in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration, by wire transfer, or by automatic clearing house (ACH) using Pay.gov. (The Pay.gov payment option is available to you after you submit a cover sheet. Click the ''Pay Now'' button). On your check, bank draft, U.S. or postal money order, please write your application's unique Payment Identification Number, beginning with the letters ''AG'', from the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write the FDA post office box number (PO Box 953877) on the enclosed check, bank draft, or money order. Your payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet can be mailed to: Food and Drug Administration, P.O. Box 953877, St. Louis, MO, 63195–3877.

If payment is made via wire transfer, send payment to U. S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account Number: 75060099, Routing Number: 021030004, Swift Number: FRNYUS33. You are responsible for any administrative costs associated with the processing of a wire transfer. Contact your bank or financial institution regarding the amount of the fees that need to be paid in addition to the wire transfer amount.

If you prefer to send a check by a courier such as FEDEX or UPS, the courier may deliver the check and printed copy of the cover sheet to: US Bank, Attn: Government Lockbox 953877, 1005 Convention Plaza, St. Louis, Missouri 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery contact the US Bank at 314–418–4821. This phone number is only for questions about courier delivery.)

The tax identification number of the Food and Drug Administration is 530196965. (Note: In no case should the payment for the fee be submitted to FDA with the application.)

It is helpful if the fee arrives at the bank at least a day or two before the abbreviated application arrives at FDA's Center for Veterinary Medicine. FDA records the official abbreviated application receipt date as the later of the following: The date the application was received by FDA's Center for Veterinary Medicine, or the date US Bank notifies FDA that your payment in the full amount has been received, or when the U. S. Department of the Treasury notifies FDA of payment. US Bank and the United States Treasury are required to notify FDA within one working day, using the Payment Identification Number described previously.

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log onto the AGDUFA website at *http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm* and scroll down the page until you find the link ''Create AGDUFA User Fee Cover Sheet.'' Click on that link and follow the directions. For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated animal drug application. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the Cover Sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique Payment Identification Number.

Step Three—Send the Payment for your application as described in Section VII.A of this document.

Step Four—Please submit your application and a copy of the completed Animal Generic Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

C. Product and Sponsor Fees

By December 31, 2009, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2010 using this fee schedule. Fees will be due and payable 30 days after the issuance of the invoices. FDA will issue invoices in November 2010 for any products and sponsors subject to fees for FY 2010 that qualify for fees after the December 2009 billing.

Dated: July 28, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–18458 Filed 7–31–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0347]

Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons.'' This draft guidance is intended to cover the entire melon supply chain, both domestic firms and foreign firms exporting melons into the United States, to enhance the safety of melons by recommending practices to minimize microbial food safety hazards and to prevent microbial contamination. This draft guidance, when finalized, will supplement existing FDA guidances, including the 1998 ''Guidance to Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables,'' which applies to fresh produce commodities, and the 2008 ''Guidance to Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables,'' which applies to fresh-cut produce.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by October 2, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Food Safety (HFS–317), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–436–2651. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Willette Crawford, Center for Food

Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1111.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons.'' This draft guidance covers melons that are grown and harvested for fresh market (i.e., fresh, unprocessed form) or for ''fresh-cut/value-added products'' (i.e., minimally processed, such as trimmed, peeled, sliced or diced, and then bagged or prepackaged), cooled, shipped to retail, wholesale or for processing, and offered for sale to the consumer. The term ''melons'' as used in this draft guidance includes raw agricultural commodities and fresh-cut/value-added products derived from cantaloupe (also known as muskmelons), honeydew, watermelon, and variety melons (e.g., ''Canary,'' ''Crenshaw,'' and ''Galia''). This draft guidance is based primarily on melon industry guidelines issued in 2005 (Ref. 1), along with agency experience and information from other recent public and private programs.

FDA is issuing this draft guidance as Level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the microbiological hazards presented by fresh and fresh-cut melons and the recommended control measures for such hazards in production and harvesting, postharvest operations, processing, distribution, and retail and food service handling of such produce. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (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 publish notice in the **Federal Register** soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA will publish a 60-day notice on the proposed collection of information in a future issue of the **Federal Register**.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. 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*.

V. References

The following reference has been placed on display in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Fleming, P., Pool, W., and Gorny, J., editors; ''Commodity Specific Food Safety Guidelines for the Melon Supply Chain'' (1st ed.); Produce Marketing Association and United Fresh Produce Association; November 7, 2005. Accessed online at *http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/GuidanceComplianceRegulatoryInformation/ucm168609.htm*.

Dated: July 28, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–18452 Filed 7–31–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0346]

Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Tomatoes; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Tomatoes.'' This guidance is intended to cover the entire tomato supply chain, both domestic firms and foreign firms exporting tomatoes into the United States, to enhance the safety of tomatoes by recommending practices to minimize microbial food safety hazards and to prevent microbial contamination. This draft guidance, when finalized, will supplement existing FDA guidances, including the 1998 ''Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables,'' which applies to fresh produce commodities, and the 2008 ''Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables,'' which applies to fresh-cut produce.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by October 2, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Food Safety (HFS–317), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–436–2651. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2024.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Tomatoes.'' This draft guidance covers the growing,