in regulatory submissions. Technical specifications guidances are available at: *https://www.fda.gov/ForIndustry/DataStandards/default.htm.*

II. Establishment of a Docket

FDA is establishing a public docket so that anyone can share information, comments, and ideas on any matters related to the use of technical specifications that are not specific to the documents or issues addressed in other dockets. This information will give the Agency insight into stakeholders' experiences and views regarding the use of technical specifications guidances and the data standards they contain. The docket also permits anyone to share information, comments, or ideas that are specific to one or more technical specifications guidances. Instructions regarding how to submit comments to specific technical specifications documents have been posted within the docket.

This docket will be open for comment simultaneously with several other dockets that are specific to particular electronic common technical document (eCTD) submissions and FDA data standards documents. (For more information on eCTD submissions and FDA data standards, see *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm* and *https://www.fda.gov/ForIndustry/DataStandards/default.htm,* respectively). Do not submit comments to this general docket that have already been submitted to other dockets. As FDA finalizes specific documents or requests comments on specific issues for which another docket exists, the Agency will generally consider only those comments that have been submitted to that specific docket. Do not submit comments related to another specific docket to this general technical specifications docket, as the Agency may not consider them. FDA will not respond directly to questions or requests submitted to this docket but will consider any submitted information in its work to develop and issue technical specifications guidances.

Dated: June 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12969 Filed 6–15–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2155]

Foods Produced Using Animal Cell Culture Technology; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing a public meeting entitled ''Foods Produced Using Animal Cell Culture Technology.'' FDA is holding the public meeting to provide the public with an opportunity to provide comments related to the production of foods using animal cell culture technology.

DATES: The public meeting will be held on July 12, 2018, from 8:30 a.m. until 3 p.m. EST. Submit either electronic or written comments on this public meeting by September 25, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Wiley Auditorium, 5001 Campus Dr., College Park, MD 20740.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 25, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 25, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2018–N–2155 for ''Foods Produced Using Animal Cell Culture Technology; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1731, *Juanita.yates@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Technological advances and consumer interest are spurring development of commercial-scale production of foods that are intended to resemble traditional meat, poultry, and seafood but are manufactured using, generally, a small amount of cells from the type of animal the food is intended to resemble. The collected cells are multiplied using nontraditional food technologies adapted from cell culture applications widely used in research and increasingly in medicine. We expect that most or all starter cells for food applications will come from living animals for the foreseeable future for commercial and marketing reasons (for example, firms currently working on developing these food applications appear to be targeting consumers motivated by animal welfare concerns). Currently, animal cells can be produced from the starter cells in bioreactors, a scaled-up application of traditional cell culture techniques. Firms are also working to commercialize processes by which cells can be cultured using biocompatible scaffolding or other techniques to permit the formation of complex tissues, similar to strategies being explored for therapeutic organ or tissue replacement. In either case, a significant technical challenge with respect to the use of animal cell culture technology to develop foods intended to resemble traditional meat, poultry, and seafood products involves the development of the growth medium used to multiply the cells and ensure that they differentiate into the correct cell types. Commercial incentives are driving research into non-animal derived components for such media instead of traditional animal-derived materials. Finally, after creation, both suspension-cultured (unstructured) and scaffold-cultured (structured) products would be further processed using traditional food technologies, including seasoning, forming, and packaging.

Just as we have been in the past with respect to rapidly evolving areas of technological innovation in food, FDA will be involved in the regulation of foods generated by animal cell culture technology in light of our broad statutory authority and our extensive expertise and experience in relevant scientific areas. Currently, FDA evaluates microbial, algal, and fungal cells generated by large-scale culture and used as direct food ingredients, administers safety assessment programs for a broad array of food ingredients and foods derived from genetically engineered plants, manages safety issues associated with animal cell culture technology in therapeutic settings, and manages risks associated with the processing, manufacture, and packaging of food incorporating seafood tissues.

Under the Federal Food, Drug, and Cosmetic Act, FDA has jurisdiction over ''food,'' which includes ''articles used for food'' and ''articles used for components of any such article.'' Thus, as a starting point, both substances used in the manufacture of these products of animal cell culture technology and the products themselves that will be used for food are subject to FDA's jurisdiction and applicable statutory and regulatory food safety and food labeling requirements.

The use of animal cell culture technology as a method of food production and manufacturing involves many interesting issues from both technical and regulatory perspectives. FDA believes that all stakeholders will benefit from a robust and open dialogue that explores these issues and gathers relevant data and information. The primary subject of this notice is food safety, but FDA recognizes the importance of other issues related to foods produced through animal cell culture technology such as naming. Although not the primary subject of this notice, FDA welcomes comment on these other issues and expects that they will be the focus of future engagement with stakeholders and the public.

II. Topics for Discussion at the Public Meeting

FDA is holding the public meeting to provide the public with an opportunity to provide comments related to production of foods using animal cell culture technology. We invite interested persons, including those participating in the public meeting, to provide information on topics such as the following (a more detailed agenda will be made available prior to the meeting):

- FDA has evaluated a variety of foods produced by cell culture, including microbial (*e.g.,* probiotics), algal (*e.g.,* spirulina), and fungal products (*e.g.,* mycoprotein). What considerations specific to animal cell culture technology would be appropriate to include in evaluation of food produced by this method of manufacture?
- FDA has issued guidance on how to assess the effects of significant manufacturing process changes on the safety of a food ingredient. (See ''Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives'' at *https://www.fda.gov/RegulatoryInformation/Guidances/ucm300661.htm.*) What kinds of variations in manufacturing methods would be relevant to safety for foods produced by animal cell culture technology?
- FDA has a variety of pre- and postmarket programs for evaluating the safety of substances used in the production and manufacture of foods, including, for example, food additive and color additive regulations and preventive control requirements. What kinds of substances would be used in the manufacture of foods produced using animal cell culture technology and what considerations would be appropriate in evaluating the safety of these uses?
- Are the hazards associated with production of foods using animal cell culture technology different from those associated with traditional food production/processing (such as, for example, insanitary conditions, improper temperature controls, or control of contaminants)? Is there a need for unique control measures to address the hazards associated with production of foods using animal cell culture technology?

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following

website: *https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by July 5, 2018. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Juanita Yates (see **FOR FURTHER INFORMATION CONTACT**) no later than June 28, 2018.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by July 3, 2018. Speakers will be limited to making oral remarks; there will not be an opportunity to display materials such as slide shows, videos, or other media during the meeting. All requests to make oral presentations must be received by June 28, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Webcast participants are asked to preregister at *https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*

Other Issues for Consideration: A summary of key information on participating in the meeting follows:

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING

Date	Address	Preregister	Electronic address	Request to make an oral presentation	Special accommodations	Submit either electronic or written comments
July 12, 2018, from 8:30 a.m. until 3 p.m. EDT.	Food and Drug Administration, Center for Food Safety and Applied Nutrition, Wiley Auditorium, 5001 Campus Drive, College Park, MD 20740.	July 5, 2018: Closing date for registration.	*https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*	June 28, 2018	June 28, 2018: Closing date to request special accommodations due to a disability.	Submit Comments by September 25, 2018 to: *https://www.regulations.gov,* or Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12939 Filed 6–15–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2016]

Epidermolysis Bullosa: Developing Drugs for Treatment of Cutaneous Manifestations; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Epidermolysis Bullosa: Developing Drugs for Treatment of Cutaneous Manifestations.'' The purpose of this draft guidance is to assist sponsors with the development of drugs for treatment or prevention of the serious cutaneous manifestations of the heterogeneous group of disorders collectively known as epidermolysis bullosa (EB). There is an unmet medical need for EB patients due to the paucity of effective treatment options.

DATES: Submit either electronic or written comments on the draft guidance by August 17, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and