Additionally, an estimated 996 local agencies will take approximately three hours to collect the data and one hour to submit the data to their lead NWD System state agency. If all state and local agencies respond bi-annually, the national burden estimate for the NWD MT would be a total of 8,080 hours annually. This burden estimate is calculated based upon a sample of three states that tested a demonstration of the NWD MT as a part of the grantee requirements under the NWD System Implementation grant, a competitive funding opportunity funded in 2016 through 2018. Each state entity submitting data will receive local-level data from designated NWD System entities. The estimated response burden includes time to review the instructions, gather existing information, and complete and review the data entries in a web-based system.

An estimated 400 VDC program entities will respond to the VDC Tool on a monthly basis, all of which are also NWD local-level entities, for an annual burden of 2,400 hours. This burden estimate is calculated based upon information provided by a current VDC program provider testing a demonstration of the VDC tool. The NWD MT and the VDC tool have been developed to increase ease and uniformity of reporting and improve the ability of ACL to manage and analyze data.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
NWD Management Tool data collection and entry—State Level	56	2	1.0	112
NWD Management Tool data collection and entry—Local Level	996	2	4.0	7,968
Veteran Directed Care Tool	400	12	0.5	2,400
Total:	1,452			10,480

Dated: October 23, 2018.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2018–24053 Filed 11–1–18; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3903]

Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs and biologics for the treatment of chronic hepatitis B virus (HBV) infection from the initial investigational new drug application (IND) through the new drug application (NDA)/biologics license application (BLA) and postmarketing phases.

DATES: Submit either electronic or written comments on the draft guidance by January 2, 2019 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–2018–D–3903 for ''Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment.'' 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. 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: Poonam Mishra, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6100, Silver Spring, MD 20993, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs and biologics for the treatment of chronic HBV infection from the initial IND through the NDA/BLA and postmarketing phases. The guidance includes general considerations for nonclinical toxicology and virology studies, early phase clinical development, clinical pharmacology assessments, and phase 3 safety and efficacy trials. The guidance discusses phase 3 trial design considerations and efficacy endpoints for the development of combination therapies for the treatment of chronic HBV infection. Drug development considerations for specific subpopulations such as patients coinfected with hepatitis D virus or human immunodeficiency virus and pediatric HBV-infected patients are also included.

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 ''Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment.'' 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. Paperwork Reduction Act of 1995

This 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 (PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The submission of prescription drug labeling under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910–0572.

III. Electronic Access

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

Dated: October 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23951 Filed 11–1–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3693]

Product Development in Hemophilia; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Product Development in Hemophilia.'' The purpose of the public workshop is to discuss issues related to development and regulation of novel hemophilia products.

DATES: The public workshop will be held on December 6, 2018, from 8:30 a.m. to 4:30 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Docket: For access to the docket to read background documents 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: Joan Ferlo Todd, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Hematology and Oncology Products, 10903 New Hampshire Ave., Bldg. 22, Rm. 2139, Silver Spring, MD 20993–0002, 301–796–6079, *Joan.Todd@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Hemophilia is a bleeding disorder caused by deficiency of coagulation factor VIII (hemophilia A) or coagulation factor IX (hemophilia B). Hemophilia treatment strategies are intended to prevent or control bleeding and the attendant complications. Recently, hemophilia treatment strategies have led to the development of factor concentrates, recombinant DNA technology products, antibodies, and potential curative strategies such as gene therapy. These new emerging technologies raise new considerations about trial design, novel endpoints, patient-reported outcomes, and long-term safety collection.

This public workshop is intended to provide a platform for engaging in a discussion with experts in hemophilia treatment, patients, and caregivers. The purpose of this workshop is to advance further development of patient-experience and patient-reported outcomes for use in clinical trials, facilitate reliable and interpretable measurements of factor VIII/IX activity