A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product TREMFYA (guselkumab). TREMFYA is indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Subsequent to this approval, the USPTO received patent term restoration applications for TREMFYA (U.S. Patent Nos.7,935,344 and 7,993,645) from Janssen Biotech, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated January 9, 2018, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of TREMFYA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for TREMFYA is 2,968 days. Of this time, 2,728 days occurred during the testing phase of the regulatory review period, while 240 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* May 30, 2009. The applicant claims April 30, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 30, 2009, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* November 16, 2016. FDA has verified the applicant's claim that the biologics license application (BLA) for TREMFYA (BLA 761061) was initially submitted on November 16, 2016.

3. *The date the application was approved:* July 13, 2017. FDA has verified the applicant's claim that BLA 761061 was approved on July 13, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,252 days or 1,203 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: October 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22571 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–3516]

Agency Information Collection Activities; Proposed Collection; Comment Request; Disease Awareness and Prescription Drug Promotion on Television

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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, ''Disease Awareness and Prescription Drug Promotion on Television.''

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 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–3516 for ''Disease Awareness and Prescription Drug Promotion on Television.'' 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: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10:00 a.m.–12:00 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.* For copies of the questionnaire contact: Office of Prescription Drug Promotion (OPDP) Research Team, *DTCresearch@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under 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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Disease Awareness and Prescription Drug Promotion on Television (OMB Control Number 0910—NEW)

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

The FDA's Center for Drug Evaluation and Research (CDER), Office of Prescription Drug Promotion (OPDP) is responsible for ensuring that prescription drug promotional materials are truthful, balanced, and accurately communicated. This project is being proposed as part of the research program of OPDP. OPDP's research program supports this mission by providing scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that we believe are most central to our mission, focusing in particular on three main topic areas: Advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits; focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience; and our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues. This study falls under the topic of both target populations and advertising features.

Because we recognize the strength of data and the confidence in the robust nature of the findings is improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our

policies as well as our research program. Our research is documented on our homepage, which can be found at: *https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090276.htm.* The website includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office. The website maintains information on studies we have conducted, dating back to a DTC survey conducted in 1999.

The present research concerns disease awareness and prescription drug promotion communications on television. When pharmaceutical companies market a new drug, they often also release disease awareness communications about the medical condition the new drug is intended to treat (Ref. 1; Ref. 2). FDA is interested in whether and to what extent this practice may result in consumers confusing or otherwise misinterpreting the different information and claims presented in disease awareness communications and prescription drug promotion. Prior research has documented that in both print (Ref. 3) and online (Ref. 4) contexts, consumers tend to conflate the information presented in prescription drug promotional materials with information presented in disease awareness communications. Specifically, the results of these studies suggest consumers incorrectly ascribe benefits to a prescription drug as a result of being exposed to information in a disease awareness communication that broadly describes the symptoms and negative consequences of the disease. There are ways in which this effect can be attenuated. For example, prior research has indicated that greater visual distinctiveness between the two ad types can ameliorate such confusion (Ref. 3). The present research seeks to extend previous studies of print and online promotion to the context of television promotion, and broadly examine how perceptual similarity between the two communication types, as well as their temporal proximity and exposure frequency, may impact the nature and extent of viewer confusion.

Fors Marsh Group (FMG) is conducting this research under the guidance and supervision of FDA to determine how the similarity, temporal positioning, and frequency of exposure to disease awareness communications and prescription drug television promotion impact consumer perception and understanding of the benefits and risks of a prescription drug product. These objectives will be achieved using two experimental studies. The first study will explore the impact on consumer perception and comprehension of different levels of temporal separation between the disease awareness communication and prescription drug promotion within a single period of television programming, as well as the level of similarity versus distinctiveness between these communication types. Temporal separation is defined as the spacing or proximity between the disease awareness communication and prescription drug promotion in the hour-long programming, for example, if they are shown back-to-back or if they are separated by other ads or television programming. Similarity/distinctiveness is defined by variations between the disease awareness communication and prescription drug promotion, including visual and presentation elements such as the setting, actors, and colors. The second study will experimentally examine the impact of disease awareness communication temporal separation and exposure frequency on consumer perception and comprehension. Temporal separation in this second study again refers to the spacing or proximity between the disease awareness communication and prescription drug promotion but is operationally defined as either one day or one week. Exposure frequency is defined as the number of times that participants will view the disease awareness communication, either one, three, or six times. The results of this latter study will examine the practice of ''seeding the market,'' in which pharmaceutical companies release disease awareness communications before releasing product promotion communications. Similarity versus distinctiveness will also be examined in this study.

We propose the following hypotheses for this research:

Study 1:

H1: Increased perceptual similarity between a disease awareness communication and a prescription drug promotion will result in significantly more conflation of the information presented in both pieces.

H2: Increased temporal proximity between a disease awareness communication and a prescription drug promotion will result in significantly more conflation of the information presented in both pieces.

Study 2:

H1: Increased frequency of exposure to a disease awareness communication before exposure to a prescription drug promotion will result in significantly more conflation of the information presented in both pieces.

H2: Increased temporal proximity between a disease awareness communication and a prescription drug promotion will result in significantly more conflation of the information presented in both pieces.

H3: Increased perceptual similarity between a disease awareness communication and a prescription drug promotion will result in significantly more conflation of the information presented in both pieces.

In each instance, conflation is operationalized as the extent to which an individual remembers and attributes benefits to a product that is based on information presented in a disease awareness communication and not in the drug promotion.

To address these hypotheses, Study 1 will employ a 3x4 factorial design in which participants are randomly assigned to one disease awareness communication condition, plus one control condition where participants will not view a disease awareness communication. The extent to which the disease awareness communication is perceptually similar to the product promotion communication will vary, as will the temporal separation of the disease awareness communication and product promotion communication. Table 1 depicts our design visually.

TABLE 1—STUDY 1 EXPERIMENTAL DESIGN

Disease awareness ad	Perceptual similarity to product ad	Disease awareness and product ad temporal separation			
		Back to back	Within same commercial pod [1]	In neighboring commercial pods	In non-neighboring commercial pods
Yes	Similar. Semi-similar. Distinct.				

TABLE 1—STUDY 1 EXPERIMENTAL DESIGN—Continued

Disease awareness ad	Perceptual similarity to product ad	Disease awareness and product ad temporal separation			
		Back to back	Within same commercial pod [1]	In neighboring commercial pods	In non-neighboring commercial pods
No	N/A.				

Table 2. Study 1 Sequence

Condition	Sequence														
	6min	2min	5min	2min	5min	2min	5min	2min	6min	2min	5min	2min	5min	2min	5min
Back to back		DA, P												DA, P	
Same pod		DA, P												DA, P	
Neighboring pods		DA		P								DA		P	
Non-neighboring pods		DA				P				DA				P	
Control		P												P	

TV Program ☐ Commercial Pod ▒

DA = Disease Awareness Communication; P = Product Promotion

Study 2 will employ a 2x2x3 factorial design in which participants are randomly assigned to one disease awareness communication condition. The varying factors in Study 2 are the temporal separation between the disease awareness and product promotion communication, the number of exposures to the disease awareness communication, and the perceptual similarity of the disease awareness communication to the product promotion communication. Table 3 visually depicts our design. Of note, to reduce the overall number of experimental conditions for Study 2, no semi-similar experimental condition is used.

TABLE 3—STUDY 2 EXPERIMENTAL DESIGN

Time delay until product ad exposure (temporal separation)	Perceptual similarity of ads	Exposures to disease awareness ad		
		One exposure	Three exposures	Six exposures
One Day	Similar.			
	Distinct.			
One Week	Similar.			
	Distinct.			

Table 4. Study 2 Sequence

			Disease awareness ad exposure phase						Product ad exposure phase						
			Day →												
			1	2	5	6	9	10	11	12	13	14	15	16	17
	Delay	**Similarity**													
Six exposures	1 day	similar	x	x	x	x	x	x	x						
		distinct	x	x	x	x	x	x	x						
	1 week	similar	x	x	x	x	x	x							x
		distinct	x	x	x	x	x	x							x
Three exposures	1 day	similar				x	x	x	x						
		distinct				x	x	x	x						
	1 week	similar				x	x	x							x
		distinct				x	x	x							x
One exposure	1 day	similar						x	x						
		distinct						x	x						
	1 week	similar						x							x
		distinct						x							x

Study 1 and 2 Sample. The targeted voluntary sample for both studies will comprise adults who self-report a current asthma diagnosis, a lifetime incidence of asthma, or experience a large number of asthma symptoms. These groups are believed to be very likely to be targeted by disease awareness and product promotion

[1] A commercial pod refers to a group of ads into which the test ad is inserted, designed to simulate an advertising break during a television program. As depicted in Table 2, by neighboring commercial pods, we mean commercial pods separated only by television programming and no other commercial pods. By non-neighboring commercial pods, we mean commercial pods separated by both television programming and one or more (one, as studied here) other commercial pods.

communications for asthma. The combined incidence rate of these groups is 22.2% (Ref. 5; Ref. 6). In addition, several exclusion criteria are specified. These include: (1) Training or employment as a healthcare professional, (2) employment with a pharmaceutical company, an advertising agency, a market research company, or the Department of Health and Human Services (HHS), and (3) participation in market research within the past three months on the topic of prescription drugs. Pretest participants will also be ineligible for the main study.

Pretesting. Pretesting will take place before the main studies to evaluate the procedures used in the main studies. Each of the two pretests will have the same design as its respective main study (pretest 1 for Study 1 and pretest 2 for Study 2). The purpose of both pretests will be to: (1) Ensure that the mock stimuli are understandable, viewable, and delivering intended messages; (2) identify and eliminate any challenges to embedding the mock stimuli within the online survey; (3) ensure that survey questions are appropriate and meet the analytical goals of the research; and (4) pilot test the methods, including examining response rates and timing of survey. The two pretests will be conducted simultaneously.[2] Based on pretest findings, we will refine the mock stimuli, survey questions, and data collection process, as necessary, to optimize the full-scale study conditions.

Measurement. Our planned analyses are designed to address the key hypotheses. For both Study 1 and Study 2, we anticipate that the primary analysis will be analysis of variance (ANOVA) to compare the main and interaction effects of the experimental factors.

The focal dependent variable will be *conflation*—a measure of memory and perceptions regarding the promoted drug relative to the information presented in the disease awareness communication. Conflation will be measured by using the number of benefits that are incorrectly attributed to the prescription drug product based on responses to a number of both open-ended and closed-ended items.

Other key dependent variables will reflect perceptions and attitudes toward the product ad. These include measures of:

1. Perception of product promotion effectiveness;
2. Behavioral intentions toward the drug;
3. Perceived efficacy of the drug; and
4. Perceived risks of the drug.

In addition to the primary variables of interest, we have also identified potential covariates that will be included in the analyses:

1. Knowledge about asthma;
2. Health literacy; and
3. Perceived ad effectiveness.

We expect that knowledge about asthma and increased health literacy may moderate any conflation that results from ad similarity, temporal proximity, and frequency of exposure. Perceptions of promotion effectiveness, on the other hand, can be examined both as an outcome/dependent variable but also as a covariate that examines involvement with the product promotion. Greater involvement may attenuate conflation in that it directs more in-depth processing of both the disease awareness communication and product promotion, and therefore more correct understanding of the claims in each (Ref. 7; Ref. 8; Ref. 9).

FDA estimates the burden of this collection of information as follows:

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Study 1 Pretest screener	385	1	385	0.08 (~5 min.)	31
Study 2 Pretest screener	329	1	329	0.08 (~5 min.)	26
Study 1 screener	3,007	1	3,007	0.08 (~5 min.)	241
Study 2 screener	2,643	1	2,643	0.08 (~5 min.)	211
Study 1 Pretest	270	1	270	1.33 (~1 hr 20 min.)	360
Study 2 Pretest	158	1	158	0.53 (~32 min.)	84
Study 1	2,105	1	2,105	1.33 (~1 hr 20 min.)	2,800
Study 2	1,269	1	1,269	0.53 (32 min.)	673
Total					4,426

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) 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 *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. *https://www.fiercepharma.com/marketing/unbranded-pharma-ad-what-are-they-good-for-actually-quite-a-bit-marketer-panelists-say?mkt_tok=eyJpIjoiWkRnelpUSmlORFpoWkdNMSIsInQiOiJPaENIUERpT0tnUmt6Y1BPMk9LTnpreUI3bUtPOVRzRnh1RzNuWUtYQmp0cWJhcW05UFhlcllwTzI3V0RJSndjVkZLR3NGUHBLamJOZmJSK2FZeWtIVXczeFRFcmtEV0NFaVdCSjArUmx4dUlRVHZpUzFFOWlVY0dNb1RzOU9XayJ9&mrkid=20932234.*
2. *https://www.fiercepharma.com/marketing/avanir-launches-nuedexta-brand-campaign-retires-danny-glover-pba-disease-awareness-ad.*
3. Aikin, K. J., Sullivan, H. W., & Betts, K. R. (2016). Disease information in direct-to-consumer prescription drug print ads. *Journal of Health Communication, 21,* 228–239.
4. Sullivan, H. W., O'Donoghue, A. C., Rupert, D. J., Willoughby, J. F., Amoozegar, J. B., & Aikin, K. J. (2016). Are disease awareness links on prescription drug websites misleading?

[2] Pretesting will be preceded by cognitive interviewing, not described here. Cognitive interviews are used to probe a small sample of participants on how and why they responded to various questions as they did, resulting in strong measurement instruments.

A randomized study. *Journal of Health Communication, 21,* 1198–1207.
5. Centers for Disease Control and Prevention. (2018a, May 18). *2016 National Health Interview Survey (NHIS) data.* Retrieved from *https://www.cdc.gov/asthma/nhis/2016/table2-1.htm.*
6. Centers for Disease Control and Prevention. (2018b, May 15). *Most recent asthma data.* Retrieved from *https://www.cdc.gov/asthma/most_recent_data.htm.*
7. Petty, R. E., & Cacioppo, J. T. (1979). Issue involvement can increase or decrease persuasion by enhancing message-relevant cognitive responses. *Journal of Personality and Social Psychology, 37,* 1915–1926. doi: 10.1037/0022-3514.37.10.1915.
8. Petty, R. E., & Cacioppo, J. T. (1986). The elaboration likelihood model of persuasion. *Advances in Experimental Social Psychology, 19,* 123–205. doi: 10.1016/S0065-2601(08)60214-2.
9. Petty, R. E., Cacioppo, J. T., & Goldman, R. (1981). Personal involvement as a determinant of argument-based persuasion. *Journal of Personality and Social Psychology, 41,* 847–855. doi: 10.1037/0022-3514.41.5.847.

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://*