $34,000,000 (North American Industry Classification System (NAICS) code 115114, Postharvest Crop Activities), and small agricultural producers of walnuts as those having annual receipts of less than $3,750,000 (NAICS code 111335, Tree Nut Farming) (13 CFR 121.201).

Data from USDA's National Agricultural Statistics Service (NASS), indicate a three-year average value of utilized inshell walnut production of $737.1 million for the most recent seasons for which data is available (2022 through 2024 crop years). Dividing that figure by the number of walnut growers (4,500) yields an average annual crop value per grower of approximately $163,787. This figure is well below the SBA small agricultural producer threshold of $3,750,000 in annual sales. Assuming a normal distribution, this provides evidence that a large majority of walnut growers would likely be considered small agricultural producers according to the SBA definition. Additionally, data from NASS's 2022 Agricultural Census show that 96 percent of California farms growing walnuts at the time had walnut sales of less than $1 million.

Further, based on information from the Board, approximately 78 percent of California's walnut handlers shipped assessable walnuts valued under $34 million during the 2023–2024 marketing year and would, therefore, be considered small handlers according to the SBA definition. Considering the above-mentioned information, it is reasonable to conclude that a substantial majority of both walnut growers and handlers would be considered small business entities according to current SBA definitions.

This final rule provides a defined payment schedule for required handler assessment payments, establishes interest and late payment charges on overdue handler assessments, and modifies the reporting requirements for walnut acquisitions. These changes were recommended by the Board to enhance the efficiency of the Board's administrative function.

The Board discussed alternatives to the recommendations contained in this rule, including different options for the reporting of walnut acquisitions, the timing of assessment payment installments, various late payment penalty rates, and the appropriate interest rate charged on unpaid assessments. The Board also considered making no changes and maintaining the Order's status quo. However, the Board recognized the financial and administrative inefficiencies inherent in the existing administrative provisions and believed that taking no action would have been imprudent. Further, the Board determined that the late penalty and the interest rate charge would serve to incentivize compliance with the Order's provisions without being excessive and burdensome.

In accordance with the Paperwork Reduction Act of 1995, (44 U.S.C. chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0178, ''Vegetable and Specialty Crops.'' This final rule requires changes to the

Board's existing CWB Form #1. Further, this final action may result in additional report submissions from some handlers. However, the changes are minor and the currently approved burden for the form would only be minimally increased by these changes. The revised form has been submitted to OMB for approval.

This final rule may impose some additional reporting or recordkeeping requirements on either small or large California walnut handlers. However, the Board anticipates that the requirement to submit supplemental acquisition reports for walnuts that are acquired after the submission of the handler's initial CWB Form #1 report would only impact a small percentage of the total number of handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

AMS has not identified any relevant Federal rules that duplicate, overlap, or conflict with this final rule.

A proposed rule concerning this action was published in the **Federal Register** on October 1, 2025 (90 FR 47248). Copies of the proposed rule were provided to all California walnut handlers. In addition, the proposal was made available through the internet by AMS and the Office of the Federal Register via *https://www.regulations.gov.* A 30-day comment period ending October 31, 2025, was provided to all interested persons to respond to the proposal. AMS received nine comments during the comment period. We address these comments below.

Of the comments received, five suggested modifications to either the payment schedule, late payment and interest charges, and/or grace period. The commenters did not self-identify as handlers or producers within the regulated production area. These commenters stated they understood the need to strengthen administrative requirements through the payment schedule and the late penalty and interest charges in order to incentive the timely collection of assessments and efficient operation of the Order. However, the comments expressed concern with the proposal, citing the potential economic impact the proposal would have on small businesses. Of the four remaining comments, two expressed support for the proposals, one recommended a more thorough burden analysis to demonstrate positive impacts on small producers, one did not address the merits of the proposal, and one raised concern about possible procedural deficiencies.

Commenters recommended the addition or extension of a grace period, a tiered penalty structure based on the handler size, lower penalty rates and interest charges, and/or a more flexible payment schedule. This rule includes a 60-day grace period before late penalties are assessed, which AMS and the Board view to be reasonable and appropriate to reduce financial burden, especially for small businesses. Additional time and the creation of a tiered penalty structure, as suggested by some commenters, would extend the grace period and delay payments further, potentially encouraging late payments. It may also result in different interest rates rather than a flat penalty fee of 1.5 percent, potentially raising fairness concerns among handlers and producers. In addition, payments being made at different intervals would increase administrative burden. The Board, which locally administers the Order, believes that applying the 60-day grace period and monthly penalty structure creates regulatory consistency across all handlers which it believes necessary to ensure timely and consistent payments for its efficient operation.

Prior to making its recommendation to amend the Order's administrative requirements, the Board met on two occasions to discuss the proposal's impact on industry handlers. The Board considered the regulatory impact on small businesses in formulating its recommendation. Ultimately, Board members representing small businesses unanimously supported the proposed changes, as evidenced by meeting minutes.

Moreover, AMS notes that this final rule aligns with other marketing orders that utilize late payment and interest charges as a standard business practice. AMS has reviewed the comments and ultimately concluded that the regulatory changes are appropriate, will enhance the efficient collection of assessments, and penalties will be administered proportionately, without bias, to all handlers regardless of size.

One comment raised concerns regarding the new reporting requirement and the extra paperwork burden that would be experienced by small businesses and one commenter suggested simplifying the acquisition report or offering technical assistance. While the action may impose some additional reporting and recordkeeping requirements on handlers who acquire walnuts after January 15, AMS anticipates that the change will have a minimal impact on burden, will only impact a limited number of handlers because acquiring additional walnuts is uncommon, will not impose an undue burden on small businesses specifically, and that modifying the reporting requirement is necessary for the efficient and equitable administration of the Order.

Lastly, one comment raised concerns about procedural deficiencies and lack of adherence to the Administrative Procedure Act, the Regulatory Flexibility Act, the Paperwork Reduction Act, and Executive Order 12866 in the rulemaking process. Specifically, the commenter claims that AMS procedurally bypassed notice and comment, failed to present an analysis of the impacts on small businesses, and deprived interested parties a meaningful opportunity to comment. After reviewing the comment, AMS determined that all of the statutory and procedural requirements for rulemaking have been met regarding this action.

Contrary to the comment's assertions, AMS did not bypass notice and comment or invoke good cause. Interested persons had numerous opportunities to review pertinent information, present their views, and participate in the rulemaking process. AMS notes that in conducting all meetings publicly, the Board provided, rather than deprived, interested persons a meaningful opportunity to comment. In addition, AMS published a notice of proposed rulemaking in the **Federal Register** on October 1, 2025, that included a 30-day comment period, ending October 31, 2025.

The proposed rulemaking also included an Initial Regulatory Flexibility Analysis, pursuant to requirements set forth in the Regulatory Flexibility Act, that considered and detailed for the public's review the economic impact of this final rule on small entities. AMS has provided adequate opportunity for interested persons to consider the proposal and provide comments. This final rule follows the applicable procedures and is compliant with the Regulatory Flexibility Act and Administrative Procedure Act. The comment also asserted that the affected information collection was not clearly identified and that OMB approval is required. As stated in the proposed rule, this final rule reiterates the affected information collection as CWB Form #1 and that revised changes to the form are minor, do not significantly increase burden, and that the form has been submitted to OMB. This final rule is compliant with information collection requirements under the Paperwork Reduction Act. Accordingly, AMS made no changes to the rule as proposed after review and consideration of all comments received.

Lastly, to address comments concerning Executive Order 12866, AMS reiterates that this final rule falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from the review process required by Executive Order 12866.

After consideration of all relevant material presented, including the information and recommendations submitted by the Board and other available information, AMS has determined that this final rule is consistent with and will effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 984

Marketing agreements, Nuts, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Agricultural Marketing Service amends 7 CFR part 984 as follows:

PART 984—WALNUTS GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR Part 984 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Add § 984.348 to subpart B to read as follows:

§ 984.348 Payment of assessments.

(a) Each handler shall pay assessments on walnut receipts reported by the handler pursuant to § 984.473(a) in three installments, invoiced by the Board, on January 31, April 30, and July 31 of each marketing year.

(b) Each handler shall pay assessments on walnut receipts reported by the handler pursuant to § 984.473(b), as requested by the Board, on demand.

■ 3. Add § 984.349 to subpart B to read as follows:

§ 984.349 Late payment and interest charges.

(a) The Board shall impose a late payment charge of ten percent (10%) on any handler whose assessment payment has not been received within sixty (60) days of the invoice date shown on the handler's assessment statement.

(b) Payments not received more than sixty (60) days after the invoice date shown on the handler's assessment statement shall be subject to a one and one-half percent (1.5%) interest charge per month. Interest shall be applied to the total outstanding assessment balance, including any late payment charge, at the end of each subsequent thirty (30) day period until final payment is made.

■ 4. Revise § 984.473 to read as follows:

§ 984.473 Report of walnut receipts.

(a) Each handler shall file a report of his or her walnut receipts from growers on or before January 15 of each marketing year on forms supplied by the Board.

(b) Each handler acquiring walnuts from growers after submission of their initial report of walnut receipts pursuant to paragraph (a) of this section shall file a revised report of walnut receipts by the 15th of the month following such receipt on forms supplied by the Board.

Erin Morris,

Administrator, Agricultural Marketing Service.

[FR Doc. 2026–16723 Filed 8–14–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. FDA–2025–N–1243]

Hematology and Pathology Devices; Reclassification of In Situ Hybridization Test Systems for Use With a Corresponding Approved Oncology Therapeutic Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final order reclassifying in situ hybridization (ISH) test systems indicated for use with a corresponding approved oncology therapeutic product (product codes NYQ, MVD, OWE, and PNK), all postamendments class III (premarket approval) devices, into class II (special controls), subject to premarket notification. FDA is also establishing a new device classification regulation, along with the special controls that are necessary to provide a reasonable assurance of safety and effectiveness of this device type.

DATES: This order is effective September 16, 2026. See further discussion in section IV, ''Implementation Strategy.''

FOR FURTHER INFORMATION CONTACT: Soma Ghosh, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3316, Silver Spring, MD 20993, 240–402–5333, *Soma.Ghosh@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices that were not introduced or delivered for introduction into interstate commerce for commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require approval of a premarket approval application (PMA), unless and until: (1) the Food and Drug Administration (FDA) reclassifies the device into class I or class II; or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. FDA determines whether new devices are substantially equivalent to predicate devices by means of the procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and our implementing regulations (part 807, subpart E (21 CFR part 807, subpart E)).

A postamendments device that has been initially classified into class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA, acting by administrative order, can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.[1]

FDA relies upon ''valid scientific evidence,'' as stated in section 513(a)(3) of the FD&C Act and defined in 21 CFR

[1] See section 513 of the FD&C Act.