support findings of effectiveness and safety and helps identify appropriate doses in pediatric populations. The draft guidance also describes the use of quantitative approaches (*i.e.,* pharmacometrics) to employ disease and exposure-response knowledge from relevant prior clinical studies to design and evaluate future pediatric studies. The draft guidance does not describe: (1) Standards for approval of drugs and biological products in the pediatric population, (2) criteria to allow a determination that the course of a disease and the effects of a drug or a biologic are the same in adults and pediatric populations, or (3) clinical pharmacology studies for vaccine therapy, blood products, or other products not regulated by the Center for Drug Evaluation and Research.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the Agency's current thinking on the general clinical pharmacology considerations for pediatric studies for drugs and biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520) (PRA). The collections of information referenced in this draft guidance that are related to the burden for the submission of investigational new drug applications are covered under 21 CFR part 312 and have been approved under OMB control number 0910–0014. The collections of information referenced in this draft guidance that are related to the burden for the submission of new drug applications are covered under 21 CFR part 314 and have been approved under OMB control number 0910–0001. The submission of prescription drug product labeling under 21 CFR 201.56 and 201.57 is approved under OMB control number 0910–0572.

In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances* or *http://www.regulations.gov.*

Dated: December 2, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28716 Filed 12–8–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1492]

Two-Phased Chemistry, Manufacturing, and Controls Technical Sections; Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for a notice of availability of draft guidance for industry (GFI #227) entitled ''Two-Phased Chemistry, Manufacturing, and Controls Technical Sections'' that appeared in the **Federal Register** of October 20, 2014. In that notice, FDA made available for comment the draft guidance, which provides recommendations to sponsors submitting chemistry, manufacturing, and controls (CMC) data submissions. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the draft guidance. Submit either electronic or written comments on the draft guidance by February 17, 2015.

ADDRESSES: Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Heather Longstaff, Center for Veterinary Medicine (HFV–145), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0651, email: *heather.longstaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 20, 2014 (79 FR 62635) FDA published a notice announcing the availability of draft guidance for industry (GFI #227) entitled ''Two-Phased Chemistry, Manufacturing, and Controls (CMC) Technical Sections.'' It is intended to provide recommendations to industry regarding CMC data submitted to the Center for Veterinary Medicine to support approval of a new animal drug or abbreviated new animal drug. The notice invited comments on the draft guidance by December 19, 2014.

The Agency received a request for a 60-day extension of the comment period for the draft guidance. The request conveyed concern that the current 60-day comment period does not allow sufficient time to respond.

FDA has considered the request and is extending the comment period for the draft guidance for 60 days, until February 17, 2015. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying further FDA action on this guidance document.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: December 2, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28713 Filed 12–8–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1814]

Bacterial Detection Testing by Blood Collection Establishments and Transfusion Services To Enhance the Safety and Availability of Platelets for Transfusion; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Bacterial Detection Testing by Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion'' dated December 2014. The draft guidance document provides blood collection establishments and transfusion services with recommendations for initial testing (primary testing) for bacterial contamination of platelets intended for transfusion, and provides additional considerations for blood collection establishments and transfusion services for subsequent retesting (secondary testing) of platelets prior to transfusion. The recommendations for primary testing of platelets and the additional considerations for secondary testing of platelets described in this guidance are expected to enhance the detection of bacteria in platelet products and thus enhance transfusion safety. The draft guidance, when finalized, is intended to supersede the recommendation in section VII.A.2, in regard to bacterial contamination testing in the document entitled ''Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods'' dated December 2007.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 9, 2015. Submit either electronic or written comments on the collection of information by February 9, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance and information collection to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jonathan McKnight, 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 document entitled ''Bacterial Detection Testing by Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion'' dated December 2014. The draft guidance document provides blood collection establishments and transfusion services with recommendations for primary testing for bacterial contamination of platelets intended for transfusion and additional considerations for blood collection establishments and transfusion services for secondary testing of platelets prior to transfusion. FDA also provides recommendations to licensed blood establishments for submitting Biologics License Application supplements to include bacterial testing of platelet components. Furthermore, the guidance informs transfusion services that are currently exempt from registration and blood product listing that if they choose to perform secondary testing of platelets to extend the dating period, should this option become available, they must register with FDA and list the blood products they manufacture.

The draft guidance addresses all platelet products, including platelets manufactured from Whole Blood (Whole Blood Derived (WBD) platelets), platelets collected by automated methods from a single donor (apheresis platelets), pooled platelets, and platelets stored in additive solutions. The recommendations for primary testing of platelets and the additional considerations for secondary testing of platelets described in this guidance are expected to enhance the detection of bacteria in platelet products and thus enhance transfusion safety. The draft guidance, when finalized, is intended to supersede the recommendation in section VII.A.2, in regard to bacterial contamination testing in the document entitled ''Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods'' dated December 2007.

Platelets are associated with a higher risk of sepsis and are related to more fatalities than any other transfusable blood component. The risk of bacterial contamination of platelets stands out as a leading risk of infection from blood transfusion. This risk has persisted despite numerous interventions including the introduction, in the last decade, of analytically sensitive culture-based bacterial detection methods, which are widely used to test platelets prior to their release from blood collection establishments to transfusion services.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

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 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** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice