(3) *Young Adult Survey:* We will administer this to young adults ages 19–24 as a web survey. Topics align with the youth survey, but with slight wording changes to reflect the older population.

Respondents: The survey respondents are from an online panel of a probability-based sample of the U.S. population of parents of youth ages 14–18 and their youth ages 14–18 and of young adults ages 19–24.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
(1) Parent Survey	1,550	1	.333	516	172
(2) Part I Youth Survey	675	1	.333	225	75
(3) Part II Youth Survey	590	1	.333	197	66
(4) Young Adult Survey	775	1	.583	452	151

Estimated Total Annual Burden Hours: 464.

(Authority: Sec. 510. [42 U.S.C. 710])

John M. Sweet,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–17680 Filed 8–12–20; 8:45 am]

BILLING CODE 4184–83–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1550]

New Drugs Regulatory Program Modernization: Implementation of the Integrated Assessment of Marketing Applications and Integrated Review Documentation; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the following public workshop entitled ''New Drugs Regulatory Program Modernization: Implementation of the Integrated Assessment of Marketing Applications and Integrated Review Documentation.'' The purpose of the public workshop is to seek public comments/feedback on the Integrated Review documentation generated by the new Integrated Assessment of marketing applications for new drug products developed as part of the New Drugs Regulatory Program Modernization. The Agency hopes to receive public feedback on how this Integrated Review documentation can continue supporting our stakeholders' needs. Please see information and examples relevant to the Integrated Review at *http://wcms-internet.fda.gov/drugs/news-events-human-drugs/integrated-assessment-marketing-applications-workshop-10302020-10302020.*

DATES: The public workshop will be held virtually and broadcast via webcast only on October 30, 2020, from 9 a.m. to 3 p.m. Registration to attend the meeting and other information can be found at *http://wcms-internet.fda.gov/drugs/news-events-human-drugs/integrated-assessment-marketing-applications-workshop-10302020-10302020.* The public meeting may be extended or may end early depending on the level of public participation. Submit either electronic or written comments on this public workshop by December 30, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

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 30, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 30, 2020. 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–2020–N–1550 for ''New Drugs Regulatory Program Modernization: Implementation of the Integrated Assessment of Marketing Applications and Integrated Review Documentation.'' 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, 240–402–7500.

• 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Rhonda M. Hearns-Stewart, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3249, Silver Spring, MD 20993–0002, 240–402–3180, *Rhonda.Hearns-Stewart@fda.hhs.gov,* with the subject line ''Collecting Public Feedback on the Integrated Assessment.''

SUPPLEMENTARY INFORMATION:

I. Background

The Integrated Assessment of marketing applications includes a new process and review template for the assessment and documentation of new drug product marketing applications (*e.g.,* new drug applications or biologics license applications (BLAs)) in the Center for Drug Evaluation and Research. The resultant Integrated Review is the product of an interdisciplinary team assessment process that provides collaborative discussions of key review issues that span multiple disciplines and includes resolution of important issues pertinent to benefit-risk assessments. This interdisciplinary approach facilitates clarity of decision making and ensures input from relevant disciplines in the consideration of scientific issues. FDA believes the format and content of the Integrated Review documentation will provide sufficient detail concerning the evidence of efficacy and assessment of risk and risk management as well as a clearer description of FDA's analysis of the scientific issues raised by the application and the scientific reasoning supporting the benefit-risk determination. The overall objective is to more effectively communicate the basis for FDA's decision on applications.

This new Integrated Review document replaces the current documentation, which included a separate review document authored by each discipline. It also replaces the multidisciplinary review (*i.e.,* Unireview) in which each discipline provided a separate review section but within a single review document. FDA is currently undergoing a phased implementation of the Integrated Review documentation for new molecular entities, original BLAs, and select efficacy supplements. FDA plans to expand the scope to other marketing application types in the near future.

The following guiding principles informed the Integrated Assessment process and associated Integrated Review documentation:

• The importance of conducting an issue-focused assessment,

• enhanced communication both within the review team and with the applicant, and

• strong interdisciplinary collaboration.

The Integrated Review documentation template has three main components:

• Executive Summary:

○ Represents FDA's conclusions regarding key scientific and regulatory issues while describing any differences of scientific opinion or perspective,

○ provides a summary of FDA's decision and assessment of the application, including FDA's benefit-risk determination (as currently employed in marketing application reviews), and

○ provides an overall Agency assessment, including an overview of the major decisions made during the review process, and a brief discussion of the basis for the decisions.

• Interdisciplinary Assessment:

○ Includes succinct, integrated, focused analyses of the evidence of benefit, risk and risk management, and therapeutic individualization (*e.g.,* special populations, drug interactions).

○ Highlights key review issues (including analyses specific to key issues) the review team thinks are pertinent to the decision-making process. Issues are presented and assessed in an interdisciplinary manner.

○ Includes any dissenting data interpretations.

• Discipline-Specific Appendices:

○ Contains assessments and analyses that are supportive and/or important to key facts/data or conclusions included in the overall review, and in certain instances may include discipline-specific content (*e.g.,* relevant pharmacology/toxicology information),

○ May contain work that did not directly impact the overall assessment of benefit-risk, regulatory action, labeling, or risk-mitigation plans, and

○ includes separate reviews of reviewers who disagree with significant elements of the Executive Summary and Interdisciplinary Assessment sections or the decision of the Signatory Authority.

In general, the first two parts of the Integrated Review document would be expected to provide a complete explanation of FDA's action and supporting analyses, with the third component (the appendices) providing additional detail on the comprehensive analyses FDA conducted in its review of the drug application.

The target audiences for this document are diverse and include those with a specific interest in the application such as the lay public, drug sponsors, researchers, and others who are seeking to understand the basis for FDA's decision.

As part of FDA's ongoing evaluation of the Integrated Assessment and its implementation, the Agency is interested in receiving responses to the following questions/topics, in addition to any general comments the public might have. For convenience, it would be helpful if commenters refer to the numbered question and topic when submitting responses and comments.

II. Topics for Discussion at the Public Workshop

The Agency is soliciting public feedback on how the Integrated Review can continue supporting our stakeholders' needs.

The Agency welcomes any relevant information specific to the Integrated Review that stakeholders wish to share

at the meeting or in a submission to the docket, but we emphasize that the focus of this meeting is to seek input that prioritizes feedback specifically on characteristics of the Integrated Review document. Please see information and examples relevant to the Integrated Review at *http://wcms-internet.fda.gov/drugs/news-events-human-drugs/integrated-assessment-marketing-applications-workshop-10302020-10302020.*

Furthermore, we anticipate that the most informative suggestions would not be specific to an indication, a therapeutic area, or a disease but rather apply across multiple indications, therapeutic areas, or diseases. We are particularly interested in the topics that follow:

1. We are interested in preserving for stakeholders what they find most useful in FDA reviews.

a. Comparing the Integrated Review to previous reviews, is there any information you are having difficulty locating?

b. Are you able to use the Integrated Review for the same purpose that you used previous reviews? If not, please provide specific examples.

2. We are interested in specific recommendations about any areas of the Integrated Review documentation of the Integrated Assessment that can be improved to meet the needs of stakeholders.

3. We are interested in stakeholders' views regarding the advantages and disadvantages of an interdisciplinary assessment presentation of key review issues and resulting integration of the assessments of multiple disciplines into a single Integrated Review document.

4. We would like to know whether the new format of the Integrated Review document for the Integrated Assessment can provide clarity of benefit-risk assessments and inform your knowledge of FDA's basis for making decisions.

III. Participating in the Public Workshop

Registration: Please visit the following website to register: *https://www.eventbrite.com/e/integrated-assessment-of-marketing-applications-workshop-tickets-102979608782.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Persons interested in attending this virtual public workshop must register by September 30, 2020, by 11:59 p.m. Eastern Time.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments and requests to participate in the focused sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by October 14, 2020. All requests to make oral presentations must be received by the close of registration on September 30, 2020, by 11:59 p.m. EST. If selected for presentation, submit electronic copies of any presentation materials (Power Point or PDF) to *ONDPublicMTGSupport@fda.hhs.gov* no later than October 21, 2020. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This webcast for this public workshop is available at *https://collaboration.fda.gov/newdrugs103020/.* If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *http://wcms-internet.fda.gov/drugs/news-events-human-drugs/integrated-assessment-marketing-applications-workshop-10302020-10302020.*

Dated: August 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–17721 Filed 8–12–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4951]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Humanitarian Use Devices

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 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for humanitarian use devices (HUDs).

DATES: Submit either electronic or written comments on the collection of information by October 13, 2020.

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 October 13, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 13, 2020. 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