

Guidance for Industry

Availability of FDA's eSubmitter Program for Regulatory Submissions from Licensed Blood Establishments

This guidance document is for immediate implementation.

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(4)(i). Submit written comments on this guidance at anytime to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. You should identify all comments with the Docket No. FDA-2011-D-0579.

Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD) (HFM-40), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800, or email ocod@fda.hhs.gov, or from the Internet at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

For questions on the content of this guidance, contact OCOD at the phone numbers or email address listed above.

**U.S. Department of Health and Human Services
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Contains Nonbinding Recommendations

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This guidance represents the Food and Drug Administration's (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. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the appropriate FDA staff. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

We, FDA, the Center for Biologics Evaluation and Research (CBER), are announcing to you, licensed blood establishments that collect Whole Blood and blood components, including Source Plasma, the availability of CBER's eSubmitter Program (eSubmitter), an electronic submissions program. The eSubmitter program is intended to facilitate submission and processing of regulatory filings, including biologics license applications (BLAs), BLA supplements (BLSs), annual reports and amendments to pending eSubmitter applications and supplements. In this guidance, we describe how you may obtain and use the eSubmitter program.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, these guidances describe the FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA's guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

FDA's eSubmitter is an electronic submissions program that is available for voluntary use by sponsors, manufacturers, and importers to submit a variety of submission types for FDA-regulated products. The eSubmitter application software, which can be downloaded free of charge, assists applicants in the preparation of submissions that contain the minimum elements necessary for FDA to perform a comprehensive review.

The eSubmitter program is designed to ensure that applicants include necessary information in their regulatory submissions. The eSubmitter program also functions to guide users as they complete the filing process. FDA believes that eSubmitter will help improve the consistency, quality and completeness of regulatory submissions and make the submission and review process more user-friendly for applicants. In the future, additional instructions for electronic submissions may be posted on the FDA website.

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The FDA eSubmitter program is government-issued software governed by the Government Paperwork Elimination Act of 1998. As a user of this software, you are not required to perform your own validation. However, if you decide to use the software for purposes other than the intended uses identified in this guidance, you may be required to comply with additional requirements applicable to those intended uses.

In the Federal Register of March 26, 2009, FDA announced an invitation to participate in a pilot evaluation program for the use of eSubmitter for BLAs and BLSs submitted by blood establishments that collect Source Plasma (74 FR 13210). In the Federal Register of September 7 2010, FDA announced an invitation to participate in another pilot evaluation program, this time for the use of eSubmitter for BLAs and BLSs submitted by blood establishments that collect Whole Blood and blood components (75 FR 54343). These pilot programs were intended to provide industry and CBER regulatory staff the opportunity to evaluate the effectiveness of eSubmitter for these purposes. FDA has completed its evaluation of these pilot programs and the agency now has decided to make this system broadly available.

III. RECOMMENDATIONS

We have determined that eSubmitter is an acceptable mechanism for the submission of BLAs, BLSs, annual reports and amendments to pending eSubmitter regulatory submissions by licensed blood establishments that collect Whole Blood and blood components, including Source Plasma. The eSubmitter program is available to you at no charge from the FDA's website at <http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm>.

You may use the eSubmitter program for the submission of BLAs, BLSs, annual reports and amendments to pending eSubmitter regulatory submissions. If you choose to prepare regulatory submissions using eSubmitter, you do not need to also submit a cover letter and/or paper copies of these submissions.

Information entered into eSubmitter during preparation of regulatory submissions is currently required to be saved as a zip file onto a CD-ROM or DVD and mailed to CBER for review according to current managed review procedures.

At this time, FDA will continue to accept paper regulatory submissions. If you do not use eSubmitter for your submissions, you may still access eSubmitter to obtain and print a PDF file that contains the eSubmitter submission contents.

Additional information for downloading, installing and using the eSubmitter program is available on FDA's website at <http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm>.