

**§ 260.3 Applicability.**

Except as noted in § 260.11, this part applies to the following:

(a) U.S. and foreign air carriers marketing scheduled or charter air transportation where voice calls are permitted onboard flights; and

(b) Ticket agents doing business in the United States that market scheduled or charter air transportation where voice calls are permitted onboard flights.

**§ 260.5 Definitions.**

As used in this part:

*Air transportation* means foreign air transportation or intrastate or interstate air transportation.

*Carrier* means any air carrier or foreign air carrier as defined in 49 U.S.C. 40102(a)(2) or 49 U.S.C. 40102(a)(21), respectively, that is marketing scheduled or charter passenger air transportation.

*Mobile wireless device* means any portable wireless telecommunications device not provided by the covered carrier that is used for the transmission or reception of voice calls. The term includes, but is not limited to, passenger cellular telephones, computers, tablets, and other portable electronic devices using radio signals or Voice over Internet Protocol.

*Ticket agent* has the meaning ascribed to it in 49 U.S.C. 40102(a)(45), and DOT regulations.

*Voice call* means an oral communication made or received by a passenger using a mobile wireless device.

**§ 260.7 Unfair and deceptive practice.**

The holding out or sale of scheduled or charter passenger air transportation is prohibited as unfair and deceptive in violation of 49 U.S.C. 41712 unless, in conjunction with such holding out or sale, carriers and ticket agents follow the requirements of this part.

**§ 260.9 Notice requirement.**

(a) *Notice in flight itineraries and schedules.* Each air carrier, foreign air carrier, or ticket agent providing flight itineraries and/or schedules for scheduled or charter passenger air transportation to the public in the United States shall ensure that each flight within, to, or from the United States on which voice calls are permitted is clearly and prominently identified and contains the following disclosures.

(1) In flight schedule information provided to U.S. consumers on desktop browser-based or mobile browser-based internet Web sites or applications in response to any requested itinerary search, for each flight on which voice

calls are permitted, notice that voice calls are permitted must appear prominently in text format on the first display following the input of a search query, immediately adjacent to each flight in that search-results list. Roll-over, pop-up and linked disclosures do not comply with this paragraph.

(2) For static written schedules, each flight in passenger air transportation where voice calls are permitted shall be identified by an asterisk or other easily identifiable mark that leads to disclosure of notification that voice calls are permitted.

(b) *Notice in oral communications with prospective consumers.* In any direct oral communication in the United States with a prospective consumer, and in any telephone call placed from the United States by a prospective consumer, concerning a flight within, to, or from the United States where voice calls are permitted, a ticket agent doing business in the United States or a carrier shall inform the consumer, the first time that such a flight is offered to the consumer, or, if no such offer was made, the first time a consumer inquires about such a flight, that voice calls are permitted.

(c) Each air carrier and foreign air carrier that permits voice calls via passenger devices shall provide notification to all ticket agents that receive and distribute the U.S. or foreign carrier's fare, schedule, and availability information of the fact that voice calls via passenger devices are permitted during the flight. This notification shall be useable, current, and accurate, and suitable for providing the notices to prospective air travelers required by paragraphs (a) and (b) of this section.

**§ 260.11 Exceptions.**

This Part does not apply to:

(a) Air carriers or foreign air carriers providing air transportation only with aircraft having a designed passenger capacity of less than 60 seats.

(b) Ticket agents with \$20.5 million or less in annual revenues, or that qualify as a small business pursuant to 13 CFR part 121.

Issued in Washington, DC, on December 7, 2016.

**Anthony R. Foxx,**

*Secretary of Transportation.*

[FR Doc. 2016-29830 Filed 12-13-16; 8:45 am]

**BILLING CODE 4910-9X-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 73**

[Docket No. FDA-2016-D-4120]

**Fruit Juice and Vegetable Juice as Color Additives in Food; Draft Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled "Fruit Juice and Vegetable Juice as Color Additives in Food." The draft guidance, when finalized, will help manufacturers determine whether a color additive derived from a plant material meets the specifications under certain FDA color additive regulations.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 13, 2017.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment 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):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, 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-2016-D-4120 for the draft guidance for industry entitled “Fruit Juice and Vegetable Juice as Color Additives in Food.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments 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 our 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the

electronic and written/paper comments 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.

Submit written requests for single copies of the draft guidance to the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

#### FOR FURTHER INFORMATION CONTACT:

*With regard to the draft guidance:* Laura A. Dye, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1275. *With regard to the proposed collection of information:* Ila Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North (3WFN), 10A63, 11601 Landsdown St., North Bethesda, MD 20852.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

We are announcing the availability of a draft guidance for industry entitled “Fruit Juice and Vegetable Juice as Color Additives in Food.” We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

When a food substance, including plant material, is deliberately used as a color, it is a color additive (see 21 CFR 70.3(f)). We have a statutory obligation to ensure that authorized (or listed) color additives are suitable and safe for their intended use. FDA has authorized the use of the color additive “fruit juice,” under § 73.250 (21 CFR 73.250), that is prepared either by expressing the juice from mature varieties of fresh, edible fruits, or by the water infusion of the dried fruit. Similarly, § 73.260 establishes that the color additive “vegetable juice” is prepared either by expressing the juice from mature varieties of fresh, edible vegetables or by the water infusion of the dried

vegetable. The underlying premise of §§ 73.250 and 73.260 is that the safety of fruit juice and vegetable juice as color additives for use in food is assured by the fact that the fruit or vegetable from which the color additive is derived has been safely consumed as food, such that there would not be safety concerns in using the juice or water soluble color components from the fruit or vegetable as a color additive. The fact that plant material can be eaten does not necessarily mean that juice from such plant material meets the specifications of these regulations. We also note that, in addition to the color additive regulations for fruit juice in § 73.250 and vegetable juice in § 73.260, we have authorized color additives derived from plant materials in separate color additive regulations, including § 73.169 (grape skin extract) and § 73.500 (saffron).

The draft guidance, when finalized, is intended to help manufacturers determine whether a color additive derived from a plant material meets the specifications for fruit juice under § 73.250 or vegetable juice under § 73.260. The draft guidance, including our interpretation of the terms used in §§ 73.250 and 73.260, is limited to these color additive regulations. The draft guidance does not address the use of fruit- or vegetable-derived color additives that are authorized under different color additive regulations or that are the subject of a color additive petition.

Since we issued the color additive regulations for fruit juice and vegetable juice, we have received inquiries from industry regarding whether certain plant materials are covered by these color additive regulations. The draft guidance provides the criteria that should be used to determine if a plant material is a mature, fresh, edible fruit or a mature, fresh, edible vegetable under §§ 73.250 and 73.260. The draft guidance also encourages firms to consult us if they are unsure of the regulatory status of a substance that they propose to derive from plant materials for use as a color additive for food. Separately, we have posted on our Web site a summary table of the informal opinions that we have issued in response to the specific inquiries we have received regarding the applicability of §§ 73.250 and 73.260. The draft guidance document contains the Web site link to the summary table.

##### II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of

Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR 71.1 have been approved under OMB control number 0910–0016.

The draft guidance also refers to new collections of information found in FDA regulations. Under the PRA, Federal Agencies must obtain approval from OMB for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the information to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed new collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s

estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*Title: Fruit Juice and Vegetable Juice as Color Additives in Food; Draft Guidance for Industry—OMB Control Number 0910—NEW*

The draft guidance, when finalized, will help manufacturers determine whether a color additive derived from a plant material meets the specifications for fruit juice under § 73.250 or vegetable juice under § 73.260. Information in the draft guidance regarding submission of a color additive petition has been previously approved by OMB in accordance with the PRA under OMB control number 0910–0016.

The proposed new information collection provides manufacturers the opportunity to request a meeting with FDA if they are unsure whether a color additive that is derived from plant material and that is intended for use in food meets the identity for fruit juice or vegetable juice in § 73.250 or § 73.260. When manufacturers request a meeting,

the draft guidance suggests that they provide the scientific name, common name(s), origin, cultivation state, and life-stage of the plant material from which they wish to derive the color additive, and which plant structure will be declared the mature, fresh, edible fruit or vegetable, as well as a complete description of the manufacturing process for the color additive. Manufacturers also may provide information to us to verify that the plant material can be consumed for its taste, aroma, or nutrient properties in its fresh state and to document the amount and frequency of consumption and the history of safe consumption. If we determine that a proposed color additive does not meet the specifications for fruit juice or vegetable juice under § 73.250 or § 73.260, the manufacturer may submit a color additive petition, the collection of information for which has been approved under OMB control number 0910–0016.

*Description of respondents:* The respondents to this collection of information are manufacturers who are trying to determine whether a color additive derived from a plant material meets the specifications for fruit juice under § 73.250 or vegetable juice under § 73.260.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Color manufacturer’s request for meeting and identification of fruit juice or vegetable juice information .....	5	1	5	1	5
Manufacturer’s collection of data supporting the plant material as a consumable food, amount and frequency of consumption, and history of safe consumption by humans .....	5	1	5	24	120
<b>Total</b> .....					<b>125</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA’s estimate of the number of respondents and number of responses in table 1 is based on the average number of meetings that are expected to be requested annually by manufacturers over the next 3 years. Based on past experience, we expect the request for a meeting and the submission of fruit juice or vegetable juice information can be completed by a qualified plant taxonomist in less than 1 hour. We also expect that some manufacturers may want to provide research supporting the plant material as a consumable food, the amount and frequency of consumption,

and the history of safe consumption of the mature fruit or vegetable by humans. We estimate that, in these cases, it would take a qualified toxicologist up to 3 days (24 working hours) to perform a thorough literature and plant database search. This estimate includes the time we expect it would take for a submitter to compile the information for submission to FDA.

To be conservative, the total number of annual burden hours, therefore, would be 125 hours, which would include 5 hours to complete the initial request for a meeting and of the

submission of associated information to FDA, and 120 hours to complete a literature and database search and to present this information for submission to FDA.

Before the proposed information collection provisions contained in the draft guidance become effective, we will publish a notice in the **Federal Register** announcing OMB’s decision to approve, modify, or disapprove the information collection provisions. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection

of information unless it displays a currently valid OMB control number.

### III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the draft guidance.

Dated: December 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-29968 Filed 12-13-16; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF DEFENSE

### Department of the Army

#### 32 CFR Part 516

[Docket No. USA-2015-0016]

RIN 0702-AA69

#### Release of Official Information and Appearance of Witnesses in Litigation

**AGENCY:** Department of the Army, DoD.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of the Army proposes to amend its regulation concerning policies and procedures for release of official information and testimony of Army witnesses in federal and state courts where the Army or Department of Defense (DoD) has an interest in the matter. This regulation was last published in the **Federal Register** on July 29, 1994 (59 FR 38236). At that time, a complete Army Regulation was codified. This revision removes a large portion of the currently codified part that does not apply to the public, and is now included in DoD internal guidance. Army Regulation 27-40, *Litigation*, dated 19 September 1994, is the corresponding document where the internal guidance is located.

**DATES:** Consideration will be given to all comments received by: February 13, 2017.

**ADDRESSES:** You may submit comments, identified by 32 CFR part 516, Docket No. USA-2015-0016 and or RIN 0702-AA69, by any of the following methods:

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

- *Mail:* Department of Defense, Deputy Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, ATTN: Box 24, Alexandria, VA 22350-1700.

*Instructions:* All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

#### FOR FURTHER INFORMATION CONTACT:

Major Thomas S. Hong, (703) 693-1093; [thomas.s.hong@mail.mil](mailto:thomas.s.hong@mail.mil).

#### SUPPLEMENTARY INFORMATION:

##### Executive Summary

The rule discusses departmental responsibilities, procedures for service of process, procedures for government officials sued in their official capacities, and procedures for requests for release of official information, to include witness testimony. The rule also discusses the release of official information and the appearance of present and former Army personnel as witnesses in response to requests for interviews, notices of depositions, subpoenas, and other requests or orders related to judicial or quasi-judicial proceedings.

For the purposes of this rule, Army personnel include the following:

- Present, former and retired Army military personnel, including the U.S. Army Reserve, regardless of current status.
- Present, former and retired civilian employees of the U.S. Army, regardless of current status.
- Soldiers of the Army National Guard of the United States (Title 10, U.S.C.) and, when specified by statute or where a Federal interest is involved, Soldiers in the Army National Guard (Title 32, U.S.C.).
- Technicians under 32 U.S.C. 709.
- USMA cadets.
- Nonappropriated fund employees.
- Foreign nationals who perform services for the Army overseas.
- Other individuals hired by or for the Army, including individuals hired through contractual agreements by or on behalf of the Army.

##### Background

This regulation was most recently published in the **Federal Register** on July 29, 1994 (59 FR 38236). It implements 32 CFR part 97. Department of Defense Directive 5405.2, "Release of Official Information in Litigation and Testimony by DoD Personnel as Witnesses" (available at [\[www.dtic.mil/whs/directives/corres/pdf/540502p.pdf\]\(http://www.dtic.mil/whs/directives/corres/pdf/540502p.pdf\)\) is where DoD's internal guidance that corresponds to 32 CFR part 97 is located. The proposed revision also removes a large portion of the currently codified part that does not apply to the public, such as items that solely deal with internal Army procedures and actions, e.g., annual reporting requirements to Headquarters, Department of the Army.](http://</a></p>
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##### Authority for This Action

Authorities for this rulemaking include the following:

- The Freedom of Information Act at 5 U.S.C. 552 which provides the public with a right to request access to federal agency records or information, except to the extent the records are protected from disclosure by any of nine exemptions or by one of three special law enforcement record exclusions.

- The Privacy Act of 1974 at 5 U.S.C. 552a, which establishes a code of fair information practices that governs the collection, maintenance, use, and dissemination of information about individuals that is maintained in systems of records by federal agencies.

- Confidentiality of records at 42 U.S.C. 290 which requires certain medical records shall be confidential and disclosed only for authorized purposes.

- Executive Order No. 12988, Civil Justice Reform (add a link to the E.O.) which establishes several requirements on Federal agencies involved in litigation or contemplating filing an action on behalf of the United States.

##### Costs and Benefits

The proposed revisions benefit the Department of the Army agencies, Army support to the Department of Justice, and interaction with state courts in affirmative and defensive litigation information. With the updates to the CFR for statutory and other changes since the document was published in 1994, Army's support of federal litigation and response to requests to support state and private litigation will be improved.

Although no formal study or collection of data are available, a review of the closed Touhy requests for FY 2016 shows that hundreds of hours were expended by Army personnel responding to these requests. Similar to costs in Freedom of Information Act processing, there are substantial costs for searching, reviewing, and producing Army records and personnel for depositions and trial.

This rule will be included in DoD's retrospective plan, completed in August 2011, and will be reported in future