by paragraph (i) of this AD, do a detailed inspection for discrepancies (including finish damage, corrosion, pitting, and base metal scratches) of the transition radius of the left and right MLG trunnion pins, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–32–1402, dated August 6, 2008. At the times specified in paragraph 1.E., ''Compliance,'' of the service bulletin, do all applicable repetitive inspections and corrective actions, in accordance with the service bulletin. Accomplishing the detailed inspections (initial and repetitive) and all applicable corrective actions specified in this paragraph terminates the repetitive lubrication requirements of paragraph (g) of this AD.

No Report Required

(i) Although Boeing Special Attention Service Bulletin 737–32–1402, dated August 6, 2008, specifies to send inspection reports to the manufacturer, this AD does not include that requirement.

Optional Terminating Action

(j) Overhauling or replacing a trunnion pin in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–32–1402, dated August 6, 2008, ends the repetitive lubrication requirements of paragraph (g) of this AD, and the actions required by paragraph (h) of this AD, for that pin. Replacement or overhaul of the left and right MLG trunnion pins in accordance with Boeing Special Attention Service Bulletin 737–32–1402, dated August 6, 2008, terminates the requirements of this AD.

Alternative Methods of Compliance (AMOCs)

(k)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Nancy Marsh, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle ACO, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6440; fax (425) 917–6590. Or, e-mail information to *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov*.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before *using* any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and the approval must specifically refer to this AD.

Issued in Renton, Washington, on April 27, 2009.

Stephen P. Boyd,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9–10303 Filed 5–4–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 601

[Docket No. FDA–2009–N–0100]

Revision of the Requirements for Publication of License Revocation; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations to clarify the regulatory procedures for notifying the public about the revocation of a biologics license to be consistent with current practices. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written or electronic comments on or before July 20, 2009. If FDA receives any significant adverse comments, the agency will publish a document withdrawing the direct final rule within 30 days after the comment period ends. FDA will then proceed to respond to comments under this proposed rule using the usual notice and comment procedures.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2009–N–0100, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

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, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, 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.regulations.gov* 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: Paul E. Levine, Jr., 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 January 25, 1977 (42 FR 4680), FDA issued a final rule revising, among other things, the procedures under part 601 (21 CFR part 601) for issuing, revoking, and suspending biologics licenses; and publishing license revocations. FDA revised these procedures in order to simplify and codify existing practices, establish new requirements where appropriate, and ensure that practices and procedures would be consistently applied throughout the agency.

A provision under the January 25, 1977, final rule provided that a ''Notice of revocation of a license, with statement of the cause therefor, shall be issued by the Commissioner and published in the **Federal Register**'' (§ 601.8). FDA interprets this requirement to apply only to a license which the Commissioner of Food and Drugs (the Commissioner) has found grounds to revoke under § 601.5(b). FDA has not routinely published, in the **Federal Register**, a notice of revocation of a biologics license resulting from a manufacturer's voluntary request for revocation for reasons unrelated to a finding by the Commissioner that

reasonable grounds to revoke the license exist under § 601.5(b). Examples of situations in which a manufacturer might voluntarily request that a license be revoked include economic loss, change in product marketing strategy, lack of public need, corporate reorganization, or the emergence of innovative replacement products. FDA does not consider the revocation of licenses in such circumstances to require publication in the **Federal Register**. However, FDA may publish a notice of revocation for licenses revoked at the voluntary request of a manufacturer in situations where such notice is in the interest of public health.

II. Highlights of the Proposed Rule

FDA is proposing to amend § 601.8 to read: ''The Commissioner, following revocation of a biologics license under 21 CFR 601.5(b), will publish a notice in the **Federal Register** with a statement of the specific grounds for the revocation.''

This proposed amendment revises the existing regulation to clarify that FDA will publish a notice of license revocation in cases where the Commissioner has made a finding that reasonable grounds for revocation exist under § 601.5(b). This proposed amendment also clarifies that the phrase ''with statement of the cause therefor,'' (§ 601.8) refers to the specific grounds for revocation enumerated in § 601.5(b). The proposed rule does not affect other regulations or procedures for notification of license revocation. The proposed rule does not alter existing FDA practices for publishing notices of voluntary withdrawal, including notices of voluntary withdrawal of new drug applications.

III. Legal Authority

FDA is issuing this regulation under the biological products provisions of the Public Health Service Act (42 U.S.C. 262 and 264) and the drugs and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (sections 201, 301, 501, 502, 503, 505, 510, 701, and 704) (21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 371, and 374). Under these provisions of the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act, we have the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, and potent; and prevent the introduction, transmission, and spread of communicable disease.

IV. Companion Document to Direct Final Rulemaking

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described the agency's procedures for when and how we will employ direct final rulemaking. We have determined that the rule is appropriate for direct final rulemaking because it includes only noncontroversial amendments, and we anticipate no significant adverse comments. Consistent with our procedures on direct final rulemaking, this proposed rule is a companion to the direct final rule published elsewhere in this issue of the **Federal Register**. This companion proposed rule provides the procedural framework to finalize the rule in the event that the direct final rule receives any significant adverse comment and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period for the direct final rule. Any comments received in response to this companion proposed rule will also be considered as comments regarding the direct final rule.

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure.

A comment recommending a regulation change in addition to that in this rule will not be considered a significant adverse comment unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule that can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of a significant adverse comment.

If any significant adverse comments are received during the comment period, FDA will publish, before the effective date of the direct final rule, a document withdrawing the direct final rule. If we withdraw the direct final rule, any comments received will be applied to the companion proposed rule and will be considered in developing a final rule using the usual notice-and-comment procedures under the APA (5 U.S.C. 552a *et seq*).

If FDA receives no significant adverse comments during the specified comment period, FDA intends to publish a document confirming the effective date within 30 days after the comment period ends. Additional information about direct rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

V. Analysis of Impacts

A. Review Under Executive Order 12866, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act of 1995

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule makes current regulations consistent with existing FDA practices and procedures, the agency proposed to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Environmental Impact

The agency has determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant adverse effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

C. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. Paperwork Reduction Act of 1995

This proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

VII. Request for Comments

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

List of Subjects in 21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 601 is amended as follows:

PART 601—LICENSING

1. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

2. Revise § 601.8 to read as follows:

§ 601.8 Publication of revocation.

The Commissioner, following revocation of a biologics license under 21 CFR 601.5(b), will publish a notice in the **Federal Register** with a statement of the specific grounds for the revocation.

Dated: March 25, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–10243 Filed 5–4–09; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2008–0031; FRL–8899–4]

Approval and Promulgation of Air Quality Implementation Plans; Indiana; Extended Permit Terms for Renewal of Federally Enforceable State Operating Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve Indiana's rule revision to extend permit terms for the renewal of Federally Enforceable State Operating Permits (FESOPs) from five years to ten years. Indiana submitted this rule revision for approval on December 19, 2007. FESOPs apply to non-major sources that obtain enforceable limits to avoid being subject to certain Clean Air Act (Act) requirements, including the Title V operating permit program. Neither the Act nor its implementing regulations specify a permit-term requirement for FESOPs. This rule revision will provide relief to Indiana's resource burden of processing permit renewals. It will also allow the Indiana Department of Environmental Management to devote more resources to major source Title V permitting actions and permit modifications for both Title V and FESOP sources.

DATES: Comments must be received on or before June 4, 2009.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2008–0031, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *E-mail: blakley.pamela@epa.gov.*

3. *Fax:* (312) 692–2450.

4. *Mail:* Pamela Blakley, Chief, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery:* Pamela Blakley, Chief, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Sam Portanova, Environmental Engineer, Air Permits Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–3189, *portanova.sam@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register,** EPA is approving Indiana's state implementation plan submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register.**