The FAA is proposing an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to the description of high altitude RNAV route Q–108. The route currently extends between the GADAY and CLAWZ waypoints. This action would realign the route to terminate at the HKUNA WP, instead of CLAWZ, where it would join the PIGLT TWO standard terminal arrival (STAR) serving the Orlando International Airport, FL. In addition, two new WPs, IZZEY and FRNKS, would be added to Q–108 between GADAY and HKUNA. This change would shift the alignment of Q–108 slightly to the south of its current track. This revision would enhance the efficiency of the route structure in the northern Florida area.

High altitude RNAV routes are published in paragraph 2006 of FAA Order 7400.9T dated August 27, 2009, and effective September 15, 2009, which is incorporated by reference in 14 CFR 71.1. The RNAV route listed in this document would be subsequently published in the Order. The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation: (1) Is not a ‘‘significant regulatory action’’ under Executive Order 12866; (2) is not a ‘‘significant rule’’ under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA’s authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency’s authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it revises the route structure as required to preserve the safe and efficient flow of air traffic.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E, ‘‘Environmental Impacts: Policies and Procedures,’’ prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:


§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9T, Airspace Designations and Reporting Points, Dated August 27, 2009, and effective September 15, 2009, is amended as follows:


SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 232

[Release No. 33–9074; File No. S7–23–09]

RIN 3235–AK44

Extension of Filing Accommodation for Static Pool Information in Filings With Respect to Asset-Backed Securities

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule.

SUMMARY: The Commission proposes to amend Rule 312 of Regulation S–T which provides a temporary filing accommodation for filings with respect to asset-backed securities that allows static pool information required to be disclosed in a prospectus to be provided on an Internet Web site under certain conditions. Under Rule 312, such information is deemed to be included in the prospectus included in the registration statement for the asset-backed securities. Rule 312 currently applies to filings with respect to asset-backed securities filed on or before December 31, 2009. We propose to amend Rule 312 to extend its application for one year. Under the proposed extension, the rule would apply to filings with respect to asset-backed securities filed on or before December 31, 2010.

DATES: Comments should be received on or before November 23, 2009.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commission’s Internet comment form [http://www.sec.gov/rules/proposed.shtml]; or
• Send an e-mail to rule-comments@sec.gov. Please include File...
Number S7–23–09 on the subject line; or
• Use the Federal Rulemaking Portal (http://www.regulations.gov). Follow the instructions for submitting comments.

Paper Comments
• Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number S7–23–09. This file number should be included on the subject line if e-mail is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s Internet Web site (http://www.sec.gov/rules/proposed.shtml). Comments are also available for public inspection and copying in the Commission’s Public Reference Room, 100 F Street, NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.


SUPPLEMENTARY INFORMATION: We are proposing an amendment to Rule 312 1 of Regulation S–T. 2

I. Background and Discussion of the Proposed Amendment

In December, 2004, we adopted new and amended rules and forms to address the registration, disclosure and reporting requirements for asset-backed securities (“ABS”) under the Securities Act of 1933 3 (the “Securities Act”) and the Securities Exchange Act of 1934 4 (the “Exchange Act”). 5 As part of this rulemaking, we adopted Regulation AB, 6 a new principles-based set of disclosure items forming the basis for disclosure with respect to ABS in both Securities Act registration statements and Exchange Act reports. Compliance with the revised rules was phased in; full compliance with the revised rules became effective January 1, 2006. One of the significant features of Regulation AB is Item 1105, which requires, to the extent material, static pool information to be provided in the prospectus included in registration statements for ABS offerings. 7 While the disclosure required by Item 1105 depends on factors such as the type of underlying asset and materiality, the information required to be disclosed can be extensive. For example, a registrant may be required to disclose multiple performance metrics in periodic increments for prior securitized pools of the sponsor for the same asset type in the last five years. 8

As described in the Adopting Release, in response to the Commission’s proposal to require material static pool information in prospectuses for ABS offerings, many commenters representing both asset-backed issuers and investors requested flexibility in the presentation of such information. In particular, commenters noted that the required static pool information could include a significant amount of statistical information that would be difficult to file electronically on EDGAR as it existed at that time and difficult for investors to use in that format. Commenters accordingly requested the flexibility for asset-backed issuers to provide static pool information on an Internet Web site rather than as part of an EDGAR filing. 9 In response to these comments, we adopted Rule 312 of Regulation S–T, which permits, but does not require, the posting of the static pool information required by Item 1105 on an Internet Web site under the conditions set forth in the rule. 10 We recognized at the time that a Web-based approach might allow for the provision of the required information in a more efficient, dynamic and useful format than was currently feasible on the EDGAR system. At the same time, we explained that we continued to believe at some point for future transactions the information should also be submitted with the Commission in some fashion, provided issuers continue to receive the information in the form they have requested. Accordingly, we adopted Rule 312 as a temporary filing accommodation applicable to filings filed on or before December 31, 2009. 11 We explained that we were directing our staff to consult with the EDGAR contractor, EDGAR filing agents, issuers, investors and other market participants to consider how static pool information could be filed with the Commission in a cost-effective manner without undue burden on those that still allows issuers to provide the information in a desirable format. We also noted, however, that it might be necessary, among other things, to extend the accommodation. 12

We are proposing to extend the temporary filing accommodation set forth in Rule 312 of Regulation S–T for one year so that it would apply to filings with respect to ABS filed on or before December 31, 2010. During the proposed extension, the existing requirements of Rule 312 would continue to apply. Pursuant to these requirements, the registrant must disclose its intention to provide static pool information through a Web site in the prospectus included in the registration statement at the time of effectiveness and provide the specific Internet address where the static pool information is posted in the prospectus filed pursuant to Rule 424. 13 The registrant must maintain such information on the Web site unrestricted and free of charge for a period of not less than five years, indicate the date of any updates or changes to the information, undertake to provide any person without charge, upon request, a copy of the information as of the date of the prospectus if a subsequent update or change is made to the information and retain all versions of the information provided on the Web site for a period of not less than five years in a form that permits delivery to an investor or the Commission. In addition, the registration statement for the ABS must contain an undertaking pursuant to Item 512(f) of Regulation S–K 14 that the information provided on the Web site pursuant to Rule 312 is deemed to be part of the prospectus included in the registration statement. 15

See Form S–1 and Form S–3 under the Securities Act. Static pool information indicates how groups, or static pools, of assets, such as those originated at different intervals, are performing over time. By presenting comparisons between originations at similar points in the assets lives, the data allows the detection of patterns that may not be evident from overall portfolio numbers and thus may reveal a more informative picture of material elements of portfolio performance and risk.

See Adopting Release, Section III.B.4.b.

See Adopting Release, Section III.B.4.b.

17 CFR 232.1105.

See Adopting Release, Section III.B.4.b.

17 CFR 232.312(a). Instead of relying on Rule 312, an issuer can include information required by Item 1105 of Regulation AB physically in the prospectus or, if permitted, through incorporation by reference from an Exchange Act report.

See Form S–1 and Form S–3 under the Securities Act. Static pool information indicates how groups, or static pools, of assets, such as those originated at different intervals, are performing over time. By presenting comparisons between originations at similar points in the assets lives, the data allows the detection of patterns that may not be evident from overall portfolio numbers and thus may reveal a more informative picture of material elements of portfolio performance and risk.

11 17 CFR 232.312(a); see also Adopting Release, Section III.B.4.b.

12 Adopting Release, Section III.B.4.b.


14 17 CFR 229.512(f).

15 17 CFR 232.312. As we indicated in the Adopting Release, if the conditions of Rule 312 are satisfied, then the information will be deemed to be part of the prospectus included in the registration statement.
We believe that it is appropriate to extend the filing accommodation provided by Rule 312 before its expiration after December 31, 2009. Based on the staff’s experience since Rule 312 became effective in 2006, the vast majority of residential mortgage-backed security issuers and a significant portion of ABS issuers in other asset classes have relied on the accommodation provided by the rule to disclose static pool information on an Internet Web site. Furthermore, we believe that it remains the case that it could be difficult to file the information electronically on EDGAR as it exists today and difficult for investors to use in that format.

Since the adoption of Rule 312 in December, 2004, technological advances and expanded use of the Internet have enabled the Commission to adopt additional rules incorporating electronic communications. The Commission continues to recognize that, in certain circumstances and under certain conditions, the Internet can present a reliable and cost-effective alternative or supplement to traditional disclosure methods. On the other hand, we are mindful of the benefit of having information filed on the EDGAR system.

The staff of the Division of Corporation Finance is currently engaged in a broad review of the Commission’s regulation of ABS including disclosure, offering process, reporting of asset-backed issuers. Along with this review, the staff of the Division of Corporation Finance is continuing to explore whether a filing mechanism for static pool information that fulfills the objectives identified above is feasible. As the staff considers this issue further, we believe it is appropriate to extend the temporary filing accommodation for one year. We believe a proposal for a long-term solution for providing static pool disclosure would be better considered together with other possible proposals to revise the regulations governing the offer and sale of ABS. The proposed one-year extension of Rule 312 is intended to provide time to enable us to proceed in this manner.

We are soliciting comments in this release about current practice and potential alternatives for providing static pool disclosure and will consider the responses we receive in determining whether to extend Rule 312 or to address the issue more broadly as part of a package of ABS proposals.

Request for Comment

We request and encourage any interested person to submit comments regarding the proposed amendment described above. In particular, we solicit comment on the following questions:

- Is an extension of the filing accommodation appropriate? What would be the consequences if the accommodation lapsed on December 31, 2009 and static pool information was required in an EDGAR filing beginning January 1, 2010?
- How could static pool information be filed with the Commission in a cost-effective manner that continues to allow the information to be provided in a format that promotes utility and functionality? Are there alternative filing mechanisms that could replace or supplement Rule 312?
- Have investors or other market participants had any difficulties with locating, accessing, viewing or analyzing static pool information posted on an Internet Web site pursuant to the filing accommodation provided by Rule 312 of Regulation S–T?
- Has the information remained on the Web site for the required duration and have updates and changes been appropriately reflected?
- Have issuers found that the Internet Web site posting accommodation provided by Rule 312 has enabled them to provide the required static pool information in a cost-effective, efficient and useful manner? Have issuers encountered any issues or problems with Internet Web site posting pursuant to Rule 312? How should we address those issues or problems?
- Would the proposed one-year extension present particular problems for investors? Would a shorter or more narrowly tailored extension ameliorate those concerns?
- Should the filing accommodation be extended for longer than one year, for example, two, three or five years, or made permanent? If so, are there any revisions to the rule that should be made?
- Are there any other changes we should consider making to Rule 312 of Regulation S–T?

Paperwork Reduction Act

Rule 312 of Regulation S–T was adopted along with other new and amended rules and forms to address the registration, disclosure and reporting requirements for ABS under the Securities Act and the Exchange Act. In connection with this prior rulemaking, we submitted a request for approval of the “collection of information” requirements contained in the amendments and rules to the Office of Management and Budget (“OMB”). OMB approved these requirements.

Item 1105 of Regulation AB requires certain static pool information, to the extent material, to be provided in prospectuses included in registration statements for ABS offerings. Rule 312 is a temporary filing accommodation that permits the posting of the static pool information required by Item 1105 on an Internet Web site under the conditions set forth in the rule. The proposed amendment to Rule 312 extends the existing temporary filing accommodation provided by the rule for one additional year. As is the case today, issuers may choose whether or not to take advantage of the accommodation. The conditions of Rule 312 remain otherwise unchanged. The disclosure requirements themselves, which are contained in Forms S–1 and S–3 under the Securities Act and require the provision of the information set forth in Item 1105 of Regulation AB, also remain unchanged. Therefore, the proposed amendment, if adopted, will not result in an increase or decrease in the costs and burdens imposed by the “collection of information” requirements previously approved by the OMB.

III. Cost-Benefit Analysis

In this section, we examine the benefits and costs of our proposed amendment. We request that commenters provide views and supporting information as to the benefits and costs associated with the

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proposal. We seek estimates of these costs and benefits, as well as any costs and benefits not already identified.

A. Benefits

We adopted the filing accommodation provided by Rule 312 of Regulation S–T because commenters requested flexibility in the presentation of required static pool information. Given the large amount of statistical information involved, commenters argued for a Web-based approach that would allow issuers to present the information in an efficient manner and with greater functionality and utility than might be available if an EDGAR filing was required. We believe this greater functionality and utility has enhanced an investor’s ability to access and analyze the static pool information and also removed the burden on issuers of duplicating the information in each prospectus as well as easing the burdens of updating such information. As we discussed in the Adopting Release, since the information is deemed to be part of the prospectus included in the registration statement, the rule is designed to give investors access to accurate and reliable information.

By extending the accommodation provided by Rule 312, these benefits to both issuers and investors would continue to apply. As discussed above, many ABS issuers rely on Rule 312 to provide static pool information on an Internet Web site rather than in an EDGAR filing. We do not believe we would meet the objectives of both issuers and investors to present static pool information in an efficient, cost-effective form that would provide investors utility and functionality in terms of accessing and analyzing that information. Therefore, if we do not amend Rule 312 to extend its application, static pool information would be required in EDGAR filings beginning on January 1, 2010. We believe this would result in costs for issuers as they attempt to adjust their procedures in a short period of time in order to present the information in a format acceptable to the EDGAR system and could result in costs to investors if the information filed on EDGAR was presented in a less useful format.

By extending Rule 312, we seek to avoid these potentially negative effects for issuers and investors as we continue to explore the best format in which to require the filing of static pool information. As indicated above, the staff of the Division of Corporation Finance is considering this issue along with other proposals addressing the disclosure, offering process and reporting of asset-backed issuers.

B. Costs

We do not believe a one-year extension of the Rule 312 accommodation would impose any new or increased costs on issuers. In the Cost-Benefit Analysis section of the Adopting Release, we noted that asset-backed issuers electing the Web-based accommodation provided by Rule 312 would incur costs related to the maintenance and retention of static pool information posted on a Web site and might also incur start-up costs. It is likely that certain of those costs would continue to impact asset-backed issuers that elect the Web-based approach during the extension period, we do not believe our proposed amendment would impose any new or increased costs for asset-backed issuers because it does not change any other conditions to the accommodation or the underlying filing and disclosure obligations. As a result of the proposed extension of the accommodation, asset-backed issuers would be able to continue their current practices for an additional year.

For investors, there may be costs associated with the static pool information not being electronically filed with the Commission. For example, when information is electronically filed with the Commission, investors and staff can access the information from a single, centralized location, the EDGAR Web site. We think these costs are mitigated by the fact that ABS issuers relying on the Rule 312 accommodation must ensure that the prospectus for the offering contains the Internet Web site address where the static pool information is posted, the Web site must be unrestricted and free of charge, such information must remain on the Internet Web site for five years with any changes clearly indicated and the issuer must undertake to provide the information to any person free of charge, upon request, if a subsequent update or change is made. Furthermore, because the information is deemed included in the prospectus under Rule 312, it is subject to all liability provisions applicable to prospectuses and registration statements.

Investors and issuers may have incurred costs to adjust their processes in anticipation of the lapse of the Rule 312 accommodation and potential reversion to a requirement to file static pool information on EDGAR. In this case, benefits to investors or issuers of not having to change their procedures regarding static pool reporting in a short time frame would be diminished by any costs already incurred in anticipation of the change. We believe such anticipatory action and any associated costs are minimal.

We request comment on the amount of any additional costs issuers or investors may incur as a result of the proposed amendment.

IV. Small Business Regulatory Enforcement Fairness Act

For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996, or “SBREFA,” we solicit data to determine whether the proposal constitutes a major rule. Under SBREFA, a rule is considered “major” where, if adopted, it results or is likely to result in:

• An annual effect on the economy of $100 million or more (either in the form of an increase or a decrease);

• A major increase in costs or prices for consumers or individual industries;

• Significant adverse effects on competition, investment or innovation.

We request comment on the potential impact of the proposed amendment on the U.S. economy on an annual basis, any potential increase in costs or prices for consumers or individual industries, and any potential effect on competition, investment or innovation. Commenters are requested to provide empirical data and other factual support for their views if possible.

V. Consideration of Impact on the Economy, Burden on Competition and Promotion of Efficiency, Competition and Capital Formation

Section 2(b) of the Securities Act requires us, when engaging in rulemaking where we are required to consider or determine whether an action is necessary or appropriate in the public interest, to also consider whether the action will promote efficiency, competition, and capital formation. As discussed in greater detail above, Rule 312 of Regulation S–T was adopted as a temporary filing accommodation so that issuers of ABS could present static pool information on an Internet Web site. The proposed amendment to Rule 312 of Regulation S–T extends its application for one year. We are not proposing changes to the conditions of Rule 312 or to the disclosure obligations

22 See Section I above and Adopting Release, Section V.D.

23 See Section I above.

24 See Adopting Release, Section V.D.

to which it applies. We do not believe that a one-year extension would impose a burden on competition. We also believe the extension of the filing accommodation would continue to promote efficiency and capital formation by permitting ABS issuers to disclose static pool information in a format that is more useful to investors and cost-effective and not unduly burdensome for asset-backed issuers.

We request comment on whether the proposed amendment, if adopted, would promote efficiency, competition, and capital formation. Commenters are requested to provide empirical data and other factual support for their view to the extent possible.

VI. Regulatory Flexibility Analysis Certification

The Commission hereby certifies pursuant to 5 U.S.C. 605(b) that the proposed amendment contained in this release, if adopted, would not have a significant economic impact on a substantial number of small entities. The proposal relates to the disclosure requirements for ABS in Securities Act registration statements. Securities Act Rule 157 26 defines an issuer, other than an investment company, to be a “small business” or “small organization” if it had total assets of $5 million or less on the last day of its most recent fiscal year. In 2004, when we proposed the new and amended rules and forms to address the registration, disclosure and reporting requirements for ABS, we certified that the proposals would not have a significant economic impact on a substantial number of small entities. As the depositor and issuing entity are most often limited purpose entities in an ABS transaction, we focused on the sponsor in analyzing the potential impact of the proposals under the Regulatory Flexibility Act. The staff analyzed sponsors that conducted registered public offerings of ABS during 2003. No sponsor had total assets of $5 million or less. 27 Based on staff experience, we continue to believe that few, if any, sponsors are small entities. In addition, even if some sponsors are small entities, the proposed amendment to Rule 312 would not have a significant economic impact on any such entities because it only extends a temporary filing accommodation that is currently in effect. As discussed above in Section III, we do not believe the proposed extension would impose any new or increased costs on ABS issuers.

Accordingly, we do not believe that the extension, if adopted, would have a significant economic impact on a substantial number of small entities.

We solicit written comments regarding this certification. We request comment on whether the proposals could have an effect that we have not considered. We request that commenters describe the nature of any impact on small entities and provide empirical data to support the extent of the impact.

VII. Statutory Authority and Text of the Proposed Amendment

The amendment described is being proposed under the authority set forth in Sections 6, 7, 10, 19 and 28 of the Securities Act of 1933 (15 U.S.C. 77f, 77g, 77h, 77j, 77s and 77z–3).

List of Subjects in 17 CFR Part 232

Reporting and recordkeeping requirements, Securities.

Text of the Proposed Amendment

For the reasons set out in the preamble, the Commission proposes to amend title 17, chapter II, of the Code of Federal Regulations as follows:

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

1. The authority citation for part 232 continues to read, in part, as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78(b), 78l, 78m, 78n, 78o(d), 78w(a), 78ll, 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, and 7201 et seq.; and 18 U.S.C. 1350.

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§ 232.312 [Amended]

2. Amend § 232.312 by removing “December 31, 2009” and in its place adding “December 31, 2010” in the first sentence of paragraph (a).

* * * *

By the Commission.

Elizabeth M. Murphy,
Secretary.

[FR Doc. E9–25496 Filed 10–22–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. FDA–2009–N–0436]

New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulations regarding new animal drug applications (NADAs). Specifically, this proposed rule is being issued to provide that NADAs shall be submitted in the form and containing the information described, as appropriate for the particular submission. Currently, the regulation requires that all NADAs contain the same informational sections and does not explicitly provide the appropriate flexibility needed to address the development of all types of new animal drug products. This amendment will allow the agency to appropriately review safety and effectiveness data submitted to support the approval of new animal drug products. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the Federal Register.

DATES: Submit written comments on or before January 6, 2010. 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–0436 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.

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

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