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[Proposed Rules]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 211, 226, 300, 500, 530, 600, 895, and 1271

[Docket No. 2005N-0373]
RIN 0910-AF54

Use of Materials Derived From Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until May 14, 2007, the comment period for the proposed rule published in the Federal Register of January 12, 2007 (72 FR 1582). The proposed rule would prohibit the use of certain cattle material in, or in the manufacture (including processing) of, drugs, biologics, and medical devices intended for use in humans and human cells, tissues, and cellular and tissue-based products (HCT/Ps) (collectively, medical products for humans), and in drugs intended for use in ruminant animals (drugs for ruminants) and would also require new recordkeeping provisions for medical products for humans and drugs for ruminants that are manufactured from or otherwise contain material from cattle. The agency is reopening the comment period in response to a request for more time to enable industry to generate more information on products that might be affected by the rule.

DATES: Submit written or electronic comments on the proposed rule by

May 14, 2007.

ADDRESSES: You may submit comments, identified by Docket No. 2005N-0373 and RIN number 0910-AF54, 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) 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 section II ``Comments'' in 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:

For information concerning products regulated by the Center for

Drug Evaluation and Research: Audrey A. Thomas, Center for Drug Evaluation and Research (HFD-007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5533, e-mail: audrey.thomas@fda.hhs.gov.

For information concerning products regulated by the Center for Biologics Evaluation and Research: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210, e-mail: stephen.ripley@fda.hhs.gov.

For information concerning products regulated by the Center for Devices and Radiological Health: Scott G. McNamee, Center for Devices and Radiological Health, Food and Drug Administration, 2094 Gaither Rd., rm. 230, Rockville, MD 20850, 240-276-0105, e-mail: scott.mcnamee@fda.hhs.gov.

For information concerning products regulated by the Center for Veterinary Medicine: Michael J. Popek, Center for Veterinary Medicine (HFV-144), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6462, e-mail: michael.popek@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 12, 2007 (72 FR 1582), FDA published a proposed rule that, if finalized, would prohibit the use of certain cattle material in, or in the manufacture (including processing) of, medical products for humans and drugs for ruminants. FDA also proposed new recordkeeping requirements for medical products for humans and drugs for ruminants that are manufactured from or otherwise contain material from cattle.

Interested persons were given until March 13, 2007, to submit written or electronic comments to the agency on the proposal. On February 12, 2007,

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FDA received a request to extend the comment period. FDA believes that extending the comment period by 45 days is appropriate to allow industry to generate information on products that might be affected by the rule. Therefore, FDA is extending the comment period until May 14, 2007. This extension will provide the public with a total of 105 days to submit comments.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments on the proposed rule. 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 No. 2005N-0373. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 23, 2007.
Jeffrey Shuren,
Assistant Commissioner for Policy.
[FR Doc. E7-5894 Filed 3-29-07; 8:45 am]

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