some cases, the passengers may choose to receive notice when their bags arrive and pick up the bags at the carrier's baggage office at the destination airport. How should we determine that the bags have been ''delivered'' to the passenger and therefore stop the clock from running in each of these situations?

DOT seeks comment on the number of bags that are delayed annually based on the 12 and 18 hour and 15 and 30 hour statutory timeframes, and lost bags. The Department receives information on the number of mishandled-baggage reports filed by passengers, but we do not have data on how many of these are delayed bags, and how many are lost. Information on the number of delayed and lost bags that would be affected by this rulemaking would help the Department to better estimate the impact this rule would have on consumers and airlines.

Method for Refunding Delayed Baggage

The Department is also seeking comment on the appropriate method for providing a refund for delayed baggage. The Department's credit card refund regulation, 14 CFR part 374, implements the Consumer Credit Protection Act and Regulation Z of the Board of Governors of the Federal Reserve System, 15 U.S.C. 1601–1693r and 12 CFR part 226 (Regulation Z) with respect to air carriers and foreign air carriers. It states that when refunds are due on purchases with a credit card, a carrier must transmit a credit statement to the credit card issuer within seven business days of receipt of full documentation for the refund requested. In addition, the Department requires that, with respect to purchases with forms of payment other than credit cards, an airline must provide a refund within 20 days of receipt of full documentation of such a request. See 14 CFR 259.5(b)(5). The Department applies these refund standards to all refunds that are due to consumers, including airfare refunds and ancillary fee refunds. In order to receive a refund under Regulation Z, a consumer must request the refund from the carrier and provide all necessary supporting documents. In contrast, the Act states that carriers should ''promptly provide an automated refund'' to an eligible passenger when the carriers fail to meet the applicable time limit in delivering the checked bag, and the passenger has notified the carrier of the lost or delayed checked baggage. Under the Act, an ''automated refund'' should be issued to passengers as long as the delay has met the threshold timeframe and the passenger has notified the carrier about the delayed or lost bag. In that regard, we view the delayed baggage fee refund provision in the FAA Extension Act differently from Regulation Z in that the Act only requires a passenger to notify the carrier that a bag is delayed or lost, and there is not a requirement for the passenger to request a refund for the baggage fee. We emphasize that since the Act's automated refund requirement covers all bags that are delayed for more than a set number of hours, it will also cover ''lost bags,'' refunding fees charged for which is already required by 14 CFR 259.5(b)(3).[6] As such, both bags delayed for more than the set number of hours and bags that are considered ''lost'' would be eligible for an automated refund.

The Department seeks comment on whether prescribing a specific mechanism for the carriers to use to provide the statutorily required automated refund would negatively or positively impact carriers and consumers. What procedures would be necessary on interline itineraries, for which the carrier to whom the passenger reports the delayed bag at his or her destination or stopover is not the carrier to whom the passenger had paid the baggage fee? In addition to soliciting comment on all of the issues and concerns identified above, we also welcome and any other information relevant to this issue. This specifically includes comments and data on the cost impact on new-entrant carriers (many of whom do not have interline agreements) of the time standard developed in this proceeding, and the cost impact on regional airlines.

Issued this 18th day of October, 2016, in Washington, DC.

Anthony R. Foxx,

Secretary of Transportation.

[FR Doc. 2016–26199 Filed 10–28–16; 8:45 am]

BILLING CODE 4910–9X–P

[6] We have not defined ''lost'' for purposes of 14 CFR 259.5(b)(3) mandating a refund of the baggage fee for lost bags. Instead, in a Frequently Asked Questions document issued by the Department's Office of Aviation Enforcement and Proceedings, that office states that if a carrier unreasonably refuses to consider a bag to be lost after it has been missing for a considerable period of time, it could be subject to enforcement action for violating the statutory prohibition against unfair and deceptive practices. See, Answers to Frequently Asked Questions Concerning the Enforcement of the Second Final Rule on Enhancing Airline Passenger Protections (EAPP #2), last updated May 8, 2015, *https://www.transportation.gov/sites/dot.gov/files/docs/EAPP_2_FAQ_2_0.pdf.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 112, 117, and 507

[Docket No. FDA–2016–D–2841]

Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a draft guidance for industry entitled ''Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry.'' This draft guidance explains our current thinking on disclosure statements made by an entity, in documents accompanying food, that certain hazards have not been controlled by that entity as required by certain provisions in four final rules. This document describes our current thinking on how to describe the hazard under each of the four rules and which documents we consider to be ''documents of the trade'' for the purpose of disclosure statements.

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 this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 1, 2017. Submit either electronic or written comments on the proposed collection of information by May 1, 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–2841 for ''Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry.'' 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.'' The Agency 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 *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 Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration (HFS–300), 5001 Campus Drive, 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 this draft guidance: For questions regarding this draft guidance as it relates to our regulation entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food,'' contact Jenny Scott, Center for Food Safety and Applied Nutrition, (HFS–300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2166.

For questions regarding this draft guidance as it relates to our regulation entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals,'' contact Jeanette Murphy, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6246.

For questions regarding this draft guidance as it relates to our regulation entitled ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,'' contact Samir Assar, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–401–1636.

For questions regarding this draft guidance as it relates to our regulation entitled ''Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals,'' contact Rebecca Buckner, Office of Food and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4576.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry.'' We are issuing the draft guidance consistent with FDA's 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 create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

The draft guidance relates to four of the seven foundational rules that we have established in Title 21 of the Code of Federal Regulations (21 CFR) as part of our implementation of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353). Table 1 lists these four rules. Each of these rules includes ''customer provisions'' as specified in table 1.

TABLE 1—THE FOUR FOUNDATIONAL FSMA RULES RELEVANT TO THE DRAFT GUIDANCE

Title and abbreviations for the purpose of this document	Regulatory codification	''Customer provisions''	Publication
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (part 117).	21 CFR part 117	21 CFR 117.136(a)(2), (3), and (4).	80 FR 55908, September 17, 2015.

TABLE 1—THE FOUR FOUNDATIONAL FSMA RULES RELEVANT TO THE DRAFT GUIDANCE—Continued

Title and abbreviations for the purpose of this document	Regulatory codification	''Customer provisions''	Publication
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (part 507).	21 CFR part 507	21 CFR 507.36(a)(2), (3), and (4).	80 FR 56170, September 17, 2015.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (produce safety regulation).	21 CFR part 112	21 CFR 112.2(b)	80 FR 74354, November 27, 2015.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (FSVP regulation).	21 CFR part 1, subpart L ..	21 CFR 1.507(a)(2)(i), (a)(3)(i), and (a)(4)(i).	80 FR 74226, November 27, 2015.

The ''customer provisions'' of part 117 and part 507 each include a requirement for a ''disclosure statement'' in which a manufacturer/processor must disclose, in documents accompanying the food, in accordance with the practice of the trade, that the food is ''not processed to control [identified hazard]'' in certain circumstances. Likewise, the ''customer provisions'' of the FSVP regulation include a requirement for a ''disclosure statement'' in which an importer must disclose, in documents accompanying the food, in accordance with the practice of the trade, that the food is ''not processed to control [identified hazard]'' in certain circumstances. The ''customer provisions'' of the produce safety regulation relate to an exemption from that regulation that includes a requirement for a ''disclosure statement'' in which a farm must disclose, in documents accompanying the food, in accordance with the practice of the trade, that the food is ''not processed to adequately reduce the presence of microorganisms of public health significance.''

The draft guidance responds to industry questions regarding these requirements for a disclosure statement. On March 23, 2016, FDA met with a food trade association at their request to listen to concerns regarding the customer provisions of part 117 (Ref. 1), including concerns regarding the disclosure statement in part 117. At the meeting, the trade association expressed concern about providing a disclosure statement when multiple hazards may be present, including chemical hazards (such as mycotoxins) and physical hazards (such as stones in raw agricultural commodities), as well as for multiple biological hazards (such as microbial pathogens). The trade association also asked us to allow a variety of types of documents that accompany the food to have the disclosure statement (*e.g.,* contractual agreements, Web sites referenced on labels and in contracts, labels, letters of guarantee, shipment-specific certificates of analysis, shipping documents, specifications, and terms and conditions).

The trade association focused its discussion on the requirements of part 117, but noted that it had parallel concerns for the analogous provisions of part 507 and the FSVP regulation (Ref. 1). Although the trade association did not express concern with the disclosure statement in the produce safety regulation, we believe it will be helpful to businesses subject to the produce safety regulation, to include our current thinking on the disclosure statement in all four rules that have requirements for a disclosure statement, not just the three rules mentioned by the trade association.

II. Paperwork Reduction Act of 1995

This 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 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 117 have been approved under OMB control number 0910–0751. The collections of information in 21 CFR part 507 have been approved under OMB control number 0910–0789. The collections of information in 21 CFR part 112 have been approved under OMB control number 0910–0816. The collections of information in 21 CFR part 1, subpart L have been approved under OMB control number 0910–0752.

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 guidance.

IV. References

The following references are on display in the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 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 *http://www.regulations.gov.*

1. Grocery Manufacturers Association, ''21 CFR 117.136. Industry Impacts from Disclosure and Written Assurance Requirements,'' 2016.

Dated: October 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26245 Filed 10–28–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 58

[Docket No. FDA–2010–N–0548]

Good Laboratory Practice for Nonclinical Laboratory Studies; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the proposed rule that appeared in the **Federal Register** of August 24, 2016. In the proposed rule, FDA requested comments on its proposal to amend the regulations for good laboratory practice for nonclinical studies. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rule published August 24, 2016 (81 FR 58342). Submit either electronic or written comments by January 21, 2017.

ADDRESSES: You may submit comments as follows: