

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**21 CFR Parts 606, 610, 630, 640, 660, 820, and 1270**

[Docket No. 2006N-0221]

#### Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use; Extension of Comment Period

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

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to August 4, 2008, the comment period for the proposed rule that appeared in the **Federal Register** of November 8, 2007 (72 FR 63416). In the proposed rule, FDA had requested comments by February 6, 2008. The agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** Submit written and electronic comments by August 4, 2008.

**ADDRESSES:** You may submit comments, identified by Docket No. 2006N-0221, by any of the following methods:  
*Electronic Submissions*

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
  - Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.
- Written Submissions*

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration,

5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

*Instructions:* All submissions received must include the agency name and Docket No(s), and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Brenda R. Friend, 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**

In the **Federal Register** of November 8, 2007 (72 FR 63416), FDA published a proposed rule with a 90-day comment period to request comments on the proposed rule. The proposed rule would establish regulations for blood and blood components, including Source Plasma and Source Leukocytes, to add donor requirements that are consistent with current practices in the blood industry, and to more closely align the regulations with current FDA recommendations.

The agency has received requests for a 180-day extension of the comment period for the proposed rule. Each

request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule for 180 days, until August 4, 2008. The agency believes that a 180-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

##### **II. Request for Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

Dated: January 2, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

#### **30 CFR Part 931**

[Docket ID: OSM-2007-0021; SATS No. NM-047-FOR]

#### **New Mexico Regulatory Program**

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.