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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2769]

21st Century Cures: Announcing the Establishment of the BEST Resource Taxonomy; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the establishment of a public docket to receive comments from interested parties (including academic institutions, regulated industry, and patient groups) on the Agency's publication of a glossary of terms which is part of the BEST (Biomarkers, EndpointS, and other Tools) Resource Taxonomy. FDA has developed a web page that describes the BEST Resource Taxonomy and links out to the official National Library of Medicine web page for the BEST glossary of terms. Comments on the BEST Resource Taxonomy will help FDA enhance its utility and may assist FDA in developing future versions of this resource and identifying best methods for conveying information about biomarkers, endpoints, and other drug development tools to the general public.

DATES: Submit either electronic or written comments on this notice by September 23, 2019.

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 September 23, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 23, 2019. 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–2019–N–2769 for ''21st Century Cures: Announcing the Establishment of the BEST Resource Taxonomy.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christopher Leptak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6461, Silver Spring, MD 20993–0002, 301–796–0017, *Christopher.Leptak@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3011 of the 21st Century Cures Act (Pub. L. 114–255) added a new section 507 to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357). Section 3011(b)(3)(A) requires FDA to collaborate with biomedical research consortia and other interested parties to ''establish a taxonomy for the classification of biomarkers (and related scientific concepts) for use in drug development.'' FDA is meeting this legislative requirement through updates to the BEST Resource on the National Library of Medicine website, available at *https://www.ncbi.nlm.nih.gov/books/NBK326791/,* is FDA's response to this

legislative requirement. In Spring 2015, the FDA–NIH (National Institutes of Health) Joint Leadership Council identified the harmonization of terms used in translational science and medical product development as a priority need, with a focus on terms related to study endpoints and biomarkers (see *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm614359.htm*). Working together with the goals of improving communication, aligning expectations, and improving scientific understanding, the two agencies developed the BEST Resource. The current phase of BEST comprises a glossary that clarifies use of important terms in the context of biomarkers and related scientific concepts and describes some of the hierarchical relationships, connections, and dependencies among the terms it contains. For example, the BEST glossary aims to capture distinctions between biomarkers and clinical assessments and to describe their distinct roles in biomedical research, clinical practice, and medical product development. FDA refers the public to the following web page for additional background information as well as a link to the BEST glossary of terms: *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm614359.htm.* FDA has previously discussed taxonomy for biomarkers used in drug development at its public meeting on Drug Development Tool Process on December 11, 2018, and invited comment on the BEST taxonomy in guidance published on December 12, 2018, on the evidentiary framework for biomarker qualification.

II. Establishment of a Docket and Issues for Consideration

To help FDA determine the utility of the BEST glossary of terms, develop future iterations, and identify best methods for conveying this information, FDA is soliciting public comments on the BEST glossary that can be found on the following web page: *https://www.ncbi.nlm.nih.gov/books/NBK338448/?report=reader.* The BEST glossary is meant to be a resource that will be periodically updated with additional terms and clarifying information. Specifically, FDA welcomes comments concerning: (1) The utility of the BEST glossary; (2) specific proposed edits, including additions and removal of terms, with a rationale supporting these proposed edits; (3) the best approach for developing future iterations of the glossary; and (4) questions pertaining to the BEST glossary that you would like FDA to address in future communications. As the glossary is refined, the goal is to elaborate on these terms, so they will remain relevant, thus fostering consistent usage. Ultimately, FDA hopes that the BEST glossary will help to accelerate development and refinement of medical products, which will lead to improvements in health outcomes. The Agency will consider comments submitted to the docket as it revises the BEST glossary of terms.

Dated: July 22, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15827 Filed 7–24–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0994]

Modified Risk Tobacco Product Applications for VLN™ King and VLN™ Menthol King, Combusted, Filtered Cigarettes, Submitted by 22nd Century Group, Inc.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for public comment of modified risk tobacco product applications (MRTPAs) for VLN™ King and VLN™ Menthol King, combusted, filtered cigarettes, submitted by 22nd Century Group, Inc.

DATES: Electronic or written comments on the application may be submitted beginning July 25, 2019. FDA will establish a closing date for the comment period as described in section I.

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 (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–2019–N–0994 for ''Modified Risk Tobacco Product Applications for VLN™ King and VLN™ Menthol King, Combusted, Filtered Cigarettes Submitted by 22nd Century Group Inc.'' 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.'' 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