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]

BILLING CODE 4160–01–S

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

comment period that originally ended on January 19, 2007. The reopened comment period will close on March 20, 2007. The EPA is reopening the comment period because of the number of requests we received in a timely manner.

DATES: *Comments.* Comments must be received on or before March 20, 2007.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2003–0076, by one of the following methods:

- *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *E-mail: a-and-r-docket@epamail.epa.gov.*
- *Fax:* 202–566–1741.
- *Mail:* Attention Docket ID No. EPA–HQ–OAR–2003–0076, U.S. Environmental Protection Agency, EPA West (Air Docket), 1200 Pennsylvania Avenue, Northwest, Mailcode: 6102T, Washington, DC 20460. Please include a total of 2 copies. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th St., NW., Washington, DC 20503.
- *Hand Delivery:* U.S. Environmental Protection Agency, EPA West (Air Docket), 1301 Constitution Avenue, Northwest, Room 3334, Washington, DC 20004, Attention Docket ID No. EPA–HQ–OAR–2003–0076. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions. Direct your comments to Docket ID No. EPA–HQ–OAR–2003–0076. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the U.S. Environmental Protection Agency, Air Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For technical information, contact Jessica Montanez, Air Quality Policy Division, U.S. EPA, Office of Air Quality Planning and Standards (C504–03), Research Triangle Park, North Carolina 27711, telephone number (919) 541–3407, facsimile number (919) 541–5509, electronic mail e-mail address: *montanez.jessica@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *http://www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. Send or deliver information identified as CBI only to the following address: Roberto Morales, OAQPS Document Control Officer (C404–02), U.S. EPA, Research Triangle Park, NC 27711, Attention Docket ID No. EPA–HQ–OAR–2003–0076.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

B. Where Can I Get a Copy of This Document and Other Related Information?

In addition to being available in the docket, an electronic copy of this proposal will also be available on the World Wide Web (WWW). Following signature by the EPA Administrator, a copy of this notice will be posted in the regulations and standards section of our NSR home page located at *http://www.epa.gov/nsr* and on the tribal air home page at *http://www.epa.gov/oar/tribal.*

Dated: January 30, 2007.

Jenny Noonan Edmonds,

Acting Director, Office of Air Quality Planning and Standards.

[FR Doc. E7–2101 Filed 2–7–07; 8:45 am]

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