

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/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Documents/default.htm>, or <http://www.regulations.gov>.

Dated: May 24, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-12922 Filed 5-30-13; 8:45 am]

BILLING CODE 4160-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-1999-D-3528 (Formerly Docket No. 99D-5046)]

#### **Draft Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture; 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 "Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture" dated June 2013. The draft guidance document provides manufacturers of licensed Whole Blood and blood components intended for transfusion or for further manufacture, including Source Plasma, with recommendations intended to assist with determining which reporting mechanism is appropriate for submission of changes to an approved biologics license application. The guidance document also provides manufacturers of licensed Whole Blood and blood components recommendations in connection with the applicability and content of

comparability protocols and labeling changes. The draft guidance, when finalized, is intended to supersede the document of the same title dated July 2001 (July 2001 guidance).

**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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 29, 2013.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448. 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 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance 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 R. McKnight, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture" dated June 2013. The document provides manufacturers of licensed Whole Blood and blood components intended for transfusion or for further manufacture, including Source Plasma, with recommendations intended to assist with determining which reporting mechanism is appropriate for submission of changes to an approved biologics license application in accordance with the requirements under Title 21 Code of Federal Regulations 601.12 (21 CFR 601.12). The guidance document also provides manufacturers of licensed

Whole Blood and blood components with recommendations in connection with the applicability and content of comparability protocols under 21 CFR 601.12(e) and labeling changes under 21 CFR 601.12(f). Frequently, a manufacturer of a licensed product determines that it is appropriate to make a change in its product, production process, quality controls, equipment, facilities, responsible personnel, or labeling as documented in its approved biologics license application(s). Section 601.12 (21 CFR 601.12) states the requirements to report such changes for licensed biological products to FDA.

The recommendations contained in the guidance document reflect current FDA and industry experience with reporting changes to an approved application, including reporting the implementation of new technologies. The recommendations have been revised for reporting categories for certain changes to an approved application that is in the July 2001 guidance based on the experience gained over the last decade. The draft guidance, when finalized, is intended to supersede the document of the same title dated July 2001, published in the **Federal Register** of August 7, 2001 (66 FR 41247).

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 requirement of the applicable statutes and regulations.

##### **II. Paperwork Reduction Act of 1995**

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 21 CFR 601.12, Form FDA 2567, and Form FDA 356h have been approved under OMB control number 0910-0338; the collections of information in 21 CFR 607.21, 607.26, and Form FDA 2830 have been approved under OMB control number 0910-0052; the collections of information in 21 CFR 606.121, 606.170, and 610.40 have been approved under OMB control number 0910-0116; and the collections of information in 21 CFR 600.14 has been approved under OMB control number 0910-0458.

### III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. 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 draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: May 24, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0556]

### New Approaches to Antibacterial Drug Development; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) is seeking input from the public on the following topics related to antibacterial drug development: Potential new study designs, proposed priorities for CDER guidances, and strategies intended to slow the rate of emerging resistance to antibacterial drugs. The purpose of this notice is to request information and comments from the public on these areas of focus.

**DATES:** Submit either electronic or written comments by *July 30, 2013* at 5 p.m. EST.

**ADDRESSES:** Submit electronic comments 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:

Jonas Santiago, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-5346, FAX: 301-847-3529, email: [jonas.santiago@fda.hhs.gov](mailto:jonas.santiago@fda.hhs.gov).

### I. Background

Antibacterial drug development is critical to the public health and is an FDA priority. We recognize the mounting concern that antibacterial drug development has not kept pace with the increasing threat of drug-resistant and untreatable infections.

To address this concern, we are seeking to explore new clinical development paradigms for antibacterial drugs. Areas of ongoing need are numerous and include new drugs for treatment of hospital-acquired bacterial pneumonia, ventilator-associated bacterial pneumonia, complicated urinary tract infection, complicated intra-abdominal infection, and infections caused by drug-resistant organisms.

On September 24, 2012,<sup>1</sup> FDA announced the formation of the CDER Antibacterial Drug Development Task Force, which supports new antibacterial drug development. The task force is a multidisciplinary group of CDER scientists and clinicians seeking to identify priority areas and to develop and implement possible solutions to the challenges of antibacterial drug development. This includes the use of existing partnerships and collaborations to work with other experts in the field, including academia, industry, professional societies, patient advocacy groups, and Government Agencies. Specifically, the task force seeks to:

- Explore novel scientific approaches to facilitate antibacterial drug development (e.g., broader use of clinical pharmacology data, new statistical methods, innovative clinical trial designs, use of additional available data sources, and advancement of alternative measures to evaluate clinical effectiveness of potential new therapies);
- Identify issues related to unmet medical need for antibacterial drugs, including the reasons for the lack of a robust pipeline for antibacterial drug development;

- Identify new approaches for weighing risks, benefits, and uncertainties of potential new antibacterial drugs addressing unmet need; and

- Evaluate existing FDA guidances related to antibacterial drug development to determine if revision or elaboration is needed and identify areas where future guidance would be helpful.

### II. Potential New Study Design Approaches

The task force explores novel scientific approaches to facilitate antibacterial drug development and is seeking input from the public on study design approaches with potential utility for future antibacterial drug development. Possible elements being considered include:

- Bayesian approaches;
- Adaptive approaches;
- Use of novel point of care diagnostics to avoid use of confounding therapies;
- Evaluating safety and efficacy by enrolling patients in trials with infections at any one of a number of different body sites;
- Large simple trials; and
- Accelerated approval using either a surrogate endpoint reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit.

To advance the development of antibacterial drugs, we seek input on the listed examples as well as additional ideas regarding the design, conduct, and analysis of clinical trials.

### III. Guidance Development

The task force focuses on developing guidance to address issues related to development of new antibacterial drugs. Initial guidance efforts focused on community-acquired bacterial pneumonia, acute bacterial skin and skin structure infections, and antibacterial drugs for patients with limited or no alternative therapies (including development of drugs that have a limited spectrum of activity). As the task force works to prioritize areas of future draft and final guidance development, we seek input from the public on the following areas of priority as well as on additional areas for potential future guidance development:

<sup>1</sup> FDA's press release is available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm320643.htm>.