RUS will require Primary Recipients to evaluate each action taken with an Ultimate Recipient to ensure consistency with the terms of the executed program alternative.

Primary Recipients will be responsible for documenting activities that fall below the established threshold. RUS will review the Primary Recipient's documentation of actions that fall below the threshold prior to providing reimbursement with Federal funds.

Any EE Program activity for which exemptions and standard treatments are not applicable would be subject to Section 106 review under procedures established by the PA or other program alternative. Therefore, the program alternative must define a clear threshold for RUS involvement in Section 106 review.

Although few in number, the comments on the Conceptual Outline received thus far have been supportive of the development of a nationwide PA, the need for streamlining, especially given the large number of reviews expected to be generated by EE Program activities, and the approach reflected in the Conceptual Outline. Based on these comments, RUS is proceeding with development of the first draft of the nationwide PA. The program alternative will be executed prior to RUS issuing a finding of no significant impact (FONSI). Both the FONSI and documents related to the program alternative will be made available to the public on RUS's Web site at *http://www.rurdev.usda.gov/UWP-ea.htm.*

Dated: January 29, 2013.

Nivin Elgohary,

Assistant Administrator, Electric Programs, USDA, Rural Utilities Service.

[FR Doc. 2013–02393 Filed 2–5–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0013; Directorate Identifier 2012–CE–046–AD]

RIN 2120–AA64

Airworthiness Directives; GROB–WERKE Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Proposed rule; correction.

SUMMARY: The FAA is correcting a Notice of Proposed Rulemaking (NPRM) that published in the **Federal Register**. That NPRM applies to all GROB–WERKE Model G115EG airplanes. The docket number in the preamble and in the section titled PART 39—AIRWORTHINESS DIRECTIVES, paragraph 2, is incorrect. This document corrects that error. In all other respects, the original document remains the same.

DATES: The last date for submitting comments to the NPRM (78 FR 2910, January 15, 2013) remains March 1, 2013.

ADDRESSES: You may examine the AD docket on the Internet at http://www.regulations.gov; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Taylor Martin, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4138; fax: (816) 329–4090; email: *taylor.martin@faa.gov.*

SUPPLEMENTARY INFORMATION: Notice of Proposed Rulemaking (NPRM), Directorate Identifier 2012–CE–046–AD (78 FR 2910, January 15, 2013), currently proposes to require inspections of the elevator trim tab arms for cracks and replacement if necessary.

As published, the docket number in the preamble and in the section titled PART 39—AIRWORTHINESS DIRECTIVES, paragraph 2, is incorrect.

No other part of the preamble or regulatory information has been changed; therefore, only the changed portion of the NPRM is being published in the **Federal Register**.

The last date for submitting comments to the NPRM remains March 1, 2013.

Correction of Non-Regulatory Text

In the **Federal Register** of January 15, 2013, Directorate Identifier 2012–CE–046–AD is corrected as follows:

On page 2910, in the 2nd column, on line 4 under the preamble (below DEPARTMENT OF TRANSPORTATION), change Docket No. to ''FAA–2013–0013.''

Correction of Regulatory Text

§ 39.13 [Corrected]

■ In the **Federal Register** of January 15, 2013, on page 2911, in the 3rd column, on line 20, in paragraph (2) under PART 39—AIRWORTHINESS DIRECTIVES of Directorate Identifier 2012–CE–046–AD is corrected to read as follows:

* * * * *

* * * ''FAA–2013–0013;''

* * * * *

Issued in Kansas City, Missouri, on January 28, 2013.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–02578 Filed 2–5–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 314, and 601

[Docket No. FDA–2013–N–0059]

Center for Drug Evaluation and Research; Prescription Drug Labeling Improvement and Enhancement Initiative; Request for Comments and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of an initiative; request for comments and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a docket to receive comments on the proposed implementation of FDA's Prescription Drug Labeling Improvement and Enhancement Initiative and on a proposed pilot project relating to the voluntary conversion of labeling to the ''Physician Labeling Rule (PLR)'' format described in the 2006 FDA final rule, ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products.'' The purpose of the initiative and the pilot project is to enhance the safe and effective use of prescription drugs by facilitating optimal communication through labeling. FDA is seeking public comment on this initiative, and the pilot project, particularly from stakeholders who develop and use prescription drug labeling. Comments received from stakeholders will assist the Agency in identifying and addressing feasibility and implementation issues associated with this initiative.

DATES: Submit either electronic or written comments by March 8, 2013.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–301), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Connie Wisner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6360, Silver Spring, MD 20993–0002, 301–796–8509, FAX: 301–847–3529, email: *connie.wisner@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Prescription drug labeling, commonly called the package insert or prescribing information, is a compilation of information approved by FDA about the safe and effective use of the product, based on FDA's thorough analysis of the new drug application (NDA) or biologics license application (BLA) submitted by the applicant. Its primary purpose is to provide health care practitioners with the essential information needed to facilitate prescribing decisions, thereby enhancing the safe and effective use of prescription drug products and reducing the likelihood of medication errors.

FDA implemented standardized prescription drug labeling in 1979 (44 FR 37434, June 26, 1979). However, over the ensuing 25 years, labeling became increasingly lengthy and complex, which affected its usefulness to healthcare professionals. To address this issue, FDA evaluated the usefulness of prescription drug labeling among healthcare professionals to determine whether and how its content and format could be improved and completed a rulemaking focused on enhanced prescription drug labeling.

In 2006, FDA published the final rule, ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products,'' which revised the content and format requirements for labeling to make it easier to access, read, and use (71 FR 3922, January 24, 2006). The rule is commonly referred to as the ''Physician Labeling Rule'' (PLR or final rule) because it addresses prescription drug labeling that is used by prescribers, including physicians and other healthcare practitioners.[1]

The final rule applies to products for which an NDA, BLA, or efficacy supplement (ES) was approved between June 30, 2001, and June 30, 2006, and to NDAs, BLAs, and ESs submitted after June 30, 2006. The rule established a staggered implementation schedule, under which cohorts of drugs, from newest to oldest would be converted to the new labeling format over time.[2] The staged implementation for PLR conversion expires on June 30, 2013.[3] Older drugs approved before June 30, 2001, are not subject to the mandatory PLR conversion requirement, but FDA strongly encourages all applicants to voluntarily convert the labeling of their drug products to the PLR format, regardless of the date of approval.

As of November 2012, approximately 15 percent of all prescription drugs and biological products have labeling in the PLR format.[4] If no further action is taken, the only additional drug products with labeling in the PLR format will be new NDAs, BLAs, and ES, which are required to be submitted in PLR format, and labeling for drug products for which the NDA or BLA holder voluntarily converts to PLR format.

Generic drugs approved under an abbreviated new drug application (ANDA) are not required to convert their labeling to PLR format unless the reference-listed drug (RLD) approved in an NDA has converted to PLR format. Recent data show that only 10 percent of generic drug labeling has been converted to the PLR format.[5] Since nearly 80 percent of prescriptions today are filled with generic drugs,[6] FDA believes that it is in the best interest of the public health to facilitate conversion of generic drug labeling to the PLR format so the labeling is equally useful to prescribers as the labeling for more recently approved drug products.

Additional FDA outreach corroborates the usefulness of drug labeling in PLR format. On April 20, 2012, the Brookings Institute Engelberg Center for Health Care Reform, in cooperation with FDA, held an expert meeting[7] to obtain feedback from healthcare practitioners on the utility of the prescription drug labeling as a communication tool and to discuss strategies for making it more accessible. In general, meeting participants were very supportive of the PLR format and in agreement that it improves accessibility and use in electronic systems. Moreover, stakeholders, particularly physicians and pharmacists, requested that all labeling be available in PLR format, including labeling for generic drugs and older drug products outside the current PLR implementation schedule.

All holders of marketing applications for drugs and biological products have an ongoing obligation to ensure their labeling is accurate and up-to-date. For example, when new information comes to light that causes information in labeling to become inaccurate, the application holder must take steps to change the content of its labeling, in accordance with 21 CFR 314.70, 314.97, and 601.12. The PLR format represents a more useful and modern approach for communicating accurate and up-to-date information on the safe and effective use of drugs and makes prescription information more accessible for use with electronic prescribing tools and other electronic information resources. For these reasons, FDA is proposing to implement the Prescription Drug Labeling Improvement and Enhancement Initiative to ensure that the safe and effective use of prescription drugs is communicated optimally through labeling.

II. Prescription Drug Labeling Improvement and Enhancement Initiative

The focus of the initiative is to increase the number of drugs with labeling that complies with the PLR content and format requirements (§§ 201.56(d) and 201.57) for drugs approved before June 30, 2001, and for generic drugs. The initiative is anticipated to take place over several years. FDA intends to request that applicants with NDAs, BLAs, or ESs approved before June 30, 2001, and generic drugs for which the NDA for the RLD has been withdrawn (for reasons

[1] In this **Federal Register** document, the term ''PLR format'' refers to labeling that meets the content and format requirements at §§ 201.56(d) and 201.57 (21 CFR 201.56(d) and 201.57). The term ''old format'' refers to labeling that meets the requirements at § 201.56(e) and 21 CFR 201.80.

[2] See § 201.56(c). The Agency adopted this approach because research conducted during the final rule's development indicated that this was the ''most reasonable approach to maximizing the public health benefit and best utilizing available resources.'' See 71 FR 3922 at 3962, January 24, 2006.

[3] The last cohort of drugs approved from June 30, 2001, to June 29, 2002, must submit PLR conversion supplements to FDA by June 30, 2013.

[4] Data obtained from *http://labels.fda.gov.*

[5] Ibid.

[6] See *http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm.*

[7] For more information on the Expert Meeting, see *http://www.brookings.edu/events/2012/04/20-expert-workshop-prescribing-info.* (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

other than safety or effectiveness) voluntarily convert their labeling to PLR format and submit it to FDA for approval.[8] FDA intends to identify and prioritize certain drugs and drug classes based on public health impact (e.g., most prescribed, higher risk).

As part of the initiative, FDA is considering, through the use of a Government contractor, providing PLR conversion resources and services, including preparation of draft PLR labeling for applicants who request FDA's assistance to convert labeling to PLR format. For draft labeling converted to PLR format by a Government contractor, FDA would review the draft labeling prepared by the contractor and then send the applicant the proposed draft PLR format labeling. The applicant would then submit a labeling supplement to FDA with its proposed PLR format labeling (which may include proposed revisions to the draft PLR labeling). It should be emphasized that the application holder always bears responsibility for the content of its product labeling, and FDA's provision of contract resources is intended to facilitate conversion to the PLR format.

This initiative differs from the original PLR implementation plan in the final rule in that the Agency is not proposing rulemaking at this time. Rather, FDA would like to explore a voluntary approach to PLR conversions with NDA and BLA holders for drugs approved before June 30, 2001, and ANDA holders for drugs for which the NDA for the RLD has been withdrawn. In light of the public health benefit realized by labeling in PLR format, and previous interest by many ANDA holders in converting labeling for their drug products to PLR format, FDA anticipates that application holders will be interested in participating in this voluntary approach to enhance communication of information about the drug's safe and effective use through product labeling.

To determine the best approach to accomplish the objectives of this initiative, FDA is considering performing a pilot project to identify best practices and to standardize the approach for voluntary PLR format conversions. FDA is seeking interested applicants with NDAs, BLAs, or ESs approved before June 30, 2001, and generic drugs for which the NDA for the RLD has been withdrawn to voluntarily participate in this pilot project.

[8] See §§ 314.150(a) and (b). An NDA holder that has discontinued marketing a drug product, but has not requested withdrawal of the NDA, must still comply with applicable statutory and regulatory requirements. Such requirements include, for example, submission of an annual report (including a brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product, and a description of actions the applicant has taken or intends to take as a result of this new information) and, if appropriate, proposed revisions to product labeling.

III. Establishment of a Docket and Request for Comments and Information

FDA is soliciting public comments on the Prescription Drug Improvement and Enhancement Initiative. FDA is specifically seeking feedback on the following:

1. What specific feasibility issues or other factors should FDA consider in its proposed pilot project and implementation of the Prescription Drug Labeling Improvement and Enhancement Initiative?

2. What factors should FDA consider in identifying and prioritizing drugs and/or drug classes for voluntary PLR conversions?

3. What approaches would application holders find helpful in facilitating voluntary PLR conversions for the specified drugs or drug classes? For example, please comment on the following approaches for communicating with applicants:

- Inquiry letter that identifies a drug proposed for PLR format conversion and requests information from the application holder regarding its preferred approach for possible PLR conversion (i.e., application holder or Government contractor)?
- Supplement request letter with draft labeling that has been converted to the PLR format attached?

4. For generic drugs for which the NDA for the RLD has been withdrawn, what procedures should FDA use to harmonize feedback from multiple ANDA holders on proposed draft labeling in the PLR format?

5. Would your company be interested in participating in the pilot project and the broader Prescription Drug Improvement and Enhancement Initiative? Why or why not?

Suggestions, recommendations, or comments should describe relevant considerations that may impact the feasibility or implementation of the initiative or the impact the initiative may have on prescription drug labeling issues. We also encourage commenters to include recommendations on how such prescription drug labeling issues could be addressed.

FDA will consider all suggestions, recommendations, and comments; however, the Agency will not respond directly to the person or organization making the suggestion, recommendation, or comment.

IV. Comments

Interested persons may submit either electronic comments information regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments or information. Identify comments or information with the docket number found in brackets in the heading of this document. Received comments or information may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: January 31, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–02528 Filed 2–5–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 200 and 203

[Docket No. FR–5457–P–01]

RIN 2502–AJ03

Streamlining Inspection and Warranty Requirements for Federal Housing Administration (FHA) Single-Family Mortgage Insurance: Removal of the FHA Inspector Roster and of the Ten-Year Protection Plan Requirements for High Loan-to-Value Ratio Mortgages

AGENCY: Office of the Assistant Secretary of Housing—Federal Housing Commissioner, HUD.

ACTION: Proposed rule.

SUMMARY: This proposed rule would streamline the inspection and home warranty requirements for FHA single-family mortgage insurance. First, HUD proposes to remove the regulations for the FHA Inspector Roster (Roster). The Roster is a list of inspectors approved by FHA as eligible to determine if the construction quality of a one- to four-unit property is acceptable as security for an FHA-insured loan. HUD's regulations currently require the use of an inspector from the Roster as a condition for FHA mortgage insurance where the local jurisdiction does not perform necessary inspections. HUD's proposal to remove the Roster regulations is based on the recognition of the sufficiency and quality of inspections carried out by certified inspectors and other qualified individuals. Second, this proposed rule would also remove the regulations