DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. FDA–2010–N–0481

Center for Veterinary Medicine eSubmitter Workshop; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: “Center for Veterinary Medicine (CVM) eSubmitter Workshop.” The purpose of the public workshop is to provide the regulated animal health industry that submits new animal drug applications to CVM’s Office of New Animal Drug Evaluation (ONADE) access to the beta-release of the electronic submission tool (eSubmitter) developed by CVM as agreed to in the Animal Drug User Fee Amendments (ADUFA II) of 2008 (http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm044941.htm). The ONADE will be soliciting feedback on both the eSubmitter tool and its compatibility with the industry’s current IT systems, as well as the questions asked within the tool.

This workshop will fulfill one of the 10 workshops agreed to in ADUFA II. The workshop will provide insight on the eSubmitter template development and its customization for the animal health industry as well as providing break-out sessions in which specific submissions will be built as part of the demonstration. Lastly, the ONADE will be seeking up to nine participating companies to work with CVM in testing the transmission of eSubmitter developed files through FDA’s electronic submission gateway (ESG) and CVM’s electronic submission system (ESS). Information about the workshop and availability of the eSubmitter tool can be found on FDA’s eSubmitter Web site at http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm.

Dates and Time: The public workshop will be held on October 21, 2010, from 9 a.m. to 4 p.m. (EST/EDST).

Location: The public workshop will be held virtually through both Adobe Connect Pro on-line and with conference call-in numbers. Both the call-in numbers and the Adobe Connect Pro web link will be emailed to all registrants.

Contact Person: Charles Andres, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8229, email: charles.andres@fda.hhs.gov.

Registration: Registration for the workshop can be made at: https://collaboration.fda.gov/cvm_essubmitter_workshop_oct21/event/registration.html on or before October 15, 2010. There is no registration fee for the public workshop. If you need special accommodations due to a disability, please contact Charles Andres (see Contact Person) at least 7 days in advance.

Comments: FDA is holding this public workshop to obtain information about the eSubmitter tool. The deadline for submitting comments regarding this public workshop is December 31, 2010.

Regardless of whether a person attended the public workshop, interested persons may submit either electronic or written comments regarding this document. 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. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A recording of the public workshop will be available on the Internet at http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm.

Dated: September 17, 2010.

Leslie Kux,
Acting Assistant Commissioner for Policy.