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Dated: October 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22567 Filed 10–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3633]

Oncology Center of Excellence: Pediatric Oncology Program; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Oncology Center of Excellence (OCE) Pediatric Oncology Program of the Food and Drug Administration (FDA or the Agency) announces the creation of a list of molecular targets that have been determined to be substantially relevant to the growth or progression of a pediatric cancer (Candidate Pediatric Molecular Target List) and a list of molecular targets of new cancer drugs and biological products in development for which requirements for studies in pediatric cancers would be automatically waived. The former list includes molecular targets for which prevailing evidence and/or a scientific rationale exists to determine their potential relevance to the growth or progression of one or more pediatric cancers. The latter list details those targets that are unlikely to be associated with the growth or progression of pediatric cancers such that statutory requirements for early pediatric evaluation would be waived. These lists fulfill one of FDA's obligations under the FDA Reauthorization Act of 2017 (FDARA) and provide information to industry in planning for initial pediatric study plan submissions for certain oncology drugs or biological products in accordance with the amended provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA is establishing this docket for public comment on possible additions to or deletions from the list on the lists described above.

The lists can be found on the Oncology Center of Excellence: Pediatric Oncology website at the following link: *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OCE/ucm544641.htm.*

DATES: Submit either electronic or written comments. This docket will remain open indefinitely.

ADDRESSES: You may submit comments 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 below (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–3633 for ''Oncology Center of Excellence: Pediatric Oncology Program; Establishment of a Public Docket; Request for Comments.'' Received comments 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.'' FDA 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 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 the 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: Christine Lincoln, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 22, Rm. 2118, Silver Spring, MD 20993–0002, email: *Christine.Lincoln@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The use of tumor genetic profiling in cancer treatment decision making has transformed therapeutic strategies in many adult cancers. Extension of this approach to treatment decision making for children with cancer, however, has been greatly diminished due to delays in evaluation of potentially active drugs. Until the passage of section 504 of FDARA, section 505B of the FD&C Act (21 U.S.C. 355c) has not typically been a useful mechanism to require the development of drugs for pediatric cancers, since most of the oncology drugs approved for adults are used to treat cancers that very rarely or never occur in children (*e.g.* cancers of the lung, prostate and breast). Therefore, historically, drug sponsors have requested and obtained waivers for conducting the required assessments of these drugs in pediatric patients. Additionally, drugs developed for rare cancer indications that received orphan designation are exempted from the pre-FDARA requirement to conduct pediatric assessments—even if the cancers those products are intended to treat occur in both adult and pediatric patients—due to the fact that the orphan designation exempts them from such studies (see section 505B(k) of the FD&C Act). However, FDARA amended section 505B so that the requirement for pediatric investigations of drugs directed at molecular targets determined to be substantially relevant to the growth and progression of a pediatric cancer apply even when the adult indication has received an orphan designation, or when the adult indication does not occur, in the pediatric population (*e.g.,* prostate cancer).

Although requirements to study investigational therapies in pediatric oncology were exceedingly rare, other incentives have been put into place to promote the development of oncology products for pediatric cancer. Section 505A of the FD&C Act (21 U.S.C. 355a) provides incentives, in the form of 6 months of additional marketing exclusivity, to encourage sponsors of investigational therapies to conduct pediatric studies of medicines with the potential for use in children. To date, section 505A has been one of the few mechanisms available to incentivize evaluation of new oncology products in children and adolescents. Nevertheless, further development of more novel products that address the substantial unmet needs of the pediatric population is needed.

Section 504 of FDARA requires FDA, with input from the National Cancer Institute (NCI) and others, to develop and regularly update: (1) A list of molecular targets that are determined to be substantially relevant to the growth and progression of a pediatric cancer, and that may trigger the requirement for pediatric investigations under section 505B of the FD&C Act, and (2) a list of molecular targets of new cancer drugs and biological products in development for which the requirement for pediatric investigations under section 505B of the FD&C Act would be automatically waived.

To date, a total of 205 candidate molecular targets were identified from peer-reviewed literature searches, review of publicly available genomic databases, such as NCI Genomic Data Commons, TARGET (Therapeutically Applicable Research to Generate Effective Targets), St. Jude PeCan Data Portal, Ped PanCan, and INFORM (Individualized Therapy for Relapsed Malignancies in Childhood), and input from international subject matter experts. Of these, 62 (30.3 percent) target a gene abnormality, 40 (19.5 percent) target a cell lineage determinant, 21 (10.2 percent) target the tumor microenvironment or the immune system, and 77 (37.6 percent) are classified as ''Others.'' Five (2.4 percent) are candidates for automatic waivers.

Dated: October 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22565 Filed 10–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3138]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of an Accelerated Approval Disclosure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled ''Experimental Study of an Accelerated Approval Disclosure.'' This study will examine the presence, wording, and prominence of a disclosure communicating information related to the drug's accelerated approval in direct-to-consumer (DTC) promotional materials.

DATES: Submit either electronic or written comments on the collection of information by December 17, 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 17, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of December 17, 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