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 20, 201, 207, 314, 330, 514, 515, 601, 607, 610, and 1271

[Docket No. 2005N–0403]

RIN 0910–AA49

Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to February 26, 2007, the comment period for the proposed rule published in the **Federal Register** of August 29, 2006 (71 FR 51276). The proposed rule would amend the agency's current regulations governing establishment registration and drug listing. The initial comment period was extended (71 FR 63726, October 31, 2006) until January 26, 2007. We recently learned that, on January 26, 2007, the last day of the comment period, technical problems prevented some persons from submitting electronic comments. Therefore, FDA is reopening the comment period until February 26, 2007, to allow interested persons to submit comments for this rulemaking.

DATES: Submit written or electronic comments on the proposed rule by February 26, 2007.

ADDRESSES: You may submit comments, identified by Docket No. 2005N–0403 and RIN 0910–AA49, 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. 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 the ''Request for 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, 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 drugs regulated by the Center for Drug Evaluation and Research: John W. Gardner, Center for Drug Evaluation and Research (HFD–330), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–8920, *john.gardner@fda.hhs.gov*.

For information concerning products regulated by the Center for Biologics Evaluation and Research: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210, *valerie.butler@fda.hhs.gov*.

For information concerning animal drugs: Lowell Fried (HFV–212) or Isabel W. Pocurull (HFV–226), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9059 or 240–453–6853, *lowell.fried@fda.hhs.gov* or *isabel.pocurull@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the proposed rule (see **DATES**). 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 Docket No. 2005N–0403. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 1, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2123 Filed 2–7–07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 49 and 51

[EPA–HQ–OAR–2003–0076, FRL–8276–8]

RIN 2060–AH37

Review of New Sources and Modifications in Indian Country

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; announcement of reopening of comment period.

SUMMARY: The EPA is announcing a reopening of the public comment period on our proposed amendments for the Review of New Sources and Modification in Indian Country (August 21, 2006). The EPA is reopening the