TITON: [Amended]

Lat. 46°42′43″ N., long. 120°44′31″ W. (INT Yakima, WA, 304° and Ellensburg, WA, 212° radials).

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Paragraph 7003 Other domestic reporting points.

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ALASK: [Amended]

Lat. 16°50′13″ N., long. 66°32′15″ W. (INT Ponce, PR, 181° and St Croix, VI, 243° radials).

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BOGGY: [Amended]

Lat. 28°15′02″ N., long. 91°27′45″ W.

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CROAK: [Amended]

Lat. 36°56′19″ N., long. 73°00′00″ W. (INT Norfolk, VA, 088° and Sea Isle, NJ, 146° radials).

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DOLPH: [Amended]

Lat. 28°15′09″ N., long. 90°03′12″ W.

* * * * *

HEMLO: [Amended]

Lat. 43°18′09″ N., long. 126°40′50″ W.

HERIN: [Amended]

Lat. 42°00′10″ N., long. 67°47′26″ W.

HOBEE: [Amended]

Lat. 29°13′21″ N., long. 79°09′05″ W. (INT Carolina Beach, NC, NDB 192° bearing and Orlando, FL, VORTAC 070° radial).

IDAHO: [Amended]

Lat. 19°15′38″ N., long. 67°38′22″ W.

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SEDAR: [Amended]

Lat. 45°30′26″ N., long. 126°43′03″ W.

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TROUT: [Amended]

Lat. 30°23′01″ N., long. 76°59′59″ W.

UTAHS: [Amended]

Lat. 19°41′26″ N., long. 67°17′12″ W.

VERMO: [Amended]

Lat. 20°07′34″ N., long. 66°12′55″ W.

VIPER: [Amended]

Lat. 28°14′55″ N., long. 88°53′08″ W. (INT Leeville, FL, 130° and Pickens, FL, NDB 215° radials).

Paragraph 7004 Alaskan low altitude reporting points.

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CORVA: [Amended]

Lat. 60°16′56″ N., long. 145°14′51″ W.

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Paragraph 7006 Hawaiian reporting points.

BATES: [Amended]

Lat. 20°00′31″ N., long. 153°33′04″ W.

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FISHE: [Amended]

Lat. 21°46′38″ N., long. 155°32′08″ W. (INT Molokai, HI, 067° and Upolu Point, HI, 010° radials).

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Issued in Washington, DC, June 4, 2012.

Paul Gallant

Acting Manager, Airspace, Regulations and ATC Procedures Group.

[FR Doc. 2012–13993 Filed 6–8–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. FDA–2007–F–0390] (Formerly 2007F–0115)

Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a carbon dioxide laser for etching information on the surface of fresh, intact citrus fruit. This action is in response to a petition filed by Durand-Wayland, Inc.

DATES: This rule is effective June 11, 2012. Submit either electronic or written objections and requests for a hearing by July 11, 2012. See section VIII of this document for information on the filing of objections.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing, identified by Docket No. FDA–2007–F–0390, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2007–F–0390 for this rulemaking. All objections received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For detailed instructions on submitting objections, see section VIII. Objections in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1282.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of April 11, 2007 (72 FR 18263), FDA announced that a food additive petition (FAP 7M4768) had been filed by Durand-Wayland, Inc., c/o Hyman, Phelps & McNamara, P.C., 700 13th St. NW., suite 1200, Washington, DC 20005–5929. The petition proposed that the food additive regulations in part 179 (21 CFR part 179) be amended to provide for the safe use of a carbon dioxide laser for etching information on food, excluding meat and poultry. The intended technical effect of the carbon dioxide laser is to etch information, such as the price look-up code printed on an adhesive label placed on the surface of individual, fresh produce items sold at retail, directly onto the surface of food. The carbon dioxide laser therefore obviates the need for an adhesive label.

In a letter dated April 27, 2007, Hyman, Phelps & McNamara, P.C., informed FDA that Sunkist Growers, Inc., 14130 Riverside Dr., Sherman Oaks, CA 91423–2313, had joined Durand-Wayland, Inc., as co-petitioner of FAP 7M4768. The letter explained that Hyman, Phelps & McNamara would represent both petitioners with regard to FAP 7M4768.

Subsequent to the filing of the petition, the petitioners amended the petition by requesting a response to the proposed use of the carbon dioxide laser for etching information on the skin of fresh, intact citrus fruit not intended for commercial juice production, while the other requests in the petition remained

under review. The petitioners submitted a letter dated September 1, 2011, requesting withdrawal of all remaining uses of the petition other than to etch information on the skin of fresh, intact citrus fruit not intended for commercial juice production. On December 29, 2011, the petitioners communicated to FDA that, generally, citrus fruit intended solely for commercial juice production would not be laser etched, and that laser-etched citrus fruit would generally be intended for sale in the fresh market. However, certain circumstances (e.g., a cancelled order, expired shelf-life) could arise that would preclude laser-etched citrus fruit from being sold into the fresh market. In such circumstances, laser-etched citrus fruit could be sold for commercial juice production. To allow for this possibility, the petitioners requested that the proposed use not be limited to fruit not intended for nor used in commercial juice production. The petitioners assert that this use should be allowed because they contend there is no material difference between etched and non-etched citrus fruit. This final rule is a complete response to the petition.

II. Evaluation of Safety

A source of radiation used to treat food meets the definition of ''food additive'' under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(s)). While a source of radiation such as a carbon dioxide laser is not added to the food literally, the source is used to treat food and can affect the characteristics of the food.

Under section 409(c)(3)(A) of the FD&C Act (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is ''safe'' for that use. FDA's food additive regulations in 21 CFR 170.3(i) define ''safe'' as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

To fairly evaluate the safety of the carbon dioxide laser used to etch information on the skin of fresh, intact citrus fruit, the Agency must identify the various effects that may result from etching the fruit and assess whether any of these effects pose a public health concern. In doing so, FDA has determined that the two primary areas of possible public health concern are the potential chemical effects and the potential microbiological risk from etching the food. Each of these areas is discussed in detail within this document.

III. Evaluation of the Safety of the Petitioned Use of a Carbon Dioxide Laser

A. Background on Carbon Dioxide Laser Etching System

The low energy carbon dioxide laser that is the subject of this petition emits an infrared pulsed light with a wavelength of 10.6 micrometers (μm). The infrared energy produced by the carbon dioxide laser is non-ionizing and falls within the infrared energy spectrum that is commonly used for food processing, such as cooking, toasting, and grilling. The carbon dioxide laser beam is integrated with a dot-matrix type printer head that etches information by removing the pigmented top layer from the surface of food and revealing a contrasting sublayer. The etching penetrates the food to an average depth of 50 μm, which is about the first two to three epidermal cell layers of the food's surface.

To limit the etching depth (i.e., how far the laser penetrates the fruit) and the total surface area of the fruit that is etched, the petitioners have specified the maximum energy per laser etched area to be 9.8×10^{-3} joules per square centimeter (J/cm^2) and a maximum total surface area of fruit etched by the laser to be 0.122 cm^2. The petitioners have also proposed a limit on the total energy to which the citrus fruit is exposed from the use of the carbon dioxide laser to be 1.5×10^{-3} J. Studies that evaluated the chemical and microbiological effects of the carbon dioxide laser on fresh produce, which are discussed in section III.B and III.C of this document, were consistent with these limits. To ensure that the use of the carbon dioxide laser for etching information on citrus fruit is safe, FDA is specifying these limits as conditions of safe use in the resulting regulation.

B. Potential for Chemical Effects in Food

One of the issues considered by FDA in evaluating the safety of a carbon dioxide laser used to etch information on the skin of fresh, intact citrus fruit is the potential formation of chemical products in the fruit generated by the laser etching process. To determine whether the use of a food additive is safe, FDA typically considers the chemical identity and amount of the additive that will be ingested compared to what is known regarding its toxicity. In the case of substances added directly to food, the Agency estimates the amount of the additive that will be ingested from the proposed use levels of the additive in particular foods and the consumption patterns of those foods. Information about the chemical structure of an additive, an assessment of the likely consumption of the additive, and information regarding the toxicity of the additive, forms the basis for evaluating its safety. Similarly, for the petitioned use of the carbon dioxide laser for etching the skin of fresh, intact citrus fruit, the Agency considered the potential exposure to new chemical substances that may be generated in the laser-etched fruit in evaluating its toxicological safety.

To demonstrate the safety of the laser etching process, the petitioners provided a study that compared the chemical effects in tomatoes, potatoes, and apples exposed to the carbon dioxide laser etching system to those cooked with infrared heat. The study included chemical analyses that showed that use of the carbon dioxide laser to etch information on foods does not generate any new chemical substances that are not also typically generated by conventional cooking. Although this study was not conducted specifically on citrus fruit, the results are relevant for evaluating the potential chemical effects in fruits and vegetables exposed to laser etching in general, and therefore, support a determination that the proposed use of a laser to etch the skin of fresh, intact citrus fruit is safe.

Furthermore, the dietary exposure to any substances generated in the citrus fruit by the laser etching process is expected to be negligible due to the insignificant amount of substances formed, the very small portion of the surface area of the citrus fruit that is etched (0.122 cm^2), and the fact that the skin of citrus fruit is normally not consumed (Refs. 1 and 2). Based on this information, FDA concludes that any chemical effects generated by the laser etching process leading to the formation of products in the fruit are of no toxicological concern (Ref. 3).

C. Potential for Microbiological Risk in Food

The petitioners submitted data from a controlled study that evaluated whether the petitioned use of the carbon dioxide laser for etching information on the skin of fresh, intact citrus fruit increased the microbiological risk from changes to the surface of laser-etched fruit compared to fruit that had not been laser etched. The study assessed the ability of *Salmonella* bacteria to infiltrate, survive, or grow on the surface of fresh Valencia oranges in the area that was etched by the carbon dioxide laser under the proposed conditions of use. *Salmonella* bacteria were inoculated on the surface of oranges under typical conditions of commercial storage of fresh oranges. The study utilized *Salmonella* because

it is a human pathogen commonly associated with fresh produce contamination. Valencia oranges were used in the study because they are a fresh citrus fruit and, compared to other types of citrus fruit, have a higher hydrogen-ion concentration (pH) that is more advantageous for *Salmonella* growth.

According to the study's results, the recovery of viable *Salmonella* bacteria from the oranges after etching by the carbon dioxide laser and subsequent storage for 29 days was comparable to the recovery of *Salmonella* from control oranges that were not etched by the carbon dioxide laser. The amount of viable *Salmonella* bacteria decreased with storage time and followed a similar pattern of decline over the duration of storage under all treatment conditions. The study also evaluated the presence of viable *Salmonella* in the juice portion of inoculated and etched oranges. *Salmonella* was not detected in the juice portion of any sound, decay-free oranges that had been etched by the laser.

FDA evaluated the results of the study and concluded that *Salmonella* bacteria present on orange surfaces prior to etching by the carbon dioxide laser, and that contaminate orange surfaces after laser etching, do not infiltrate, survive, or grow during subsequent storage to a level that presents a potential public health hazard significantly greater than the survival or growth of *Salmonella* bacteria on oranges that are not etched by the carbon dioxide laser (Ref. 4).

As stated earlier, on December 29, 2011, the petitioners requested that the proposed use not be limited to citrus fruit not intended for nor used in commercial juice production because certain circumstances, such as a cancelled order or expired shelf-life, may arise that would preclude citrus fruit that is already laser etched from being sold in the fresh market, but such fruit could still be sold for commercial juice production. In these circumstances, the preferred alternative would be to use the laser-etched citrus fruit for commercial juice production. FDA concludes that no additional safety data or analysis is necessary because the evidence submitted by the petitioners has established that there is no material difference between etched and non-etched citrus fruit. Specifically, the *Salmonella* study results provided by the petitioners demonstrated the microbiological similarities between the untreated and laser-etched oranges, and the results from the same study showed no detection of *Salmonella* in the juice portion of laser-etched oranges. In addition, juice processors are required to comply with the Hazard Analysis and Critical Control Point regulation for juice (part 120 (21 CFR part 120)) (the juice HACCP regulation). Specifically, § 120.24(a) (21 CFR 120.24(a)) requires juice processors to include in their HACCP plans control measures that will consistently produce, at a minimum, a 5-log reduction in the pertinent microorganism, which is the most resistant microorganism of public health significance that is likely to occur in the juice. Juice processors must achieve the 5-log reduction through treatments applied directly to the juice, except that citrus juice processors may use treatments applied to the surface of the fruit, provided that the 5-log reduction process begins after culling and cleaning as defined in § 120.3(a) and (f), and the reduction is accomplished within a single production facility (§ 120.24(b)). FDA concludes that laser-etched citrus fruit, which has been otherwise cleaned and culled in accordance with the requirements of part 120, can be eligible to be used to make citrus juice where treatments applied only to the surface of the fruits are used to achieve the 5-log pathogen reduction control measure. In addition, § 120.11(b) requires the juice processor to validate that the HACCP plan, including any processes used to achieve the 5-log pathogen reduction requirements of § 120.24, is adequate to control food hazards that are reasonably likely to occur. If validation reveals that the HACCP plan is no longer adequate to achieve the 5-log pathogen reduction and otherwise meet the requirements of part 120, the juice processor must modify the HACCP plan immediately. Based on the data submitted by the petitioners demonstrating that there is no material difference between etched and non-etched citrus fruit, and the additional controls for the growth of pertinent microorganisms provided by the juice HACCP regulation, FDA has no safety concerns regarding the possible use of laser-etched citrus fruit for commercial juice production, and this use is not excluded from the scope of the final rule.

IV. Conclusion

Based on the data and studies submitted in the petition and other relevant information in the Agency's files, FDA concludes that the proposed use of a carbon dioxide laser for etching information on the surface of fresh, intact citrus fruit is safe under the conditions proposed in this petition. Therefore, the food additive regulations should be amended as set forth in this document.

V. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the Agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VI. Environmental Impact

The Agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 7M4768 (72 FR 18263). No new information or comments have been received that would affect the Agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VII. Paperwork Reduction Act of 1995

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

VIII. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) either electronic or written objections by (see **DATES**). Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions 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. It is only necessary to send one set of documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management

between 9 a.m. and 4 p.m., Monday through Friday.

IX. Section 301(ll) of the Federal Food, Drug, and Cosmetic Act

FDA's review of this petition was limited to section 409 of the FD&C Act. This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, the Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the FD&C Act to, among other things, add section 301(ll) of the FD&C Act (21 U.S.C. 331(ll)). Section 301(ll) of the FD&C Act 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 exceptions in section 301(ll)(1) to (ll)(4) of the FD&C Act applies. In its review of this petition, FDA did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to the laser-etching source. Accordingly, this final rule should not be construed to be a statement that a food that has been laser etched, 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 food additive final rules and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

X. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from Lee, Chemistry Review Group, Division of Petition Review, to Johnston, Regulatory Group II, Division of Petition Review, May 16, 2007.
2. Memorandum from Lee, Chemistry Review Group, Division of Petition Review, to Johnston, Regulatory Group II, Division of Petition Review, November 19, 2008.
3. Memorandum from Khan, Toxicology Team, Division of Petition Review, to Johnston, Regulatory Group II, Division of Petition Review, April 20, 2010.
4. Memorandum from Losikoff, Division of Seafood Safety, and Mahovic, Produce Safety Staff, to Johnston, Regulatory Group II, Division of Petition Review, August 15, 2011.

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 179 is amended as follows:

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

1. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

■ 2. Section 179.43 is added to subpart B to read as follows:

§ 179.43 Carbon dioxide laser for etching food.

Carbon dioxide laser light may be safely used for etching information on the surface of food under the following conditions:

(a) The radiation source consists of a carbon dioxide laser designed to emit pulsed infrared radiation with a wavelength of 10.6 micrometers such that the maximum energy output of the laser does not exceed 9.8×10^{-3} joules per square centimeter (J/cm^2);

(b) The carbon dioxide laser shall be used only for etching information on the skin of fresh, intact citrus fruit, providing the fruit has been adequately washed and waxed prior to laser etching, and the etched area is immediately rewaxed after treatment; and

(c) The maximum total energy to which the etched citrus fruit is exposed from the use of the carbon dioxide laser shall not exceed 1.5×10^{-3} J, and the maximum total etched surface area of the citrus fruit shall not exceed 0.122 cm^2.

Dated: June 5, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14035 Filed 6–8–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2012–0197]

RIN 1625–AA08

Special Local Regulations for Marine Events, Swim Event; Lake Gaston, Littleton, NC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard will establish a Special Local Regulation for ''The Crossing'' swim event to be held on the waters of Lake Gaston, adjacent to the Eaton Ferry Bridge in Littleton, North Carolina. This Special Local Regulation is necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic on Lake Gaston under the Eaton Ferry Bridge and within 100 yards west of the bridge during the swim event.

DATES: This rule is effective from 7:30 a.m. to Noon on August 11, 2012.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2012–0197]. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email BOSN3 Joseph M. Edge, U.S. Coast Guard Sector North Carolina; telephone 252–247–4525, email *Joseph.M.Edge@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR **Federal Register**
NPRM Notice of Proposed Rulemaking

A. Regulatory History and Information

The regulatory history for this action includes both a Notice of proposed