Drug Products; Questions and Answers.”
This document answers questions regarding CVM’s implementation of USP <487> Residual Solvents.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on this topic.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.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations.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 this guidance have been approved under OMB control nos. 0910–0032 and 0910–0669.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. 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.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm or http://www.regulations.gov.

Dated: November 12, 2010.
Leslie Kux,
Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30387 Filed 12–2–10; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2009–D–0533]

Guidance for Industry:
Recommendations for Blood Establishments: Training of Back-Up Personnel, Assessment of Blood Donor Suitability, and Reporting Certain Changes to an Approved Application; Availability

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.


DATES: Submit either electronic or written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, 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 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 guidance document.

Submit electronic comments on the 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:

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled “Guidance for Industry: Recommendations for Blood Establishments: Training of Back-Up Personnel, Assessment of Blood Donor Suitability and Reporting Certain Changes to an Approved Application” dated November 2010. The guidance document provides recommendations to blood establishments for training of back-up personnel, assessment of blood donor suitability, and reporting certain changes to an approved license application to FDA.

In the Federal Register of November 19, 2009 (74 FR 59982), FDA announced the availability of the draft guidance entitled “Draft Guidance for Industry: Recommendations for the Assessment of Blood Donor Suitability, Blood Product Safety, and Preservation of the Blood Supply in Response to Pandemic (H1N1) 2009 Virus” (November 2009). At that time, we anticipated that the rapid spread of pandemic (H1N1) 2009 virus had the potential to cause disruptions in the blood supply and that the usual practices for ensuring blood availability in response to local disasters (i.e., hurricanes) would not be applicable or sufficient under a severe pandemic scenario. Since we issued the draft guidance, the H1N1 influenza pandemic has waned in the United States and disruptions in the blood supply have not been observed. Therefore, we are not finalizing those recommendations set forth in the draft guidance that referred to blood donor deferral and blood product management specific to the pandemic (H1N1) 2009 virus. Instead, we are finalizing those recommendations contained in the draft guidance that are of general...
applicability (i.e., regardless of the existence of a pandemic or other emergency situation) as to training of back-up personnel, assessing blood donor suitability, and reporting certain changes to an approved application for licensed blood establishments. FDA received a few comments on the draft guidance in connection with these recommendations and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The guidance announced in this document finalizes the draft guidance dated November 2009.

The guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents 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

This 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 part 606 have been approved under OMB control number 0910–0338. The collections of information for 21 CFR part 607 have been approved under OMB control number 0910–0116. The collections of information for 21 CFR part 608 have been approved under OMB control number 0910–0339.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/ BiologicsBloodVaccines/ GuidanceComplianceRegulatory Information/Guidances/default.htm or http://www.regulations.gov.