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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building., 4th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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled ''Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological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.

This draft guidance explains to internal and external stakeholders how FDA intends to implement the provisions of the new section of the FD&C Act.

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–6880 for ''Material Threat Medical Countermeasure Priority Review Vouchers; Draft 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 office of 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 guidance to Office of Counterterrorism and Emerging Threats, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4343, Silver Spring, MD 20993–0002, 301–796–8510. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Carol Drew, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4320, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled, ''Material Threat Medical Countermeasure Priority Review Vouchers.'' Section 3086 of the Cures Act adds new section 565A to the FD&C Act. Section 565A of the FD&C Act (21 U.S.C. 360bbb–4a) was designed to encourage development of medical countermeasures by offering additional incentives for obtaining approval of new drug or biological medical products for the prevention and treatment of harm from a biological, chemical, radiological, or nuclear agent identified as a material threat. Under section 565A of the FD&C Act, a sponsor of a human drug application for a material threat medical countermeasure application may be eligible for a voucher that can be used to obtain a priority review for any application submitted under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351 of the Public Health Service (PHS) Act (42 U.S.C. 262). The draft guidance also provides information on using the priority review vouchers and on transferring priority review vouchers to other sponsors.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the current thinking of FDA on obtaining a material threat medical countermeasure priority review voucher. It does not create or confer any rights for or on any person and does not operate to bind 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. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 that 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** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

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

Under the draft guidance, sponsors of certain medical countermeasure product applications submitted under section 505(b)(1) of the FD&C Act and section 351 of the PHS Act may request a priority review voucher. Based on inquiries FDA has received on section 565A and related discussions with sponsors, we estimate that we will receive annually approximately 2 requests from 2 sponsors, and that each request will take approximately 8 hours to prepare and submit to FDA.

The draft guidance also states that sponsors should notify FDA of their intent to use a priority review voucher, including the date on which the sponsor intends to submit the application, at least 90 days before use. We estimate that we will receive annually approximately 2 notifications of intent to use a voucher from 2 sponsors, and that each notification will take approximately 8 hours to prepare and submit to FDA. The draft guidance also permits the transfer of a priority review voucher from one sponsor to another, and states that each transfer should be documented with a letter of transfer. We estimate that we will receive approximately 1 letter indicating the transfer of a voucher from 1.5 application holders, and 1 letter acknowledging the receipt of a transferred voucher from 1.5 new voucher owners acknowledging the transfer, and that it will take approximately 8 hours to prepare and submit each letter to FDA.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Reporting under Section 3086 of the Cures Act	Number of respondents	Number of responses per respondent	Total responses	Hours per response	Total hours
Priority review voucher request	2	1	2	8	16
Notifications of intent to use a voucher	2	1	2	8	16
Letters indicating the transfer of a voucher	1.5	1	1.5	8	12
Letters acknowledging the receipt of a transferred voucher	1.5	1	1.5	8	12
Total					56

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

III. Electronic Access

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

Dated: January 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00900 Filed 1–17–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners—OMB No. 0915–0126—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than February 20, 2018.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners—45 CFR part 60 Regulations and Forms, OMB No. 0915–0126—Revision.