On November 22, 2021, Secura Bio, Inc. submitted a letter asking FDA to withdraw approval of NDA 205353 for FARYDAK (panobinostat) Capsules, 10 mg, 15 mg, and 20 mg, pursuant to § 314.150(d) (21 CFR 314.150(d)) and waiving its opportunity for a hearing. In the letter, Secura Bio, Inc. stated they are requesting withdrawal of approval of the NDA for FARYDAK because it was not feasible for them to complete the required postmarketing clinical trials. On November 26, 2021, FDA acknowledged Secura Bio, Inc.'s request for withdrawal of approval of the NDA and waiver of its opportunity for hearing. FDA also cancelled the ODAC meeting scheduled for December 2, 2021, since the applicant's withdrawal request made discussion at an advisory committee meeting moot.

For the reasons discussed above, and in accordance with the applicant's request, approval of NDA 205353 for FARYDAK (panobinostat) Capsules, 10 mg, 15 mg, and 20 mg, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of FARYDAK (panobinostat) Capsules, 10 mg, 15 mg, and 20 mg, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: March 18, 2022.

Andi Lipstein Fristedt,

Deputy Commissioner for Policy, Legislation, and International Affairs, U.S. Food and Drug Administration.

[FR Doc. 2022–06182 Filed 3–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0371]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Accelerated Approval Disclosures on Direct-to-Consumer Prescription Drug Websites

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by April 25, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is ''Accelerated Approval Disclosures on Direct-to-Consumer Prescription Drug Websites.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Accelerated Approval Disclosures on Direct-to-Consumer Prescription Drug Websites

OMB Control Number 0910–NEW

Section 1701(a)(4) of the Public Health Service Act (PHS 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 Office of Prescription Drug Promotion's (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. OPDP's research program provides 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 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 our research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first topic area, advertising features, including content and format; and the second topic area, target populations.

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/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research.* 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 direct-to-consumer (DTC) survey conducted in 1999.

I. Background

Pursuant to section 506(c) of the FD&C Act (21 U.S.C. 356(c)) and 21 CFR part 314, subpart H (or 21 CFR part 601, subpart E for biological products), FDA may grant accelerated approval to a drug product under section 505(c) of the FD&C Act (21 U.S.C. 355(c)) or a biological product under section 351(a) of the PHS Act (42 U.S.C. 262(a)). This pathway enables faster approval of prescription drugs intended to treat serious or life-threatening illnesses. Accelerated approval may be based on a determination that a drug product has an effect on a surrogate endpoint (for example, a blood test result) that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit (*i.e.,* an intermediate clinical endpoint). In approving a drug under the accelerated

approval pathway, the severity, rarity, or prevalence of a condition, and the availability or lack of alternative treatments, are taken into account.

The accelerated approval pathway is limited to certain products intended to treat serious or life-threatening illnesses as there can be ''[u]ncertainty about whether clinical benefit will be verified and the possibility of undiscovered risks'' (FDA's 2014 guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics,'' available at *https://www.fda.gov/downloads/Drugs/Guidances/UCM358301.pdf*). Sponsors are generally required to conduct post-approval studies to verify and describe the predicted clinical benefit, but those confirmatory studies are not complete at the time that the accelerated approval is granted (Ref. 1). In the event that the required post-approval confirmatory studies fail to verify and describe the predicted effect or clinical benefit, a drug's approval can be withdrawn using expedited procedures.

Under FDA regulations governing physician labeling for prescription drugs, the INDICATIONS AND USAGE section of FDA-approved prescribing information for a drug approved under accelerated approval must include not only the indication (§ 201.57(c) (21 CFR 201.57(c))) but also a ''succinct description of the limitations of usefulness of the drug and any uncertainty about anticipated clinical benefits . . .'' (§ 201.57(c)(2)(i)(B)). In a guidance, FDA recommended that in addition to these required elements, the INDICATIONS AND USAGE section for drugs approved under accelerated approval should generally acknowledge that continued approval for the drug or indication may be contingent on verification and description of clinical benefit in confirmatory trials (FDA 2019 guidance for industry entitled ''Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway,'' available at *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM390058.pdf*).

Some DTC websites have included disclosures about accelerated approval, and of those, many included similar content to that seen in the INDICATIONS AND USAGE section of approved labeling. A content analysis of DTC websites for accelerated approval products found that 21 percent of the disclosures used language directly from the approved physician labeling, 79 percent of the disclosures used at least some medical language, but 27 percent of the websites did not include any disclosure that the products attained approval through this pathway (Ref. 2). The same analysis found that 84 percent of accelerated approval disclosures on DTC websites mentioned the approval basis, 68 percent mentioned unknown outcomes, and 47 percent mentioned confirmatory trials (Ref. 2).

OPDP recently conducted a general-population study testing the disclosure of FDA accelerated approval information on a DTC prescription drug website (OMB control number 0910–0872—Experimental Study of an Accelerated Approval Disclosure; the 0910–0872 Study). The study tested a control condition with no disclosure; a disclosure based on wording used in physician labeling, including more complex or technical terminology (physician-labeling disclosure); and a consumer-friendly disclosure drafted using simpler language intended to be suited for that audience (consumer-friendly disclosure). The disclosures had three elements: (1) Approval basis, (2) unknown outcomes, and (3) confirmatory trials. The physician labeling disclosure was ''This indication is based on response rate. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification of clinical benefit in subsequent trials.'' The consumer-friendly disclosure was ''In a clinical trial, [Drug X] returned blood counts to normal. However, we currently do not know if [Drug X] helps people live longer or feel better. We continue to study [Drug X] in clinical trials to learn more about [Drug X]'s benefits.'' We also varied whether the physician-labeling and consumer-friendly disclosures were presented with low or high prominence (varying the size, color, and location of the disclosure). Preliminary results related to the comprehension of the disclosures tested in that study suggest that the consumer-friendly disclosure helped participants understand information related to the drug's accelerated approval, but that participants' understanding was low overall.

II. New Proposed Study

The purpose of the current project is to replicate and extend our prior research through two studies by: (1) Testing the same experimental conditions with a different study population (cancer survivors and cancer caregivers in study 1) and, (2) testing additional consumer-friendly disclosures in study 2. Replication is an important part of science and, if confirmation of prior results is seen, can increase confidence in the results from our first study.

With regard to proposed study 1, public comments for FDA's previous accelerated approval disclosure study and other similar FDA studies have suggested conducting studies with people who have been diagnosed with the medical condition or who are caregivers to patients diagnosed with the medical condition that the fictitious drug in the study is intended to treat. Specifically, public comments on the previous study suggested enrolling participants who have been diagnosed with cancer (*i.e.,* cancer survivors) or people who have cared for loved ones with cancer (*i.e.,* cancer caregivers). Because a number of oncology products are granted accelerated approval, cancer survivors and cancer caregivers are more likely to seek out or be exposed to promotion for accelerated approval products than the general population. They may also be more familiar with cancer-related terms and concepts than the general population. Study 1 will involve cancer survivors and cancer caregivers, a different population than our prior study. It will test the ''three element'' version of the disclosure as noted above. We will also test the prominence of the disclosure (see table 1).

With regard to study 2, public comments on the original study (Docket No. FDA–2018–N–3138) expressed concern that over-disclosure could dissuade consumers from considering accelerated approval products. One public comment specifically suggested removing the ''unknown outcomes'' element in the consumer-friendly and physician-labeling disclosures. Based on these comments, in study 2, we propose testing four versions of the consumer-friendly disclosure (table 2): The ''three element'' version of the consumer-friendly disclosure as well as three other consumer-friendly disclosures that vary with respect to which of these three elements they address. This will allow us to evaluate the impact on participants' comprehension of the disclosure and perception of the fictitious drug when they view a disclosure with only the approval basis, the approval basis plus information about the unknown outcomes, the approval basis plus information about confirmatory trials, and finally the approval basis plus information about both the unknown outcomes and confirmatory trials. In study 2, the prominence of all the test conditions will be the same and will be the same as the ''high prominence'' version tested in study 1.

We plan to conduct two pretests not longer than 20 minutes, administered via internet panel, to pilot the main study procedures. We then plan to conduct two main studies not longer than 20 minutes, administered via internet panel. For the pretests and main studies, we will randomly assign the participants to one of the test conditions (see table 1 for the study 1 design and table 2 for the study 2 design). In both studies, participants will view a website for a fictitious oncology prescription drug. After viewing the website, participants will complete a questionnaire that assesses whether participants noticed the disclosure and their understanding of it, as well as perceptions of the drug's risks and benefits. We will also measure covariates such as demographics and literacy. The questionnaire is available upon request from *DTCresearch@fda.hhs.gov.*

For study 1, we hypothesize that participants will be more likely to notice the disclosure when it is presented more, rather than less, prominently. In turn, we expect that participants' perceptions of the drug are more likely to be affected by the disclosure in the high prominence condition. We also hypothesize that participants will be more likely to notice and understand the disclosure and use it to form their perceptions of the drug if they view the consumer-friendly language. For study 2, we hypothesize that participants will be more likely to understand each accelerated approval concept (*i.e.,* confirmatory trials, unknown outcomes) when the disclosure directly addresses the concept, compared with when the disclosure does not directly address the concept. Finally, we will explore whether the inclusion of the concepts of confirmatory trials and unknown outcomes in the disclosure affects participants' perceived risk, perceived risk-benefit tradeoff, perceptions of the website, or information-seeking intentions. To test these hypotheses, we will conduct inferential statistical tests such as logistic regression and analysis of variance.

For the pretests and main studies, we plan to recruit individuals who report a diagnosis with any cancer (except for certain non-melanoma skin cancers) for half the sample and individuals who report being a caregiver for someone with a diagnosis with any cancer (except for certain non-melanoma skin cancers) for the other half of the sample. We will exclude individuals who work for the U.S. Department of Health and Human Services or work in the healthcare, marketing, advertising, or pharmaceutical industries. With the sample sizes described below, we will have sufficient power to detect small-sized effects in the main study (table 3).

TABLE 1—STUDY 1 DESIGN

	High prominence	Low prominence	Absent
Physician-labeling version	Condition 1	Condition 3	Condition 5.
Consumer-friendly version	Condition 2	Condition 4.	

TABLE 2—STUDY 2 DESIGN

[Consumer-friendly disclosure elements]

	Approval basis	Approval basis + unknown outcomes	Approval basis + confirmatory trials	Approval basis + unknown outcomes + confirmatory trials
High prominence	Condition 6	Condition 7	Condition 8	Study 1 Condition 2.

In the **Federal Register** of June 11, 2021 (86 FR 31323), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one submission that was PRA-related. Within the submission, FDA received multiple comments that the Agency has addressed below. For brevity, some public comments are paraphrased and therefore may not reflect the exact language used by the commenter. We assure the commenter that the entirety of their comments was considered even if not fully captured by our paraphrasing in this document. The following acronyms are used here: DTC = direct-to-consumer; HCP = healthcare professional; FDA and the Agency = Food and Drug Administration; OPDP = FDA's Office of Prescription Drug Promotion.

(Comment 1) Comment 1 expressed concern that this research will duplicate a prior FDA study and lack practical utility. The comment asserts that while the 60-day PRA notice provided a statement of ''preliminary results'' of the prior study, full study materials, results, and conclusions of that prior study have not been published. It requested that the results of the prior study be published before this study is conducted, suggesting that, without publishing the results of the prior study, FDA has not addressed how the new proposed research would address open research issues or limitations of the prior study.

(Response 1) Contrary to the comment's suggestion, we do not plan to duplicate the prior research, although there often is value in that undertaking. Rather, the present research seeks to replicate the previous study in a new patient population and extend the previous study by testing additional versions of the disclosure. The new research is directly informed by open research issues and limitations raised in the public comments from the previous study. The proposed studies will be conducted in a new cancer survivor and caregiver sample, which differs from the sample in the prior study, which was conducted with a general population sample. As noted above, cancer survivors and cancer caregivers are more likely to seek out or be exposed to promotion for accelerated approval products than the general population. They may also be more familiar with cancer-related terms and concepts than the general population. Replications in different study samples are often proposed. Indeed, at the time of the previously proposed study (0910–0872 Study), public comments suggested conducting the study with cancer survivors who had used oncology products. Also, in response to public comments on the prior study design, we will extend the prior research by testing additional versions of the disclosure. This study therefore has practical utility to expand our information regarding website disclosures regarding accelerated approval drugs, both by extending to additional versions of the

disclosure related to our overall questions, and to determine if results are consistent with those of the earlier study. We intend to publish the results of the current study as well as the prior study.

(Comment 2) Comment 2 stated that establishing mandates to unduly emphasize a product's accelerated approval status could deter appropriate usage and lead to misconception and confusion among patients. The comment specifically referred to one statement in the disclosure, ''we currently do not know if [Drug X] helps people live longer or feel better'' to suggest that the disclosure may oversimplify the benefits of the product and thus discourage patients from getting needed treatments. The comment later stated that the availability of FDA prior review of promotional pieces for accelerated approval means there is less need to prescribe specific overarching new rules for disclosures because FDA can consider disclosures on a case-by-case basis.

(Response 2) This notice proposes a data collection for research purposes and does not establish a mandate or propose a new rule. Instead, it proposes research that may inform FDA and stakeholder thinking on accelerated approval product disclosures in DTC promotional materials. The research will specifically investigate patient understanding of and reaction to the disclosure language about a product's accelerated approval status. Study 2 was designed in direct response to public comment on the previously proposed study (0910–0872 Study) raising concerns about over-disclosure. Study 2 will test several conditions based on disclosures found in the marketplace, two of which will not include the statement ''we currently do not know if [Drug X] helps people live longer or feel better'' (see table 2).

(Comment 3) Comment 3 suggested that DTC promotional materials are not the best venue for providing information about prescription drugs, given the role of healthcare professionals (HCPs) in discussing and prescribing treatments. Based on this, the comment suggested modifying the study to focus on prescriber-patient interactions rather than DTC promotion by including a component to evaluate patient understanding of accelerated approval after consultation with a prescriber.

(Response 3) We agree that the prescriber-patient interaction is important. Consumers often wish to participate in shared decision-making with HCPs when selecting prescription drugs and may request specific prescription drugs from their HCPs based on promotions they have seen in the marketplace. Because information consumers receive through DTC prescription drug promotion can impact these requests, it is important to investigate how the information in prescription drug promotional pieces impacts consumer attention, understanding, and perceptions.

(Comment 4) Comment 4 suggested conducting qualitative interviews or a blended approach of qualitative and quantitative research rather than a quantitative study. In addition, the comment recommended that the interviews include showing the stimuli to participants, asking them questions about the stimuli, and then showing them the stimuli again so they can read the disclosure and have it in front of them while answering questions.

(Response 4) We plan to conduct nine 1-hour interviews to cognitively test the stimuli and questionnaire. These interviews will allow for indepth discussions with participants, and the findings from the interviews will help improve the study materials. In addition, the questionnaire follows the approach the commenter suggested: Participants view the stimuli and answer questions, then see the disclosure again for questions 16 and 17. This will allow us to test what participants remember and understand after visiting a website for an accelerated approval product, as well as their understanding of the disclosure language while it is in front of them. We will use the cognitive interviews and pretesting to determine whether participants will be able to view the stimuli when answering more of the questions in study 2.

(Comment 5) Comment 5 suggested screening for patients who have a personal experience with Acute Lymphoblastic Leukemia (ALL) (the cancer referred to in the study stimuli) and who have received accelerated approval products from their prescribers.

(Response 5) We will ask participants about the type of cancer and type of treatment(s) they or their loved one had. In this study, we will not ask if they used an accelerated approval product, because participants are unlikely to know this information. In the pretest, we will examine the feasibility of quotas aiming for a broad range of cancer diagnoses in the sample, including blood cancers like ALL. We will also use the pretest to examine the feasibility of restricting recruitment to cancer survivors, and caregivers for cancer survivors, who have received a systemic therapy (*e.g.,* chemotherapy, hormonal therapy, immune therapy, targeted therapy).

(Comment 6) Comment 6 questioned why caregivers are included in the sample and noted that it is unclear what direct role caregivers have in drug prescribing decisions.

(Response 6) We included caregivers in part because previous public comments have encouraged FDA to include caregivers in DTC research (for example, Docket No. FDA–2019–N–2313). Prior research also supports the inclusion of caregivers in a study on consumer understanding of health information on a DTC prescription drug website. Surveys have found that many people searching for health information online are doing so on behalf of someone else (*e.g.,* Refs. 3 and 4). These ''surrogate seekers'' are more likely to be caregivers (Ref. 5). In addition, caregivers are a known audience for DTC prescription drug websites. For instance, to enter some DTC prescription drug websites, people must select whether they are ''a patient or caregiver'' or a ''healthcare provider.'' Other DTC prescription drug websites specifically include information for caregivers.

(Comment 7) Comment 7 stated that information on the proposed number of study participants was not observed in the 60-day notice, and suggested a minimum of 200–300 participants, with 400–500 being optimal. The comment also suggested considering quotas for demographic variables such as age and education to allow for subgroup analyses.

(Response 7) The proposed number of participants can be found in table 3 of this notice. Specifically, we propose 630 participants in study 1 and 400 participants in study 2. We have not proposed any planned subgroup analyses; however, we will have quotas for age, sex, race, and education to ensure a diverse sample.

(Comment 8) Comment 8 suggested that, for study participants to understand the disclosures being tested, they must first be told that the drug received an accelerated approval; accelerated approval is based on an FDA determination that the drug is likely to provide meaningful therapeutic benefits to patients over existing treatments and likely addresses a significant unmet medical need; and the drug is approved based on adequate and well-controlled clinical trial(s) on surrogate or intermediate clinical endpoints that are reasonably likely to predict clinical benefit, but that the drug's effects need to be verified with additional data.

(Response 8) Consumers encountering DTC websites for accelerated approval

products would not have this background information, so giving this information to participants would defeat the purpose of testing what perceptions these consumers form from the website disclosures.

(Comment 9) Comment 9 suggested testing an alternative disclosure that would include background information about accelerated approval, described in the last comment, along with the disclosures currently proposed to be tested.

(Response 9) We acknowledge that we cannot test all possible disclosure language. We based the disclosures we plan to test on FDA-approved labeling for accelerated approval products and on disclosures found in the marketplace (Ref. 2). We encourage research on alternate disclosures.

(Comment 10) Comment 10 stated that question 9, which asks participants about their understanding of the confirmatory trials concept from the disclosure, is unclear and suggested deleting the question or refining the answer options.

(Response 10) We will delete this question in study 1. As noted in the questionnaire, we plan to test two versions of question 9 in the study 2 pretests. We will refine or delete this question in study 2 based on findings from the cognitive interviews and pretesting.

(Comment 11) Comment 11 suggested clarifying ''quality of life'' in consumer-friendly terms and defining specific quality of life measures in question 10.

(Response 11) Question 10 does not refer to a specific quality of life measure. In a recent survey of metastatic breast cancer patients, most participants (89 percent) reported understanding the term ''quality of life'' (Ref. 6). We expect participants in this study will also understand the term ''quality of life'' without further clarification, but we will cognitively test and pretest the question to determine if any clarification is needed.

(Comment 12) Comment 12 stated that questions 11 and 12, which ask about risk-benefit tradeoffs, are redundant and too general, not sufficient to study over-disclosure, and that these questions typically require consumers and HCPs to arrive at the answer together. The comment suggested that instead, the study ask whether, based on information on the website, participants intend to ask to take the drug, not ask to take the drug, speak with a doctor about whether the drug is right for them, or none of these.

(Response 12) We disagree that consumers do not form their own perceptions about risk-benefits tradeoffs after seeing DTC promotional materials and prior to any discussion with a HCP. Thus, we plan to ask participants about their perceptions of the risk-benefit tradeoff through question 11, which is a common and validated item in DTC research. We will delete question 12 to reduce redundancy (Ref. 7). We will also ask about behavioral intentions. Participants do not necessarily have the type of cancer the fictitious drug is indicated to treat; therefore, it would not make sense to ask them about their intentions to ask about the drug for themselves. Instead, similar to what the comment requests, question 14 asks whether participants would recommend that a loved one diagnosed with the cancer that the fictitious drug is indicated to treat ask a doctor about taking the drug.

(Comment 13) Comment 13 recommended deleting question 13, which asks about the drug side effects, because it is too general and does not test the disclosure.

(Response 13) Question 13 is intended to measure the effect of the disclosure on participants' risk perceptions. We will assess this question in cognitive interviews and pretesting and will refine it if needed.

(Comment 14) Comment 14 suggested deleting or refining question 14, which asks participants to select all actions they would suggest a loved one take (*i.e.,* asking a doctor about taking the drug, asking about the drug's risks, its benefits, and its FDA approval). The comment stated that because all options may be applicable, it is unclear how the item would yield meaningful data for this research.

(Response 14) We revised question 14 from ''select all that apply'' to separate ''yes/no'' items for each action. We will assess the utility of asking about each of these actions in cognitive interviews and pretesting. At a minimum, we will retain the ''taking [Drug X]'' item to assess intentions as discussed in a previous comment.

(Comment 15) Comment 15 suggested that participants are unlikely to have the information to provide yes or no answers to question 19, which asks participants whether they used any accelerated approval products for their own cancer, and questioned why it is important for a patient to understand the regulatory approval pathway for a drug, as opposed to information about the drug's safety and effectiveness for use in discussion with an HCP.

(Response 15) We agree that participants are unlikely to know whether the product they used was an accelerated approval product and will delete this question in this study.

(Comment 16) Comment 16 suggested deleting question 21, which asks how similar the study website was to other DTC websites the participant has seen, because it seems vague and not directly related to the research question.

(Response 16) Question 21 is for pretesting purposes only and is intended to assess the quality of the stimuli. We will keep question 21 for pretesting but will not ask it in the main studies.

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

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest 1 and 2 screener	3,600	1	3,600	0.08 (5 minutes)	288
Study 1 and 2 screener	20,600	1	20,600	0.08 (5 minutes)	1,648
Pretest 1	100	1	100	0.33 (20 minutes)	33
Main Study 1	630	1	630	0.33 (20 minutes)	208
Pretest 2	80	1	80	0.33 (20 minutes)	26
Main Study 2	400	1	400	0.33 (20 minutes)	132
Total					2,335

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

III. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. 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. Beaver J.A., L.J. Howie, L. Pelosof, et al., ''A 25-Year Experience of U.S. Food and Drug Administration Accelerated Approval of Malignant Hematology and Oncology Drugs and Biologics: A Review.'' *JAMA Oncology.* 2018; 4(6):849–856.
2. Sullivan H.W., A.C. O'Donoghue, K.T. David, et al., ''Disclosing Accelerated Approval on Direct-to-Consumer Prescription Drug websites.'' *Pharmacoepidemiology and Drug Safety.* 2018;27:1277–1280. *https://doi.org/10.1002/pds.4664.*
3. Cutrona, S.L., K.M. Mazor, S.N. Vieux, et al., ''Health Information-Seeking on Behalf of Others: Characteristics of 'Surrogate Seekers'.'' *Journal of Cancer Education.* 2015;30:12–19. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4282983/.*
4. Sadasivam, R.S., R.L. Kinney, S.C. Lemon, et al., ''Internet Health Information Seeking Is a Team Sport: Analysis of the Pew Internet Survey.'' *International Journal of Medical Informatics.* 2013;82:193–200.
* 5. Bangerter, L.R., J. Griffin, K. Harden, et al., ''Health Information-Seeking Behaviors of Family Caregivers: Analysis of the Health Information National Trends Survey.'' *JMIR Aging.* 2019;2:e11237. *https://aging.jmir.org/2019/1/e11237/.*
6. von Itzstein, M.S., E. Railey, M.L. Smith, et al., ''Patient Familiarity with, Understanding of, and Preferences for Clinical Trial Endpoints and Terminology.'' *Cancer.* 2021;126:1605–1613.
7. Kelly, B.J., D.J. Rupert, K.J. Aikin, et al., ''Development and Validation of Prescription Drug Risk, Efficacy, and Benefit Perception Measures in the Context of Direct-to-Consumer Prescription Drug Advertising.'' *Research in Social and Administrative Pharmacy.* 2021;17:942–955.

Dated: March 17, 2022.

Andi Lipstein Fristedt,

Deputy Commissioner for Policy, Legislation, and International Affairs, U.S. Food and Drug Administration.

[FR Doc. 2022–06220 Filed 3–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; (301) 443–6593, or visit our website at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that ''[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.'' Set forth below is a list of petitions received by HRSA on February 1, 2022, through February 28, 2022. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

a. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by'' one of the vaccines referred to in the Table, or

b. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine'' referred to in the Table.