++ AAAASF's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of AAAASF's staff and other resources, and its financial viability.

++ AAAASF's capacity to adequately fund required surveys.

++ AAAASF's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ AAAASF's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this proposed notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

Dated: October 19, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–23611 Filed 10–29–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3689]

21st Century Cures: Announcing the Establishment of a Surrogate Endpoint Table; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the establishment of a public docket to receive suggestions and comments from interested parties (including academic institutions, regulated industry, and patient groups) on the Agency's publication of the surrogate endpoint table (SE table). FDA has developed a web page, available at *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm613636.htm* that displays the SE table, describes the purpose of the table, and provides additional background information. Comments received on the SE table will help FDA determine its utility and may assist FDA in developing future iterations of the SE table and identifying best methods for conveying information about SEs on the FDA's website.

DATES: Submit either electronic or written comments on this notice by December 31, 2018.

ADDRESSES: 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 December 31, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 31, 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–3689 for ''21st Century Cures: Announcing the Establishment of a Surrogate Endpoint Table.'' 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.'' 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 *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: Christopher Leptak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6461, Silver Spring, MD 20993–0002, 301–796–0017, *Christopher.Leptak@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3011 of the 21st Century Cures Act established section 507 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 357), which mandates that FDA publish a list of surrogate endpoints used as a basis to approve or license a drug or biological product under both accelerated and traditional approval provisions. The SE table fulfills this legislative requirement and is intended to provide valuable information for drug developers on endpoints that may be considered and discussed with FDA for individual development programs. FDA refers the public to the following web page for additional background information as well as the SE table: *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm606684.htm.*

Section 507(e)(9) of the FD&C Act defines the term ''surrogate endpoint'' to mean a marker, *e.g.,* a laboratory measurement, radiographic image, physical sign, or other measure, that does not directly measure clinical benefit but (1) is known to predict clinical benefit and can potentially be used to support traditional approval of a drug or biological product or (2) is reasonably likely to predict clinical benefit and could be used to support accelerated approval in accordance with section 506(c) of the FD&C Act (21 U.S.C. 356(c)).

This SE table includes SEs that sponsors have used as primary efficacy clinical trial endpoints for approval of new drug applications (NDAs) or biologics license applications (BLAs). The table also includes SEs that may be appropriate for use as a primary efficacy clinical trial endpoint for drug or biologic approval, although the SEs have not necessarily been used to support an approved NDA or BLA. FDA believes that this table should facilitate discussions of potential SEs by sponsors when developers are designing their drug development programs.

II. Additional Issues for Consideration

To help FDA determine the utility of the SE table, develop future iterations of the SE table, and identify best methods for conveying this information on FDA's website, FDA is soliciting public suggestions and comments on the SE table listed on the following web page: *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm606684.htm.*

Specifically, FDA welcomes comments concerning: (1) The utility of the SE table; (2) suggestions on SEs that may not be reflected on the current SE table but that have been used for drug or biologic approvals; (3) the best approach for developing future iterations of the table, and (4) SE table questions you would like FDA to address in future communications. As required by section 507(c)(1) of the FD&C Act, FDA will update this table on the website every 6 months. The Agency will consider comments submitted to the docket as it revises the SE table.

Dated: October 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23641 Filed 10–29–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3809]

Sesame as an Allergen in Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) invites data and other information on the prevalence and severity of sesame allergies in the United States and the prevalence of sesame-containing foods sold in the United States that are not required to disclose sesame as an ingredient. We are taking this action to inform possible regulatory action on sesame to protect and promote the public health.

DATES: Submit either electronic or written comments on this document by December 31, 2018.

ADDRESSES: You may submit comments as follows. Electronic comments must be submitted on or before December 31, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 31, 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