appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 7, 2018. Oral presentations from the public will be scheduled between approximately 12:40 p.m. and 1:40 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 13, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 14, 2018.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Jay R. Fajiculay (See, **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00903 Filed 1–18–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6969]

Product Title and Initial U.S. Approval in Highlights for Human Prescription Drug and Biological Products—Content and Format; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products—Content and Format.'' The labeling regulations for human drug and biological products require that the Highlights of Prescribing Information (Highlights) contain a product title and the year of initial U.S. approval. This draft guidance provides recommendations on the content and format of the product title and initial U.S. approval to bring greater consistency to the presentation of these required elements and to help ensure these elements provide clear and useful information to the health care provider.

DATES: Submit either electronic or written comments on the draft guidance by March 20, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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–2017–D–6969 for ''Product Title and Initial U.S. Approval in Highlights for Human Prescription Drug and Biological Products—Content and Format; Guidance for Industry; Availability.'' 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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building., 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Debra Beitzell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm 6460, Silver Spring, MD 20993–0002, 301–796–0700; 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

FDA is announcing the availability of a draft guidance for industry entitled ''Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products—Content and Format.''

On January 24, 2006, FDA published a final rule amending the requirements for the content and format of labeling for human prescription drug and biological products (71 FR 3922, January 24, 2006). This rule is known as the physician labeling rule because it addresses prescription drug labeling that is used by physicians and other health care providers. Under this rule, the prescribing information of new and more recently approved prescription drug and biological products contains the following three sections: Highlights, Full Prescribing Information: Contents, and Full Prescribing Information (§ 201.56(d)(1) (21 CFR 201.56(d)(1))).

Highlights is required to contain the drug names (proprietary name and nonproprietary name (established name of the drug or, for biological products, the proper name)), dosage form, route of administration, and, if applicable, controlled substance symbol of the drug or biological product (§ 201.57(a)(2) (21 CFR 201.57(a)(2))). This set of information is referred to as the ''product title'' and follows the Highlights Limitation Statement. Highlights also must include the year of initial U.S. approval of the drug or biological product (§ 201.57(a)(3)). The initial U.S. approval must be placed immediately beneath the product title and is the four-digit year in which FDA initially approved the new molecular entity, new biological product, or new combination of active ingredients.

This draft guidance provides recommendations on the content and format of the product title in Highlights. Recommended sources for product title terminology also are provided. Appendix A, ''Dosage Form Terms for Use in Human Drug Product Labeling'' and Appendix B, ''Route of Administration Terms for Use in Human Drug Product Labeling'' contain lists of recommended dosage form and route of administration terms, respectively, for use in the product title. This draft guidance contains recommendations for products with special nomenclature considerations, recommendations for what not to include in the product title, and implications for container and carton labeling.

The draft guidance also provides recommendations on the content and format of the initial U.S. approval in Highlights. Items to consider when determining the year of initial U.S. approval are included and drug products requiring special consideration are described.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the content and format of the product title and initial U.S. approval in Highlights for human prescription drug and biological products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in §§ 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *https://www.regulations.gov.*

Dated: January 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00899 Filed 1–18–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6880]

Material Threat Medical Countermeasure Priority Review Vouchers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Material Threat Medical Countermeasure Priority Review Vouchers.'' There is stakeholder interest in FDA's implementation of the provision of the 21st Century Cures Act (Cures Act) that adds a new section to the Federal Food, Drug, and Cosmetic Act (FD&C Act) on priority review vouchers for material threat medical countermeasure applications. This new section of the FD&C Act makes provisions for awarding priority review vouchers for use with applications to sponsors of material threat medical countermeasure applications that meet the criteria specified by the FD&C Act.